

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

ANNUAL MEETING

AGENDA

February 7, 2013

Immediately following the Special Committee on Codes, Regulations and Legislation

*90 Church Street
4th Floor, Room 4A & 4B
New York City*

I. INTRODUCTION OF OBSERVERS

Dr. William Streck, Chairman

II. APPROVAL OF MINUTES

Under Separate Cover

Exhibit #1

III. ELECTION OF OFFICERS

A. Election of Vice of Chairperson

B. Announce Committee Chairpersons and Vice Chairpersons and Committee Membership

- Committee on Codes, Regulations and Legislation
- Committee on Establishment and Project Review
- Committee on Health Planning
- Committee on Public Health
- Ad Hoc Committee to Lead the State Health Improvement Plan

IV. 2012 ANNUAL REPORT

Public Health and Health Planning Annual Report

Exhibit #2

V. REGULATION

Report of the Committee on Codes, Regulations and Legislation

Exhibit #3

Angel Gutiérrez, M.D., Chair

For Adoption

11-09 Amendment of Part 16 of Title 10 NYCRR (Quality Assurance Requirements for Medical Use of Radioactive Material and Radiation Therapy)

11-24 Amendment of Parts 763 and 766 of Title 10 NYCRR (Certified Home Health Agency (CHHA) and Licensed Home Care Services Agency (LHCSA) Requirements)

For Information

13-01 Amendment of Sections 405.2 and 405.4 of Title 10 NYCRR (Hospital Sepsis Protocols)

13-02 Amendment of Part 405 of Title 10 NYCRR (Hospital Pediatric Care)

13-05 Amendment of Sections 2.59, 405.3, 415.19, 751.6, 763.13, 766.11 and 793.5 of Title 10 NYCRR (Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel)

VI. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

A. Report of the Department of Health

Nirav R. Shah, M.D., M.P.H., Commissioner of Health

B. Report of the Office of Health Systems Management Activities

Karen Westervelt, Deputy Commissioner, Office of Health Systems Management and Office of Primary Care

C. Report of the Office of Health Information Technology Transformation Activities

Rachel Block, Deputy Commissioner, Office of Health Information Technology Transformation

E. Report of the Office of Public Health Activities

Dr. Guthrie Birkhead, Deputy Commissioner, Office of Public Health

VII. PUBLIC HEALTH SERVICES

Report on the Activities of the Committee on Public Health

Jo Ivey Boufford, M.D., Chair of the Public Health Committee

VIII. HEALTH POLICY

A. Report on the Activities of the Committee on Health Planning

John Rugge, M.D., Chair of the Health Planning Committee

IX. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

Christopher Booth, Vice-Chair of Establishment and Project Review Committee

A. APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Diagnostic and Treatment Center – Construction

Exhibit #4

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122161 C	East Harlem Council for Human Services, Inc. d/b/a Boriken Neighborhood Health Center (New York County)	Contingent Approval

Transitional Care Units - Construction

Exhibit #5

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122236 T	Upstate University Hospital at Community General (Onondaga County)	Contingent Approval
2.	122237 T	St. Joseph’s Hospital (Chemung County)	Contingent Approval

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Ambulatory Surgery Center – Construction

Exhibit #6

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122085 C	Gramercy Surgery Center, Inc. (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

Acute Care – Construction

Exhibit # 7

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 131015 C	Montefiore Medical Center – Henry and Lucy Moses Division (Bronx County)	To be presented at the Special Establishment/Project Review Committee on 2/7/13 No Recommendation

**B. APPLICATIONS FOR ESTABLISHMENT AND
CONSTRUCTION OF HEALTH CARE FACILITIES**

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals,
Abstentions/Interests

CON Applications

Ambulatory Surgery Centers – Establish/Construct

Exhibit #8

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 121395 B	Havemeyer ASC, LLC d/b/a Havemeyer Ambulatory Surgery Center (Kings County)	Contingent Approval
2. 122016 B	Omnicare Multi-Specialty Center, LLC (Kings County)	Contingent Approval

Dialysis Services – Establish/Construct

Exhibit #9

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 122066 E	Hauppauge Dialysis Center, LLC (Suffolk County)	Contingent Approval
2. 122067 E	Watertown Dialysis Center, LLC (Jefferson County)	Contingent Approval
3. 122175 E	Avantus Renal Therapy New York, LLC (New York County)	Contingent Approval
4. 122242 E	LSL Newburgh, LLC d/b/a Liberty Hudson Valley Dialysis (Orange County)	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #10

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 121099 E	Parkview Care and Rehabilitation Center, Inc. d/b/a Parkview Care and Rehabilitation Center (Nassau County)	Approval

Certified Home Health Agencies – Establish/Construct

Exhibit #11

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 122078 E	Litson Certified Care, Inc. d/b/a Willcare (Greene County)	Contingent Approval
2. 122165 E	Hudson Valley Home Care (Dutchess County)	Contingent Approval

Amended and Restated Certificate of Incorporation

Exhibit #12

<u>Applicant</u>	<u>E.P.R.C. Recommendation</u>
1. JTM Health Facilities Foundation, Inc.	Approval

HOME HEALTH AGENCY LICENSURES

Exhibit #13

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
2076-L	Ideal Care SP, LLC (Ulster, Dutchess, Orange, Sullivan and Greene Counties)	Contingent Approval
2153-L	Garden Homecare, LLC (Erie County)	Contingent Approval

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Ambulatory Surgery Centers – Establish/Construct

Exhibit #14

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122051 B	Rockaways ASC Development, LLC (Queens County) Mr. Kraut - Interest Dr. Sullivan – Abstaining/Interest	Contingent Approval
2.	122164 B	Mason ESC, LLC d/b/a Mason Eye Surgery Center (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval

Diagnostic and Treatment Center – Establish/Construct

Exhibit #15

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121445 B	New Life Community Development Corporation d/b/a New Life Community Health Center (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #16

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122003 E	Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare (Steuben County) Mr. Fassler – Recusal	Contingent Approval

Certified Home Health Agencies – Establish/Construct

Exhibit #17

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121325 E	Tri-Borough Certified Health Systems of New York, LLC d/b/a Tri-Borough Certified Health Systems of New York (Nassau County) Ms. Regan - Interest	Contingent Approval
2.	121328 E	Tri-Borough Certified Health Systems of the Hudson Valley, LLC d/b/a Tri-Borough Certified Health Systems of the Hudson Valley (Westchester County) Ms. Regan - Interest	Contingent Approval

Restated Certificate of Incorporation

Exhibit #18

	<u>Applicant</u>	<u>E.P.R.C. Recommendation</u>
1.	Pluta Cancer Center Foundation, Inc. Ms. Hines – Recusal Mr. Robinson - Recusal	Approval

HOME HEALTH AGENCY LICENSURES

Exhibit #19

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
	2061-L	ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services- Northeast Westchester (Westchester, Putnam, Dutchess and Orange Counties) Ms. Regan - Interest	Contingent Approval
	2017-L	A-Plus Care HHC, Inc (New York, Kings, Queens, Bronx, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval

1946-L	ASC of New York, LLC d/b/a Affordable Senior Care of New York (Bronx, Kings, Nassau, New York, Richmond and Queens Counties) Ms. Regan - Interest	Contingent Approval
1878-L	Christine Home Care Services, Inc. (New York, Bronx, Queens, Kings and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2015-L	Eden Home Care Services, inc. (Bronx, Kings, New York, Queens, Richmond and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2082-L	JC Beginnings, Inc. d/b/a Senior Helpers (Nassau and Suffolk Counties) Ms. Regan - Interest	Contingent Approval
1995-L	Life Quality Homecare Agency, Inc. (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
2006-L	Millennium Concepts, Inc. d/b/a Exclusive Care (Bronx, Kings, New York, Queens, Richmond and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2013-L	Ochlors, Incorporated d/b/a Right at Home (Kings, New York, Queens and Richmond Counties) Ms. Regan - Interest	Contingent Approval

1979-L	SonicLeibs, Inc. d/b/a Synergy HomeCare (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
1907-L	SR Homecare of NY, Inc. (New York, Kings, Queens, Bronx, Richmond, and Westchester Counties) Ms. Regan - Interest	Contingent Approval
1812-L	St. Vincent de Paul Residence d/b/a St. Vincent de Paul LHCSA (Bronx County) Ms. Regan - Interest	Contingent Approval
1881-L	Marian Care, Inc. (Nassau, Suffolk, and Queens Counties) Ms. Regan - Interest	Contingent Approval
2070-L	Tri-Borough Health Careers, LLC d/b/a Metro Care Home Services, a division of Tri-Borough Health Careers, LLC (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
2069-L	Tri-Borough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd. (Dutchess, Orange, Putnam, Sullivan Westchester, Ulster, Nassau, Suffolk, and Rockland Counties) Ms. Regan - Interest	Contingent Approval

2013-L

Tri-Borough Home Care, Ltd.
d/b/a Metrocare Givers, a division
of Tri-Borough Home Care, Ltd.
(Bronx, Kings, New York,
Queens, Richmond and
Westchester Counties)
Ms. Regan - Interest

Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by or HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment an Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or
Establishment and Project Review Committee - with or without
Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

CON Applications

Ambulatory Surgery Center – Establish

Exhibit #20

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 121346 E	White Plains Ambulatory Surgery, LLC d/b/a White Plains Ambulatory Surgery Center, Inc. (Westchester County)	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #21

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 122194 B	SSS Operating, LLC d/b/a Atlantic Harbor Center for Rehabilitation and Nursing (Suffolk County)	To be presented at the Special Establishment/Project Review Committee on 2/7/13 No Recommendation

X. NEXT MEETING

March 21, 2012 – ALBANY
April 11, 2012 - LATHAM

XI. ADJOURNMENT

Approval of the Minutes

To be distributed under separate cover

Public Health and Health Planning Council 2012 Annual Report

I. General Council Activities in 2012

The Public Health and Health Planning Council (PHHPC) held a total of 29 meetings in 2012, inclusive of regularly scheduled and special meetings.

Special Health Planning

January 18, 2012	October 3, 2012
March 21, 2012	October 12, 2012
May 9, 2012	November 15, 2012
June 21, 2012	November 19, 2012
September 5, 2012 – Rochester	November 30, 2012
September 19, 2012	December 6, 2012

Health Planning (Regularly Scheduled Meeting)

May 24, 2012
July 25, 2012
September 20, 2012

Joint Public Health and Health Planning

January 19, 2012	May 24, 2012
March 22, 2012	

Public Health

May 24, 2012	September 20, 2012
July 25, 2012	November 19, 2012

Ad Hoc

February 1, 2012	November 16, 2012
March 5, 2012	
June 11, 2012	

Special EPRC

March 22, 2012

EPRC

January 19, 2012
March 22, 2012
May 23, 2012

July 26, 2012
September 20, 2012
November 15, 2012

Special Codes

August 7, 2012

Codes

January 19, 2012
March 22, 2012
May 23, 2012

July 25, 2012
September 20, 2012
December 6, 2012

Special Full Council

March 22, 2012
August 7, 2012

Full Council

February 2, 2012
April 5, 2012
June 7, 2012

August 9, 2012
October 11, 2012
December 6, 2012

II. Membership

William Streck, M.D., Chair
Jeffrey A. Kraut, Vice Chair
Howard S. Berliner, SC.D.
Jodumutt Ganesh Bhat, M.D.
Christopher C. Booth
Jo Ivey Boufford, M.D.
Michael Fassler
Howard Fensterman
Carla Boutin-Foster, M.D.
Ellen Grant, Ph.D.
Angel Alfonso Gutierrez, M.D.
Victoria G. Hines
Robert W. Hurlbut
Arthur A. Levin, MPH

Glenn Martin, M.D.
John M. Palmer, Ph.D.
Ellen L. Rautenberg, M.H.S.
Susan Regan
Peter G. Robinson
John Ruge, M.D., MPP
Theodore Strange, M.D.
Ann Marie Theresa Sullivan, M.D.
Anderson Torres, Ph.D., LCSW-R
Patsy Yang, Dr.P.H.
Dr. Nirav Shah, Commissioner of Health – Ex-Officio

The PHHPC consists of the following Standing Committees and Ad Hoc Committee

- Committee on Codes, Regulations and Legislation
- Committee on Establishment and Project Review
- Committee on Health Planning
- Committee on Public Health
- Ad Hoc Committee to Lead the State Health Improvement Plan

III. Major Accomplishments of Committees in 2012

A. Committee on Codes, Regulations and Legislation

Members

Angel Alfonso Gutierrez, M.D., Chair	Robert W. Hurlbut
John M. Palmer, Ph.D., Vice Chair	John Rugge, M.D., MPP
Jodumutt Ganesh Bhat, M.D.	Ann Marie Sullivan, M.D.
Jo Ivey Boufford, M.D.	Patsy Yang, Dr.P.H.
Michael Fassler	

Committee Description

Reviews new or revised regulations relating to medical facility operational and structural standards, including quality of care and the need for the facilities and/or services. Reviews amendments to the State Sanitary Code and other matters referred by the Commissioner. The Codes Committee will also include work of the SHRPC's Fiscal Policy Committee which was charged to review proposed changes to part 86 of the State Hospital Code concerning medical facility rates of Reimbursement.

EMERGENCY ADOPTIONS

The Committee recommended, and the Council subsequently Adopted, the following Emergency Regulations in 2012:

Amendment to Limitation of Operating Certificates – This regulation authorizes the Commissioner to permit an established operator of a facility to operate at an alternate or additional site approved by the Commissioner on a temporary basis in an emergency.

Nursing Home Sprinkler Systems – Federal regulations require that on or before August 13, 2013, all nursing homes be protected throughout by a supervised automatic sprinkler system. This regulation will assist financially distressed nursing homes with accessing the credit markets to finance the costs of equipment and other capital costs directly related to the installation of an automatic sprinkler system that is in compliance with the mandated federal regulations.

Prohibition of Synthetic Phenethylamines and Synthetic Cannabinoids – This measure prohibits the manufacture, sale, distribution and possession of synthetic phenethylamines (more commonly known as bath salts) and synthetic marijuana. It defines 12 specific phenethylamines along with a catchall that would include any compound that has a similar chemical structure allowing the Department and law enforcement to keep up with the illegal activity of those individuals seeking to change the structure to avoid the existing drug laws. Twelve separate classes of synthetic marijuana are defined as well.

REGULAR ADOPTIONS

The Committee recommended, and the Council subsequently Adopted, the following Regular Regulations in 2012:

Amendment to Limitation of Operating Certificates (Permanent Version) – This regulation authorizes the Commissioner to permit an established operator of a facility to operate at an alternate or additional site approved by the Commissioner on a temporary basis in an emergency.

Home Care Registry – This proposal defines the rules for implementing Chapter 594 of the Laws of 2008 requiring the Department to establish a Home Care Registry. This Registry tracks training and employment information for all individuals who have successfully completed approved home health and/or personal care aide training programs. The regulations outline the responsibilities of State approved training entities, home care services agencies and home care trainees and aides.

Nursing Home Sprinkler Systems (Permanent Version) – Federal regulations require that on or before August 13, 2013, all nursing homes be protected throughout by a supervised automatic sprinkler system. This regulation will assist financially distressed nursing homes with accessing the credit markets to finance the costs of equipment and other capital costs directly related to the installation of an automatic sprinkler system that is in compliance with the mandated federal regulations.

Prohibition of Synthetic Phenethylamines and Synthetic Cannabinoids (Permanent Version) – This measure prohibits the manufacture, sale, distribution and possession of synthetic phenethylamines (more commonly known as bath salts) and synthetic marijuana. It defines 12 specific phenethylamines along with a catchall that would include any compound that has a similar chemical structure allowing the Department and law enforcement to keep up with the illegal activity of those individuals seeking to change the structure to avoid the existing drug laws. Twelve separate classes of synthetic marijuana are defined as well.

DISCUSSION REGULATIONS

The following proposals were Discussed by the Codes and Regulations Committee in 2012:

Chronic Renal Dialysis Services – This regulation updates Part 757 of Title 10 NYCRR to conform to changes in the federal chronic renal dialysis provisions. It incorporates by reference federal definitions and 16 Conditions for Coverage for End Stage Renal Disease (ESRD) facilities set forth in Title 42 of the Code of Federal Regulations, 2008 edition. In addition, it clarifies certain definitions, water and dialysate quality provisions and personnel provisions specific to New York State standards.

Release of a Dead Body from a Hospital – This measure seeks to clarify that before releasing a dead body from a general hospital a determination regarding organ/tissue donation status and arrangements for recovery must be made. It specifies that a deceased person shall be released to a licensed funeral director only after all donor and recovery responsibilities have been met by the hospital and the existing networks for the recovery of organs and tissues. This measure also adds the definitions of “reasonably available” and “domestic partner” to conform to changes in the Public Health Law regarding the process for requesting consent to an anatomical gift, and the list of who can provide such content.

Organ Transplant Provisions – This proposal amends the anesthesia services provisions as they relate to living donor transplantation services, repeals the organ transplant center and live liver transplantation services within the critical care and special care services provisions in Section 405.22 of 10 NYCRR and creates 2 new sections in Part 405 of Title 10 regarding transplant services. Newly created Section 405.30 contains the organ and vascularized composite allograft transplant services/programs provisions. Newly created Section 405.31 contains the living donor transplantation services requirements.

Information and Other Reporting Requirements – This proposal repeals Section 400.18 of 10 NYCRR and adds a new Section 400.18 to reflect the current practices of the Statewide Planning and Research Cooperative System (SPARCS). As a result of the changes to Section 400.18, Appendices C-2, C-3 and C-5, along with Sections 405.27 and 755.10 will be repealed. Section 407.5 and 400.14 will be amended to coordinate with the revisions in Section 400.18. Section 400.18 regulates the collection, maintenance and distribution of SPARCS data. In addition this section provides the rules governing the Data Protection Review Board (DPRB), established to protect the privacy of the patient in the release of identifying SPARCS data to researchers.

Disclosure of Quality and Surveillance Related Information – Every general hospital and residential health care facility must make available to any member of the public and to the Commissioner of any state agency responsible for licensing or accrediting the facility, or responsible for overseeing the delivery of services either directly or indirectly, information regarding nursing quality indicators upon request. This measure provides definitions, nursing quality indicators, various disclosure information including methodology, outcomes and identification of the source(s) and date(s) for data disclosed, timeliness of data disclosed and data

disclosure. Regulated facilities will be required to have policies and procedures for documentation and management of requests and responses to requests for nursing quality indicator data and keep records of requests made and filled for a period of no less than three years from the date the request for information was received.

Certified Home Health Agency (CHHA) and Licensed Home Health Agency (LHCSA) Amendments – This measure incorporates 2 recommendations from the Medicaid Redesign Team (MRT). The first recommendation would add a requirement that the plans of care and medical orders required for patients of CHHAS and LHCSAs address the patients’ need for palliative care. The second recommendation would eliminate the need for a physician to serve on the quality improvement (QI) committee of LHCSAs. This proposal would also remove the requirement that CHHAs provide more than one qualifying service directly, to coincide with federal standards. It also changes the maximum period of time that may lapse before a comprehensive assessment is reviewed from 62 to 60 days which is also the federal standard.

Ionizing Radiation – Part 16 10 NYCRR is being amended to update and add new requirements for the use of radioactive material and to update and consolidate requirements currently contained in Industrial Code Rule 38. Most of the proposed changes are promulgated to ensure compatibility with those of the US Nuclear Regulatory Commission (NRC) and are required as part of New York State’s agreement with the NRC. Other changes include x-ray equipment registration updates and clarification of current requirements for Certified Radiation Equipment Safety Officers (CRESOs)

2013 OBJECTIVES

Various initiatives are currently under development in the Department that will need to go through the Codes, Regulations and Legislation Committee. Some of the major initiatives include, but are not limited to:

- Prevention of Influenza Transmission by Healthcare, Residential Facility and Agency Personnel;
- Sepsis Protocols;
- An update of the Chronic Renal Dialysis provisions;
- Part 405 Pediatric Amendments; and
- An update of the Transplant provisions.

B. Committee on Establishment and Project Review

Members

Jeffrey Kraut, Chair	Arthur Levin
Christopher Booth, Vice Chair	Glenn Martin, M.D
Howard Berliner	Susan Regan
Howard Fensterman	Peter Robinson
Ellen Grant, Ph.D.	Ann Marie Theresa Sullivan, M.D
Angel Gutierrez, M.D.	Anderson Torres, Ph.D.
Victoria G. Hines	

Committee Description

Responsible for reviewing the CON applications involving construction, service changes or establishment, and transfers of ownership.

*****See Attachments for Complete Report*****

C. Committee on Health Planning

Members

John Ruge, M.D. MPP - Chair	Jeffrey Kraut
Ellen Grant, Ph.D. - Vice Chair	Arthur Levin
Howard Berliner	Glenn Martin, M.D.
Christopher Booth	John Palmer, Ph.D.
Jo Ivey Boufford, M.D.	Ellen Rautenberg
Michael Fassler	Peter Robinson

Committee Description

Advises the Council on need-methodologies, health facility plans, and emerging health care issues. Monitors major health care initiatives and advises the Council on progress and/or problems. The Committee will also include functions from the SHPRC's Committee on Major Medical Equipment and Appropriateness whose responsibilities were to develop and review appropriateness standards (Part 708) for various services. The Committee evaluates high technology equipment, and advises the Council on such specialized services as organ transplants. The Committee will also take into consideration matters relative to the collaboration with the Rural Health Council. The Committee will also handle matters that were considered under the SHPRC's Information Systems Review Committee whose general purpose was to advance a framework for CON to ensure interoperable health information technology is an underpinning to health care delivery and supports health care stakeholders. Advise the DOH on health information policy relevant to health care stakeholders.

In 2012, Governor Cuomo and Commissioner Shah charged the Council with redesigning the State’s certificate of need (CON) program and developing a framework for regional health planning. The Health Planning Committee took the lead in soliciting stakeholder input, analyzing options, and developing recommendations to carry out that charge. Its goals were to (1) streamline the CON process by eliminating administrative steps that no longer serve their intended purpose, impede achievement of policy goals, or are not cost-effective; and (2) develop a regulatory and health planning framework that, together with payment incentives and other policy tools, drives health system improvement and population health.

The Committee's work proceeded in two phases. The first phase focused on administrative streamlining. The Committee conducted six meetings, including four joint meetings with the Public Health Committee. On June 7, 2012, PHHPC issued its Mission/Vision and Principles for Reform and nine Administrative Streamlining Recommendations. The second phase involved a more comprehensive look at CON and Health Planning. The Committee convened eleven meetings, including 3 joint meetings with the Public Health Committee. On December 6, 2012, PHHPC adopted a Report on Redesigning CON and Health Planning with 23 recommendations.

In 2013, the Committee will be monitoring implementation of the CON Redesign recommendations; reviewing recommendations related to updating and equalizing oversight of physician practices and health care facilities; considering new telemedicine and emergency and urgent care models; and working with the Codes Committee to review accountable care organization (ACO) regulations.

D. Committee on Public Health

Members

Jo Ivey Boufford, M.D., Chair	Arthur Levin
Anderson Torres, Ph.D., Vice Chair	Ellen Rautenberg
Christopher Booth	Susan Regan
Carla Boutin-Foster, M.D	Theodore Strange, M.D.
Angel Gutierrez, M.D.	Patsy Yang, Dr.P.H.
Victoria G. Hines	

Committee Description

Charged with addressing the statewide governmental public health infrastructure (including workforce, IT, laboratory and other organizational capacity consistent with the Essential Public Health Functions) and support actions to assure readiness for future public health agency accreditation and public health workforce certification. It will also promote interagency collaborations across government to support a “Health in All Policies” approach by State leadership. These activities would be combined with the current Ad Hoc Prevention Committee of PHC.

In 2012, the Public Health Committee under the leadership of Jo Ivey Boufford, Chairperson, focused on three items:

- Led the development of the *Prevention Agenda 2013-17*, New York State's health improvement plan for 2013 through 2017, developed by the New York State Public Health and Health Planning Council at the request of the Department of Health, in partnership with more than 140 organizations across the state;
- Actively participated in efforts of the Council's Health Planning committee to strengthen community health planning to ensure that it focuses on population health in addition to health services;
- Discussed maternal mortality and ways that the Committee could address it, in an effort to "move the needle" on a major public health concern in NYS.

E. Committee on Health Personnel and Interprofessional Relations

Members

Dr. Theodore Strange, M.D., Chair
Jodumutt Bhat, M.D., Vice Chair
Howard Fensterman
Robert Hurlbut
Susan Regan

Committee Description

Pursuant to 2801-b of the Public Health Law, the Council also considers verified complaints submitted by physicians, podiatrists, optometrists, dentists, and licensed midwives whose hospital privileges have been terminated, suspended or denied.

The Committee reviewed and decided on 6 health personnel cases in Executive Session.

F. Ad Hoc Committee to Lead the State Health Improvement Plan

Members

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Victoria G. Hines	Cheryl Hunter-Grant
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Ann Morse Abdella	Kyu Rhee, MD
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Patricia Clancy	Judy Wessler
Kira Geraci Ciardullo, MD	
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Committee Description

The Public Health Committee of PHHPC has established an Ad Hoc Committee to oversee the development of the next state health improvement plan. The current state health department five year plan, the *Prevention Agenda toward the Healthiest State*, ends in 2012.

The new five year plan will make an assessment of the current health status of the state's residents, describe progress to date in meeting the *Prevention Agenda* objectives, identify the state's public health priorities for the next five year period and describe evidence based strategies that the state and communities will pursue to address the priorities.

Members of the new Ad Hoc Committee include PHHPC Public Health Committee members and public health stakeholders.

The Prevention Agenda was developed by an Ad Hoc Committee to Lead the Development of the State Health Improvement Plan. The Committee developed a vision, goals and proposed priorities and then obtained stakeholder feedback before finalizing the priorities. It appointed five committees that developed action plans for each priority.

The Prevention Agenda vision is New York as the Healthiest State in the Nation. The five priority areas are:

- Prevent chronic diseases
- Promote healthy and safe environments
- Promote healthy women, infants and children
- Promote mental health and prevent substance abuse
- Prevent HIV, sexually transmitted diseases, vaccine-preventable diseases and healthcare-associated Infections

Prevention Agenda 2013-17 establishes goals for each priority area and defines indicators to measure progress toward achieving these goals, including reductions in health disparities among racial, ethnic, and socioeconomic groups and persons with disabilities.

The Agenda also identifies interventions shown to be effective to reach each goal. These interventions are displayed by stakeholder groups so that each sector can identify evidence based or promising practices they can adapt for implementation to address the specific health issues in their communities. The interventions are also displayed by the five tiers of the Health Impact Pyramid, a framework based on the potential reach and relative impact of interventions.

Prevention Agenda 2013-17 seeks to be a catalyst for action as well as a blueprint for improving health outcomes and reducing health disparities. It will also guide local health departments as they work with their community to develop mandated Community Health Assessments and to hospitals as they develop mandated Community Service Plans and Community Health Needs Assessments required by the Affordable Care Act over the coming year.



Public Health and Health Planning Council

Certificate of Need Annual Report

2012

TABLE I

Median Processing Times

(Acknowledgement to Director Action in Days)

	Admin	Full	Ltd
2011	179	268	66
2012	123	166	61

TABLE I (A)

Historical Project Volume and Values

Number of Projects				Value of Projects <i>(in thousands)</i>				Average Value <i>(in thousands)</i>	
Year	Adm	Full	Total	Adm	Full	Total	Adm	Full	
1996 ¹	393	179	572	445,148	731,651	1,196,799	1,133	4,087	
1997	383	176	559	609,796	1,173,851	1,783,647	1,592	6,670	
1998	341	173	514	588,550	1,035,393	1,623,943	1,726	5,985	
1999 ²	348	184	532	630,286	615,616	1,245,902	1,955	3,346	
2000	196	140	336	427,590	914,871	1,342,461	2,181	6,535	
2001	199	150	349	446,917	756,778	1,203,695	2,246	5,012	
2002	212	140	352	552,566	883,911	1,436,477	2,606	6,314	
2003	281	172	453	605,072	1,242,984	1,848,056	2,153	7,227	
2004	198	141	339	432,515	1,049,534	1,482,049	2,184	7,444	
2005	234	163	397	469,406	1,845,890	2,315,297	2,015	11,324	
2006	211	142	353	484,771	2,232,572	2,717,342	2,297	15,722	
2007	190	115	305	619,756	1,309,918	1,929,674	3,261	12,357	
2008	205	108	313	805,085	3,385,133	4,190,218	3,985	31,343	
2009	202	102	304	\$467,328	\$1,452,895	\$1,920,223	\$2,313	\$14,244	

Number of Submissions					Value of Submissions <i>(in thousands)</i>					Average Value <i>(in thousands)</i>				
Year	Admi	Full	Ltd	Notice	Total	Admin	Full	Ltd	Notice	Total	Admin	Full	Ltd	Notice
2010 ³	187	127	446		760	685,588	1,946,825	445,542		3,077,955	3,666	15,329	999	
2011	187	119	660		966	822,219	827,405	764,474		2,414,098	4,397	6,953	1158	
2012 ⁴	182	139	352	232	905	475,513	2,879,596	347,124	274,346	3,976,579	2,613	20,717	986.1	1183

¹ January 1996, CON threshold increased from \$400K to \$1M; administrative limit increased from \$4M to \$6M (and, in some cases, up to \$25M)

² November 1998, CON threshold increased from \$1M to \$4M; administrative limit increased from \$3M to \$10M (and, in some cases, up to \$25M)

³ July 2010, CON thresholds increased for administrative reviews from \$3M to \$6M and for full reviews \$10M to \$15M for non-general hospital facilities, \$50M for general hospitals upper limit for HIT projects

⁴ January 2012, regulatory change allowed for non-clinical projects meeting specific criteria to be submitted with only written notification

TABLE I (B)
Projects Reviewed and Related Capital Expenditures by Region
Last Two Calendar Years

2012								
Region	Number of Projects				Value of Projects <i>(in thousands)</i>			
	Admin	Full	Ltd	Total	Admin	Full	Ltd	Total
Western	17	16	32	65	20,919	14,405	33,300	68,624
Finger Lakes	10	10	28	48	22,148	167,323	23,169	212,640
Central	20	6	46	72	53,586	62	23,312	76,960
NY Penn	2	1	7	10	3,774	0	3,445	7,219
Northeast	24	16	36	76	30,027	35,818	17,351	83,196
Hudson Valley	22	18	42	82	47,825	182,940	38,266	269,031
New York City	63	53	123	239	212,704	2,418,215	158,678	2,789,597
Long Island	24	19	38	81	84,530	60,833	49,603	194,966
Total	182	139	352	673	\$475,513	\$2,879,596	\$347,124	\$3,702,233

2011								
Region	Number of Projects				Value Of Projects <i>(in thousands)</i>			
	Admin	Full	Ltd	Total	Admin	Full	Ltd	Total
Western	17	20	83	120	24,751	22,463	\$54,771	\$101,985
Finger Lakes	15	3	56	74	31,183	0	65,793	96,976
Central	22	12	54	88	85,660	54,304	65,751	205,715
NY Penn	3		19	22	240	0	7,072	7,312
Northeast	14	4	50	68	10,793	6,740	41,487	59,020
Hudson Valley	24	13	95	132	93,702	3,375	97,321	194,398
New York City	81	53	211	345	433,600	740,520	310,038	1,484,158
Long Island	11	14	92	117	142,290	3	122,241	264,534
Total	187	119	660	966	\$822,219	\$827,405	\$764,474	\$2,414,098

TABLE II (A)
Disapprovals
2012

102376	Albany County Nursing Home Construct a 250 bed skilled nursing facility to replace existing structure; Revised: 6-20-11 Construct a 200-bed replacement facility and certify a 30-slot ADHCP; reduction in total project costs. Revised: 8-30-12 Revised financial projections	\$80,829,174
112096	Nesconset Acquisition, LLC d/b/a Nesconset Center for Nursing and Rehabilitation Convert 20 residential health care facility beds into 10 adult and 10 pediatric ventilator beds with requisite construction	\$855,027
071077	North Sea Associates, LLC d/b/a The Hamptons Center for Rehabilitation and Nursing Certify a 22 bed ventilation dependent service by conversion of 22 residential health care facility beds to 22 ventilator beds	\$790,944
071024	Long Beach Memorial Nursing Home, Inc. d/b/a Komanoff Center for Geriatric and Rehabilitation Medicine Convert 10 residential health care facility beds to 10 ventilator dependent beds	\$790,944
101018	Doctors United, Inc, Construct an extension clinic providing primary medical care, physiatry, physical therapy and podiatry at 1970 7th Avenue, New York	\$409,666
092158	DV Corp. d/b/a Riverside Dialysis Change in membership through sale of 90% interests of its current sole LLC member (Leelamma Mathai) to DaVita of New York, Inc. (Amends and Supercedes CON #062342-B); Rev.: 11/9/10 -- change in ownership structure from LLC to NYS business corp.	\$0

TABLE II (B)
Withdrawals
2012

90	Withdrawals by Applicant
<u>77</u>	Withdrawals by Department
167	Total

TABLE III
Bed Changes by Facility Type by Region
2012

HOSPITALS		Finger Lakes	Hudson Valley	Long Island	New York City	North East	NY Penn	Western	TOTAL
Bed Category									
Bone Marrow Transplant				6	8				
Chemical Dependency, Detox				18	-32				-14
Chemical Dependency, Rehab									0
Coronary Care					6	-4			2
Intensive Care					128	-4			124
Maternity Beds		-8						-6	-14
Medical/Surgical	9	8			-19	-11			-13
Neonatal Intensive Care					-3			10	7
Neonatal Continuing Care					2				2
Neonatal Intermediate Care					-3				-3
Pediatric	-24				-1	-21			-46
Pediatric ICU					25				25
Physical Medicine & Rehabilitation				-28	-22				-50
Psychiatric			26		-32				
Special Use					-88				-88
Traumatic Brain Injury				10					
New York State Total	-15	0	26	-10	-39	-40	0	4	-68
RESIDENTIAL HEALTH CARE FACILITIES		Finger Lakes	Hudson Valley	Long Island	New York City	North East	NY Penn	Western	TOTAL
Bed Category									
RHCF Beds		-65	111	-108	-423	-22		-42	-549
Behavioral Intervention									
Pediatric				10					10
Traumatic Brain Injury									0
Ventilator, Adult				62					62
Ventilator, Pediatric				46					
New York State Total	0	-65	111	10	-423	-22	0	-42	-477

TABLE IV
Projects Receiving Commissioner Action by Facility Type
2012

TABLE IV (A)
Administrative Review Projects

Region	CHHA	D&TC	HOSPICE	HOSPITAL	LTHHCP	RHCF	TOTAL
Western	1	5		10		1	17
Finger Lakes		5		4		1	10
Central		3		16		1	20
NY-Penn				2			2
Northeastern		2		21	1		24
Hudson Valley	1	8		11	2		22
New York City	1	26		23	12	1	63
Long Island		3		16	2	3	24
New York State Total	3	52	0	103	17	7	182

TABLE IV (B)
Full Review Projects

Region	CHHA	D&TC	HOSPICE	HOSPITAL	LTHHCP	RHCF	TOTAL
Western	1	4	1	1	0	9	16
Finger Lakes	3	3	0	2	1	1	10
Central	3	1	1	0	0	1	6
NY-Penn						1	1
Northeastern	6	3	0	4	0	3	16
Hudson Valley	5	4	0	3	2	4	18
New York City	12	16	2	11	1	11	53
Long Island	3	3	0	2	2	9	19
New York State Total	33	34	4	23	6	39	139

TABLE IV (C)
Limited Review Projects

Region	D&TC	HOSPITAL	RHCF	TOTAL
Western	8	16	8	32
Finger Lakes	3	18	7	28
Central	9	31	6	46
NY-Penn		3	4	7
Northeastern	3	27	6	36
Hudson Valley	10	16	16	42
New York City	30	69	24	123
Nassau-Suffolk	3	24	11	38
New York State Total	66	204	82	352

TABLE V

Public Health and Health Planning Council
Establishment Projects Reviewed by Facility Type

Facility Type	2012			2011	2010	2009
	Approvals	Disapprovals	Deferrals	Total	Total	Total
Hospitals	5	0	0	6	4	5
Residential Health Care Facilities	31	0	0	27	21	18
Diagnostic and Treatment Centers	32	1	1	38	26	26
Certified Home Health Agencies	22	0	0	8	3	2
Hospices	3	0	0	1	0	2
Long Term Home Health Care	0	0	0	1	1	0
New York State Total	93	0	1	81	55	53

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2013

Report of the Committee on Codes, Regulations and Legislation Exhibit #3

Angel Gutiérrez, M.D., Chair

For Adoption

11-09 Amendment of Part 16 of Title 10 NYCRR (Quality Assurance Requirements for Medical Use of Radioactive Material and Radiation Therapy)

11-24 Amendment of Parts 763 and 766 of Title 10 NYCRR (Certified Home Health Agency (CHHA) and Licensed Home Care Services Agency (LHCSA) Requirements)

For Information

13-01 Amendment of Sections 405.2 and 405.4 of Title 10 NYCRR (Hospital Sepsis Protocols)

13-02 Amendment of Part 405 of Title 10 NYCRR (Hospital Pediatric Care)

13-05 Amendment of Sections 2.59, 405.3, 415.19, 751.6, 763.13, 766.11 and 793.5 of Title 10 NYCRR (Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel)

Summary of Express Terms

The regulatory proposal would revise Part 16 of 10 NYCRR as described in more detail below.

Subdivision (c) of section 16.1 is revised to update the address and phone number of the Department of Health's Bureau of Environmental Radiation Protection and to allow certain reports to be filed electronically with the Department.

Paragraph (15) of subdivision (a) of section 16.2 is amended to make the definition of "byproduct material" comparable to the definition of byproduct material in NRC regulations.

Paragraph (134) of subdivision (a) of section 16.2, which contains an outdated definition of the term "tutelage," is repealed.

Subdivision (a) of section 16.24 is repealed and replaced with a new subdivision (a), which includes updated quality assurance standards for licensees or registrants authorized to administer external beam therapy or brachytherapy to human beings. The new subdivision includes quality standards appropriate for newer, more complex radiation therapy treatment systems and also requires additional verification of radiation set-up equipment and treatment plans prior to administering radiation treatments to patients. New subdivision (a) also requires quality assurance programs to cover data communication/transfer between component systems of planning and treatment delivery systems to ensure complete (uncorrupted) data transfer. Additionally, the new section requires licensees and registrants to credential individuals involved

in quality assurance testing, treatment planning, and radiation treatment of patients. Finally, new subdivision (a) requires licensees and registrants to be accredited in radiation oncology by the American College of Radiology or the American College of Radiation Oncology, or another equivalent accrediting organization, within 18 months of the effective date of the regulation.

Section 16.100 is repealed and replaced with a new section 16.100 to update the licensing requirements for licensure of radioactive materials.

Sections 16.120 and 16.121 are repealed and replaced with a new section 16.120 which sets forth the licensing requirements for human use of radioactive material.

Section 16.122 is repealed. The requirements for teletherapy units are included in the proposed new section 16.123.

Current section 16.123 is repealed and replaced with a new section 16.123. The new version updates the standards for the medical use of radioactive materials, consistent with the federal Nuclear Regulatory Commission (NRC) regulations governing the medical use of radioactive materials; updates definitions to be consistent with federal regulatory definitions; updates the training and experience requirements for physicians, pharmacists and medical physicists who use radioactive materials for medical purposes; and revises and creates new categories of medical use licenses. The new section 16.123 incorporates certain federal regulatory requirements by reference; it also establishes regulatory requirements specific to New York State that are consistent with the federal regulatory requirements.

The proposed section 16.2 will have a significant impact on physicians who wish to use radiopharmaceuticals for diagnostic nuclear medicine and nuclear cardiology. The current section requires 200 hours of classroom training. By removing this requirement and incorporating the federal classroom training requirements set forth in 10 CFR Part 35, the required classroom and laboratory training hours will be reduced to 80 hours for physicians applying for authorized user status for diagnostic uses. In addition, these physicians would be allowed to obtain the practical training component in a private medical practice setting. Currently such training can be obtained only at a medical institution (hospital). By incorporating the training requirements established in 10 CFR Part 35, the total number of training hours for physicians who use radioactive materials will remain at 700 hours.

Relative to the new categories of medical use licenses, the new section 16.123 includes a category that covers gamma knife radiosurgery units and high dose rate remote afterloaders. Quality assurance requirements are modified to reflect the revised and new categories. The dose limits for members of the public and occupationally exposed individuals are modified to exclude exposure from individuals administered radioactive material and released in accordance with regulations.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Sections 16.1, 16.2, 16.24, 16.100, 16.120, 16.121, 16.122 and 16.123 of Part 16 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (c) of Section 16.1 is REPEALED and new subdivision (c) of Section 16.1 is added as follows:

(c) Communications. Except as otherwise provided for in this Part or authorized by the Department, all applications, notifications or other communications filed pursuant to this Part shall be addressed to the New York State Department of Health Bureau of Environmental Radiation Protection, Empire State Plaza, Albany, New York 12237, or by telephone (518) 402-7550. Registrants and licensees that are authorized pursuant to Article 28 of the Public Health Law to operate a hospital may comply with adverse event reporting required by this Part by electronic filing with the Department via the New York Patient Occurrence and Tracking System (NYPORTS).

Paragraph (15) of subdivision (a) of Section 16.2 is amended as follows:

(15) Byproduct material [means] shall include:

(i) Any radioactive material, except special nuclear material, yielded in, or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; [and]

(ii) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes[. Underground]; however, ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition[.];

(iii) any discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(iv) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity.

(v) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial medical or research activity that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security.

Paragraph (134) of subdivision (a) of Section 16.2 is REPEALED and reserved.

Subdivision (a) of section 16.24 is REPEALED and a new subdivision 16.24(a) is added to read as follows:

(a) External beam therapy and brachytherapy. Each licensee or registrant authorized to administer external beam therapy or brachytherapy to human beings shall implement a quality assurance program to systematically monitor, evaluate and document radiation therapy services to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissues, minimal exposure to personnel and adequate patient monitoring aimed at determining the end result of the treatment. Each such licensee or registrant shall meet or exceed all quality assurance criteria described in this subdivision.

(1) Each licensee or registrant shall adopt and maintain a quality assurance manual that includes policies and procedures that require the following:

(i) Each patient's medical record shall be complete, accurate, legible and shall include the patient's initial clinical evaluation, treatment planning data, treatment execution data, clinical assessments during treatment, a treatment summary and plan for subsequent care. Treatment related data shall be recorded in the patient's medical record at the time of each treatment.

(ii) A written and dated order or prescription for the medical use of radiation or radioactive material shall be made for each patient in accordance with subdivisions (b) and (c) of section

16.19 of this Part. The order or prescription shall be signed or approved electronically by a board certified radiation oncologist or qualified physician who restricts his or her practice to radiation oncology.

(iii) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system shall be verified by qualified clinical staff prior to patient treatment.

(iv) A radiation therapy technologist, physician or other qualified health practitioner shall verify that the patient set up on the treatment machine is in accordance with the treatment plan prior to the first fraction of a course of treatment and prior to treatment for any changes to the initial treatment plan.

(v) Clinical staff shall obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous or suspected of being erroneous.

(vi) Each patient's identification shall be verified by at least two different means by qualified clinical staff prior to each treatment.

(vii) Each patient's response to treatment shall be assessed by a board certified radiation oncologist or other qualified physician in the active practice of external beam therapy and/or brachytherapy. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record.

(viii) The medical records of patients undergoing fractionated treatment shall be checked for completeness and accuracy by qualified clinical staff at intervals not to exceed six fractions.

(ix) Radiation treatment plans and related calculations shall be checked by qualified clinical staff for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered, except the check shall be performed prior to treatment for: any single fraction treatment; any fractional dose that exceeds 300cGy or 700 monitor units; or when the output of a medical therapy accelerator exceeds 600 monitor units per minute during treatment. If a treatment plan and related calculations were originally prepared by a board certified radiation oncologist or an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part, it may be rechecked by the same individual using a different calculation method.

Treatment plans and related calculations prepared by other qualified clinical personnel must be checked by a second qualified person using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to subparagraph (2) of this paragraph, and who has received training in use of the manual pursuant to subparagraph (2) of this paragraph.

(x) All equipment and other technology used in planning and administering radiation therapy shall function properly and safely, and shall be calibrated properly and repaired and maintained in accordance with the manufacturer's instructions. The equipment and technology that is subject to such quality control includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation; dosimetry equipment;

equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and mV imaging equipment and monitors that are used to view patient imaging studies; and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems and data networks/storage media, shall be evaluated and tested to ensure accurate and complete data transfer.

(xi) Quality control tests performed on equipment and technology used in planning and implementing radiation treatment shall be documented, including:

(a) detailed procedures for performing each test;

(b) the frequency of each test;

(c) acceptable results for each test;

(d) corrective actions taken;

(e) record keeping and reporting procedures for test results including the tester's name, signature and date of the test; and

(f) the qualifications are specified for the individual(s) conducting the test and for the person who reviews test data.

(xii) Test results that exceed tolerances/limits shall be immediately reported to the authorized medical physicist.

(xiii) Records for all maintenance, repairs and upgrades of equipment and technology shall be maintained for at least five years.

(xiv) Errors or defects in technology or equipment, including computer hardware and software, shall be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this clause shall be maintained for review by the Department for at least three years.

(xv) External beam therapy equipment calibration/output required by section 16.60(c)(1) of this Part shall be verified by an independent means and records of such measurements shall be retained for review by the Department for at least three years.

(xvi) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) (incorporating 10 CFR 35.75) and the licensee's radioactive materials license, after being released from the licensee's facility.

(xvii) All personnel involved in planning or implementing radiation therapy shall be credentialed. Credentialing shall include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of

credentialing shall be maintained during the period in which the credentialed person provides services to the licensee or registrant and for three years thereafter.

(xviii) Any unintended deviation from the treatment plan that is identified shall be evaluated and corrective action to prevent recurrence shall be implemented. Records of unintended deviations and corrective action shall be maintained for audits required by paragraph (4) of this subdivision and for review by the Department.

(xix) There shall be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts and hazards.

(2) Each licensee or registrant shall adopt and maintain a radiation treatment manual that includes the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations as required in paragraph (1) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by paragraph (1) of this subdivision. The radiation treatment manual shall be included in training given pursuant to subdivision (c) of section 16.13 of this Part to facility staff who will participate in treatment planning. Each licensee or registrant shall ensure that an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility and reviews the treatment planning manual at least annually.

(3) Each licensee or registrant shall ensure that all equipment used in planning and administering radiation therapy is functioning properly, designed for the intended purpose, properly calibrated, and maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual.

(4) Each licensee or registrant shall implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that include the following:

(i) Audits shall be conducted at intervals not to exceed 12 months by an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee or registrant.

(ii) The licensee or registrant shall ensure that the individuals who conduct the audit prepare and deliver to the licensee or registrant a report which contains an assessment of the effectiveness of the quality assurance program and makes recommendations for any needed modifications or improvements.

(iii) The licensee or registrant shall promptly review the audit findings, address the need for modifications or improvements, and document actions taken. If recommendations are not acted on, the licensee or registrant shall document the reasons therefor and also alternative actions taken to address the audit findings.

(iv) Each licensee or registrant shall maintain for review and inspection by the Department complete written records relating to quality assurance and audit activities. Audit records shall be maintained for at least 6 years.

(6) Accreditation in Radiation Oncology.

(i) Effective 90 days from the effective date of this regulation, each registrant or licensee shall have an active application with, or be accredited in radiation oncology by, the American College of Radiology, the American College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(ii) Effective 18 months from the effective date of this regulation, each registrant and licensee shall maintain accreditation in radiation oncology by the American College of Radiology, the American College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(iii) The registrant or licensee shall maintain a record of accreditation, including a copy of the application, all supplemental application information and all correspondence transmitted between the accrediting body and the registrant or licensee. Records shall be maintained for at least 6 years.

Section 16.100 is REPEALED and new Section 16.100 is added to read as follows:

§16.100 Licensing requirements for use of radioactive materials.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer any radioactive materials only in accordance with a specific license issued by the Department or as allowed in paragraphs (b) or (c) of this section.

(b) A specific license is not required for persons who comply with all applicable requirements for a general license as set forth in section 16.101 of this Part.

(c) A specific license is not required for persons who comply with all applicable requirements to qualify for an exemption as set forth in section 16.4 of this Part or other exemptions provided for in this Part or for the removal of source material from its place of deposit in nature.

Section 16.120 is REPEALED and new Section 16.120 is added to read as follows:

§16.120 Specific licenses for the use of radioactive materials on human beings.

An application seeking a specific license for use of radioactive materials on human beings shall be approved if all of the following criteria are satisfied:

(a) The application is completed, signed by an appropriate individual, and submitted to the Department.

(b) The applicant is an individual, corporation, partnership or other entity that is legally authorized to do business in New York State. If the applicant is seeking a specific license

pursuant to section 16.123 of this Part, the applicant shall be legally authorized to practice medicine in New York State or operate a hospital as defined in section 2801 of the Public Health Law.

(c) The applicant satisfies the requirements set forth in section 16.103 of this Part.

(d) The applicant demonstrates to the satisfaction of the Department that it has adequate facilities for clinical care of patients.

(e) The applicant demonstrates to the satisfaction of the Department that its facilities will be appropriately equipped and staffed and will be operated as required by this Part.

(f) The applicant provides additional information as requested by the Department.

Section 16.121 is REPEALED and Reserved.

Section 16.122 is REPEALED and Reserved.

Section 16.123 is REPEALED and a new Section 16.123 is added to read as follows:

§16.123 Specific licenses for certain medical uses of byproduct materials.

(a) Purpose and scope. This section contains requirements for the medical uses of byproduct materials that are subject to specific licenses. These requirements are in addition to, and not a substitute for, other requirements in this Part. Any license issued prior to the effective date of this regulation that references paragraph (b) shall be deemed to reference paragraph (d).

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) "Authorized medical physicist" means an individual who is authorized to practice medical physics pursuant to Article 166 of the Education Law and:

(i) meets the definition and the training requirements for an authorized medical physicist set forth in 10 CFR §§ 35.2, 35.51 and 35.57; or

(ii) is named as a radiation therapy physicist on a medical use radioactive materials license issued by the Department and meets the requirements set forth in 10 CFR § 35.59.

(2) "Authorized nuclear pharmacist" means an individual who is authorized to practice pharmacy pursuant to Article 137 of the Education Law and:

(i) meets the requirements for an authorized nuclear pharmacist in 10 CFR § 35.55(a) and § 35.59; or

(ii) is identified as an authorized nuclear pharmacist on:

(a) a specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(b) a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(c) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(d) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(iii) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(iv) was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a federal government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(3) "Authorized user" means an individual who is authorized to practice medicine pursuant to Article 131 of the Education Law and:

(i) meets the applicable requirements in 10 CFR §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(ii) is identified as an authorized user on:

(a) a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of byproduct material;

(b) a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

(c) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(d) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(4) "Medical use" means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

(5) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(6) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR §§ 35.100 and 35.200. Further details concerning this referenced code are contained in subdivision (c) of this section.

(7) "Prescribed dose" means:

(i) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(8) "Radiation safety officer" means an individual who:

(i) meets the requirements set forth in 10 CFR §§ 35.50(a) or (c)(1) and 35.59; or

(ii) is identified as a radiation safety officer on a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State or a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(9) "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(10) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(c) Approved medical uses of byproduct materials. A licensee may use byproduct materials on human beings for the particular uses set forth below, provided that the licensee meets all applicable requirements of this Part:

(1) Use of unsealed byproduct material for uptake, dilution and excretion studies;

(2) Use of unsealed byproduct material for imaging and localization studies;

(3) Use of unsealed byproduct material for which a written directive is required;

(4) Use of sources for manual brachytherapy;

(5) Use of sealed sources for diagnosis;

(6) Use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit; or

(7) Other specific medical uses of byproduct material or radiation from byproduct material, as licensed by the Department.

(d) Federal standards. All licensees shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: Title 10 of the Code of Federal Regulations, Part 35, Medical Use of Byproduct Material. This code is published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington D.C. 20402. This code is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Notwithstanding any provision herein to the contrary, if a conflict occurs between the above referenced CFR and other provisions in this Part, compliance with the more restrictive regulation is required.

(e) General requirements applicable to all licensees authorized to use byproduct materials for medical purposes.

(1) Record Keeping Requirements. A licensee shall comply with all record keeping requirements set forth in Subpart L (Records) of Part 35 of 10 CFR. Further details concerning this referenced code are contained in subdivision (c) of this section.

(2) Reporting requirements: A licensee shall comply with all reporting requirements set forth in Subpart M (Reports) of Part 35 of 10 CFR as revised herein as follows: (i) in § 35.3045(c) and §35.3047(c), replace phrase "NRC Operations Center" with "Department"; (ii) in §35.3045(d) and § 35.3047(d), replace “By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter” with “shall submit a written report to the Department”; (iii) in § 35.3045(g)(1) and § 35.3047(f)(1), replace the term "NRC" with "Department"; and, (iv) in § 35.3067 replace “The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs.” with “The report shall be filed with the Department”.

(3) Training and experience requirements. A licensee shall ensure that all staff who are involved in the use of byproduct material pursuant to a specific license have the training and experience required by this Part.

(4) Other General Requirements. A licensee shall comply with requirements set forth in 10 CFR § 35.5, §35.6, §35.11(a)and (b), §35.24(b), (e), (f) and (g), §35.27, §35.40, §35.41, §35.49,

§35.60, §35.61, §35.63, §36.67, §35.69, §35.70, §35.75, §35.80, §35.92 as modified herein as follows: in § 35.27(a)(1) and (b)(1), replace “19.12 of this chapter” with “16.13(c) of this Part”.

(f) Requirements for the use of unsealed byproduct material for uptake, dilution and excretion studies. A licensee shall use unsealed byproduct material for uptake dilution and excretion studies only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with 10 CFR §§ 35.100 and 35.190 and all applicable provisions of this Part.

(g) Requirements for the use of unsealed byproduct material for imaging and localization studies. A licensee shall use unsealed byproduct material for imaging and localization studies only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with 10 CFR §§ 35.200, 35.204 and 35.290 and other applicable provisions of this Part.

(h) Requirements for the use of unsealed byproduct material for which a written directive is required. A licensee shall use unsealed byproduct material for which a written directive is required only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with Subpart E (Unsealed Byproduct Material-Written Directive Required) of Part 35 of 10 CFR and other applicable provisions of this Part.

(i) Requirements for the use of sources for manual brachytherapy. A licensee may use sources for manual brachytherapy only if authorized to do so by a specific license issued by the Department

and provided that the licensee complies with Subpart F (Manual Brachytherapy) of Part 35 of 10 CFR.

(j) Requirements for the use of sealed sources for diagnosis. A licensee may use sealed sources for diagnosis only if authorized to do so by a specific license issued by the department and provided that the licensee complies with Subpart G (Sealed Sources for Diagnosis) of Part 35 of 10 CFR and other applicable provision of this Part.

(k) Use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee may use a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit only if authorized to do so by a specific license issued by the department and provided that the licensee complies with Subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) of Part 35 of 10 CFR and other applicable provisions of this Part.

(l) Other medical uses of byproduct material or radiation from byproduct material. A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in paragraphs 1 through 6 of subdivision (b) of this section if the licensee submits to the department information required by 10 CFR §35.12(b) through (d) and the licensee has received written approval from the Department in a specific license or license amendment and uses the material in accordance with specific conditions that the department deems necessary or desirable for the safest medical use of the material.

(m) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in paragraphs (1) through (6) of subdivision (b) of this section also is authorized to use radioactive material under the general license in Appendix 16-A, Table 6, Item (i) *infra*, for the specified "in vitro" uses without filing Form GEN 373 as required by Appendix 16-A, Table 6, Item (i), subdivision (2), *infra*, provided, however, that the licensee is subject to the other provisions of Appendix 16-A, Table 6, Item (i), *infra*.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 225(5)(p) and (q) and 201(1)(r) authorize the Commissioner to promulgate SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to these regulations, as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials and ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC §§ 2021, et. seq. authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes "Agreement States" to regulate the use of radioactive materials in lieu of the NRC, provided that the "Agreement State" promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an "Agreement State" within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only to the use of radioactive materials; it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

The legislative intent of PHL §§ 225(5) and 201(1)(p) and (q) is to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective clinical uses of radioactive material and radiation producing equipment is consistent with this legislative objective.

Needs and Benefits:

The NRC has relinquished its authority to regulate the use of radioactive materials in New York State to the Department. The Act requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates the use of radioactive material at approximately 1100 facilities, including approximately 450 health care facilities. The Department's regulations are designed to require the delivery of quality care while protecting people and the environment from the harmful effects of radiation. In order to ensure that New York retains its authority under federal law to regulate the use of radioactive material, the Department's regulations must be amended to conform more closely to current federal regulatory standards. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the medical use of radioactive materials. In areas where the NRC regulations are not incorporated, the Department has promulgated comparable regulations.

In recent years, technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively

deliver high dose rate treatments to precisely defined three-dimensional tumor volumes while sparing dose to healthy tissue. Patients benefit significantly when, as is the case in the vast majority of such radiation treatments, the dose is delivered as intended. However, radiation treatment errors can cause serious consequences for patients and in extreme cases, death. An analysis of the causes of medical adverse events (radiation therapy misadministrations) reported to the Department within the past eight years has identified common errors and causes of errors that may be preventable with the implementation of more comprehensive quality assurance programs. When the current regulations for quality assurance for external beam and brachytherapy were implemented in 1993, radiation therapy equipment was much simpler in design and function, and there were fewer units in service. Most radiation therapy treatments were delivered in a hospital setting. Today there are greater numbers of patients receiving radiation therapy, and more patients are treated in freestanding radiation therapy centers. There are more medical therapy accelerators in use. Newer radiation treatment systems are very complex; these systems rely on computer networks and electronic data storage and movement. DOH regulates approximately 120 medical facilities that provide radiation therapy. The current regulations need to be revised to effectively address quality assurance requirements for newer systems, to ensure implementation of strategies to prevent the occurrence of misadministrations and ensure those facilities meet current standards of care.

Costs:

The Department estimates that regulated parties that use radioactive materials will not incur any additional costs in order to comply with the proposed changes to 10 NYCRR § 16.123. In most instances, the proposed regulatory amendments will reduce costs and regulatory burdens for

physicians who are required to qualify as "authorized users" of radioactive materials for diagnostic purposes. The current section requires 200 hours of classroom training. By removing this requirement and incorporating the federal classroom training requirements set forth in 10 CFR Part 35, the required classroom and laboratory training hours will be reduced to 80 hours for physicians applying for authorized user status for diagnostic uses. In addition, these physicians would be allowed to obtain the practical training component in a private medical practice setting. Currently such training can be obtained only at a medical institution (hospital). By incorporating the training requirements established in 10 CFR Part 35, the total number of training hours for physicians who use radioactive materials will remain at 700 hours.

This will result in lower costs for classroom training (tuition/course fee) and associated travel/lodging expenses, and will reduce the time a physician would be away from his/her clinical practice to obtain the required classroom training. The current regulations specify that such training must be obtained at a medical institution, or hospital. However, under the training requirements established in 10 CFR Part 35, which will be incorporated by the new regulation, physicians will have the option to obtain the required work experience portion of the training (620 hours) at non-institutional facilities. Costs associated with complying with the quality assurance testing for therapeutic devices, including high-dose rate brachytherapy and teletherapy should not increase or change, because the current license conditions contain these same quality assurance requirements.

The Department estimates that the cost to regulated parties that use external beam therapy or manual brachytherapy to comply with proposed 10 NYCRR § 16.24 will be limited to the fee to

become accredited in radiation oncology by either the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or an equivalent organization as approved by the Department. The cost for accreditation is approximately \$9,500 for each three-year period. However, approximately half of the affected regulated parties are either currently accredited or have an application pending with ACR or ACRO on their own accord. Many that are not accredited use the services of outside radiation oncologists and medical physicists to audit their radiation therapy quality assurance program on an annual basis. The costs for annual outside audits are estimated to cost several thousands of dollars. The proposed regulation would remove the need for outside audits, although they could be conducted to meet the requirement for an annual audit. Under the proposed rule, either an internal or an external audit may be used to fulfill the annual audit requirement. Costs saved by elimination of the requirement for outside audits are expected to offset a portion of the costs that will be incurred for accreditation. The other proposed changes to 10 NYCRR § 16.24 will impose very little or no cost to regulated parties since existing facility staff can comply with the new quality assurance requirements.

Local Government Mandates:

These proposed regulations apply to two State University hospitals, a Department operated hospital and hospitals operated by public benefit corporations. These hospitals are currently accredited by the ACR. No other additional costs are associated with implementation of these requirements. Registrants and licensees, including the hospitals operated by state and local governments, are currently required to retain all quality assurance documents for review by the department. The additional records and filing is estimated to be a small incremental amount. Affected parties will need to complete an application for accreditation initially and every three

years thereafter. The radiation oncology accrediting bodies are transitioning to an on-line application process to minimize time and effort for parties seeking accreditation.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain or file. Affected parties will have to complete an application for radiation oncology accreditation. However, the accrediting bodies are transitioning to an online application process to minimize time and effort for regulated parties seeking accreditation.

The proposed regulations will not affect license documents issued by the Department to current licensees, registrants or authorized users. The Department plans to provide updated license guidance to new applicants to facilitate completion of an application based on the new requirements.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, state or local agency for licensees, registrants or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its regulatory authority over the use of radioactive materials and New York assumed such authority. The Atomic Energy Act does not govern use of x-ray emitting equipment.

Alternatives:

There are no suitable alternatives to the revisions to these proposed regulations. As discussed above, the Atomic Energy Act (42 USC § 2021 et. seq.) requires Agreement States such as New York to adopt and implement regulatory standards that meet or exceed comparable federal standards.

Federal Standards:

These proposed revisions to 10 NYCRR §16.123 incorporate by reference certain federal requirements specified in 10 CFR Part 35.

Compliance Schedule:

The proposed regulatory amendments will be effective upon publication of a Notice of Adoption in the State Register. However, proposed 10 NYCRR §16.24(a)(6) requires that licensees and registrants apply for accreditation in radiation oncology with the American College of Radiology or the American College of Radiation Oncology or another accrediting organization approved by the Department within 90 days of the regulation's effective date and to become accredited and maintain such accreditation within 18 months of such effective date.

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Regulatory Flexibility Analysis for Small Businesses and Local Governments

Effect on Small Business:

The Department has issued radioactive materials licenses to approximately 350 private medical practices. These licensees would be affected by the proposed revisions to 10 NYCRR §16.123.

The Department estimates that there will be no new costs for these licensees and in some instances, regulated parties may save money by complying with the updated standards in proposed 10 NCR §16.123. The Department expects the cost to comply with the new training and experience requirements for physicians who wish to become authorized for certain medical uses will be reduced in most situations. Specifically the required classroom and laboratory training hours will be reduced from 200 to 80 hours for physicians applying for authorized user status for diagnostic uses. The total number of training hours will remain at 700 hours. This will result in lower costs for classroom training (tuition/course fee) and associated travel/lodging expenses, and will reduce the time a physician would be away from his/her clinical practice to obtain the required classroom training. Physicians will have the option to obtain the required work experience portion of the training (620 hours) at non-institutional facilities. The current requirements specify that such training must be obtained at a medical institution (hospital).

The proposed changes to 10 NYCRR §16.24 would apply to approximately 60 medical private practices. The draft proposed rule was sent to all medical therapy accelerator facilities, including the small businesses (non-institutions) for comments. One facility manager stated that they support the accreditation requirement although it can be a hardship to practices like hers.

However the manager's facility was already accredited and has application pending to maintain accreditation. No other facility expressed any anticipated hardship with the proposed rule.

Compliance Requirements:

Licensees and applicants will need to become familiar with the new requirements and modify their quality assurance policies and procedures accordingly. Those who are not currently accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

The vast majority of facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. The Department does not expect that it would be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements.

Capital Costs and Annual Costs of Compliance:

The amortized annual cost is estimated to be approximately \$3,200 per year for accreditation (based on a three-year accreditation cost of \$9,500). However, approximately 50 percent of the facilities are either currently accredited or have an application for accreditation pending; therefore, they will not incur any additional costs. There are no capital costs associated with this regulation.

Economic and Technology Feasibility

There are no capital costs or new technology required to comply with the proposed rule.

Minimizing Adverse Impact:

Facilities will have 90 days to apply and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. The Department has held several discussions with the proposed accrediting bodies, and has accompanied their auditors during accreditation surveys. These interactions were conducted to ensure that the bodies have the capacity to handle an influx of applications for accreditation and that the organizations operate in a professional and constructive manner, have an efficient process, and have an overall effect of improving patient safety. Further the requirement for external annual audits was eliminated which would offset the cost of accreditation.

Small Business Input:

A copy of the draft proposed rule was sent to all medical therapy accelerator facilities, which includes both private practices and hospital-based radiation therapy treatment clinics. Seven facilities submitted comments. Only one commenter addressed the cost for accreditation, however, she stated that she supports the accreditation requirement. Several comments were in regard to clarification on a few aspects of the proposed language. Guidance, which will assist the affected facilities in implementation and compliance with the new requirements, will be developed and provided to affected facilities.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

There are 105 affected facilities located in 46 rural areas (33 counties with a population of less than 200,000 and 13 counties with certain townships with a population density of more than 150 persons per square mile).

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements contained in the proposed regulations. No additional professional service costs are anticipated. Facilities will be required to maintain records of quality assurance test results and accreditation documents for review by the Department's inspectors. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

The cost to comply with the accreditation requirement will be approximately \$9,500 every three years. This will affect approximately 50 percent of the facilities that will be subject to the proposed 10 NYCRR §16.24(e), because approximately 50 percent of the facilities are either currently accredited or have an application for accreditation pending. Facilities that are currently accredited or have an application pending have done so in part to satisfy the current audit requirements in section 16.24. Such facilities have selected the option to conduct annual internal audits (by in-house staff) and have periodic audits performed by the ACR or ACRO. Such facilities will not effectively see an increase in their operating budgets to comply with the new

accreditation requirement as they have already chosen to become accredited and have budgeted for the associated cost.

Minimizing Adverse Impact:

Facilities will have 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. The Department has held several discussions with the proposed accrediting bodies, and has accompanied their auditors during accreditation surveys. These interactions were conducted to ensure that the bodies have the capacity to handle an influx of applications for accreditation and that the organizations operate in a professional and constructive manner, have an efficient process, and have an overall effect of improving patient safety.

Rural Area Participation:

A copy of a draft proposed rule was sent to all medical therapy accelerator facilities, which includes both private practices and hospital-based radiation therapy treatment clinics. Seven facilities commented. One commenter addressed the cost for accreditation but indicated they understood the value of accreditation. A few commenters requested minor clarification on a few aspects of the proposed language.

Job Impact Statement

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Radiation therapy providers in New York will need to become familiar with and implement the new regulatory requirements set forth in proposed 10 NYCRR §16.24. The proposed regulations do not significantly change the training or experience requirements of radiation therapy facility staff. Medical providers authorized to use radioactive materials would need to become familiar with and implement the new regulatory requirements set forth in proposed 10 NYCRR §16.123. The Department anticipates that few if any persons will be adversely affected. Licensee staff, specifically those designated as the radiation safety officer, medical physicist, nuclear pharmacist, and authorized user will need to become familiar with the new requirements.

Categories and Numbers Affected:

There are approximately 120 radiation therapy facilities that would be subject to the rule. Half of these are hospitals or their satellite facilities, and the other half are non-institutional entities. There are approximately 450 medical use of radioactive materials licensees.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule is expected to have minimal impact on self-employment opportunities since the majority of providers that will be affected by the rule are not sole proprietorships.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Article 36 of the Public Health Law, Sections 763.3, 763.6, 763.7, 766.3, 766.4, 766.5 and 766.9 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (b) of section 763.3 is amended as follows:

(b) An agency shall provide at least one of the services identified in paragraph (1) of subdivision (a) of this section [nursing, physical therapy, speech-language pathology or occupational therapy] directly, while any [additional service] other services may be provided directly or by contract arrangement. For purposes of this Part, the direct provision of services includes the provision by employees compensated by the agency or individuals under contract with the agency, but does not include the provision of services through contract arrangements with other agencies or facilities.

Subdivisions (c) and (e) of section 763.6 are amended as follows:

(c) The plan of care shall cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, need for palliative care, rehabilitation potential, functional limitations, activities permitted, nutritional

requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.

* * *

(e) The plan of care shall be reviewed as frequently as required by changing patient conditions but at least every [62] 60 days.

Paragraph (3) of subdivision (a) of section 763.7 is amended as follows:

(3) medical orders and nursing diagnoses to include all diagnoses, medications, treatments, [and prognosis] prognoses, and need for palliative care. Such orders shall be:

(i) signed by the authorized practitioner within 30 days after admission to the agency, or prior to billing, whichever is sooner;

(ii) signed by the authorized practitioner within 30 days after issuance of any change in medical orders or prior to billing, whichever is sooner, to include all written and oral changes and changes made by telephone by such practitioner; and

(iii) renewed by the authorized practitioner as frequently as indicated by the patient's condition but at least every [62] 60 days;

Subdivision (b) of section 766.3 is amended as follows:

(b) a plan of care is established for each patient based on a professional assessment of the patient's needs and includes pertinent diagnosis, prognosis, need for palliative care, mental status, frequency of each service to be provided, medications, treatments, diet regimens, functional limitations and rehabilitation potential;

Subdivision (d) of section 766.4 is amended as follows:

(d) Medical orders shall reference all diagnoses, medications, treatments, prognoses, need for palliative care, and other pertinent patient information relevant to the agency plan of care; and

(1) shall be authenticated by an authorized practitioner within thirty (30) days after admission to the agency; and

(2) when changes in the patient's medical orders are indicated, orders, including telephone orders, shall be authenticated by the authorized practitioner within 30 days.

Subdivision (l) of section 766.9 is amended as follows:

(l) appoint a quality improvement committee to establish and oversee standards of care.

The quality improvement committee shall consist of a consumer and appropriate health professional persons [including a physician if professional health care services are provided]. The committee shall meet at least four times a year to:

(1) review policies pertaining to the delivery of the health care services provided by the agency and recommend changes in such policies to the governing authority for adoption;

(2) conduct a clinical record review of the safety, adequacy, type and quality of services provided which includes:

(i) random selection of records of patients currently receiving services and patients discharged from the agency within the past three months; and

(ii) all cases with identified patient complaints as specified in subdivision (j) of this section;

(3) prepare and submit a written summary of review findings to the governing authority for necessary action; and

(4) assist the agency in maintaining liaison with other health care providers in the community.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (“PHL”) §3612(5) authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations to effectuate the provisions and purposes of PHL Article 36 with respect to certified home health agencies. Section 3612(6) requires the Commissioner of Health to adopt, and amend as needed, rules and regulations to effectuate the purposes of Article 36 regarding quality of care and services.

Legislative Objectives:

PHL Article 36 was intended to promote the quality of home care services provided to residents of New York State and to assure adequate availability as a viable alternative to institutional care.

Needs and Benefits:

On February 24, 2011 Governor Cuomo accepted a report from the Medicaid Redesign Team (MRT) designed to meet the Medicaid savings targets contained in the Executive Budget for 2011-12. The report included 79 recommendations to redesign and restructure the Medicaid program to be more efficient and achieve better outcomes for patients. Included among the recommendations accepted were MRT proposal numbers 109 and 147.

MRT Proposal 109 sought to expand access to palliative care services. In furtherance of that objective, the proposed amendments to the regulations add a requirement that the plans of care and medical orders required for patients of certified home health agencies (CHHAs) and licensed home care services agencies (LHCSAs) address the patient’s need for palliative care.

MRT Proposal 147 aimed to reduce regulatory burdens on providers. Accordingly, the proposed changes to the regulations eliminate the need for a physician to serve on the quality improvement (QI) committee of LHCSAs.

Finally, the proposed changes reflect minor amendments made to align these regulations with federal requirements and to correct errors. First, the amendments eliminate the requirement that CHHAs provide more than one qualifying service directly to coincide with the federal standards as defined in 42 CFR §484.14(a). The current regulation appears to require CHHAs to provide more than one service directly, which the Department of Health does not require, and this has led to confusion among interested agencies.

Second, the amendments change the maximum period of time that may lapse before a comprehensive assessment is reviewed from 62 days to 60 days, as this was an error in the regulations as originally drafted. Federal regulations, at 42 CFR §484.55(d)(1), require review at least every 60 days.

Costs:

The only new requirement imposed on agencies by these regulations is the requirement that the plan of care address palliative care, which is not anticipated to result in any appreciable burden to agencies and should not add additional costs to current operations. All other amendments are cost neutral or will decrease costs.

Local Government Mandates:

There are no mandates in this rule specific to local government. There are 28 existing county-based LHCSAs and approximately 29 county based CHHAs, and these entities will be required to comply with the same requirements as other licensed agencies.

Paperwork:

Providers are not expected to have increased paperwork as a result of these amendments.

Duplication:

The proposed regulatory changes are not duplicative of other requirements.

Alternatives:

The MRT proposals are specific in their mandates. The Department has made only those changes required to implement the MRT proposals.

Federal Standards:

There are no federal health care standards for LHCSAs. This provider type is a New York State construct. Federal regulations governing CHHAs are at 42 CFR Part 484.

Compliance Schedule:

Compliance is expected upon notice of adoption in the State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Licensed home care services agencies (LHCSAs) and certified home health agencies (CHHAs), including those operated by county health departments, provide public health services in the home as required by Public Health Law. There are approximately 28 county-based LHCSAs and approximately 29 county-based CHHAs. Additionally, based on agency reports, the Department estimates that 860 LHCSAs and 168 CHHAs have less than 100 employees, and would be categorized as small businesses.

Compliance Requirements:

There is one new requirement imposed on home care agencies as a result of these amendments, which is to include the need for palliative care in each patient's plan of care and medical orders.

Professional Services:

No additional professional staff will be required because of these amendments. The requirement that agencies address the need for palliative care will be handled as a part of procedures already undertaken by agencies.

Compliance Costs:

It is not anticipated that there will be any increase in costs incurred by agencies as a result of these amendments. The amendments either remove existing obligations or add a minimal requirement that may be assumed with no increase in cost as part of current operations.

Economic and Technological Feasibility:

These rules can be implemented with no clear economic or technological impact. The only requirement imposed by these regulations is an unappreciable addition to current operations, and no additional technology will be required to comply.

Minimizing Adverse Impact:

The MRT proposals are specific in their mandates. The Department has made only those changes required to implement the MRT proposals.

Small Business and Local Government Participation:

The Department will meet the requirements of SAPA Section 202-b(6) in part by publishing a notice of proposed rulemaking in the State register with a comment period. All agencies and associations that represent such agencies were able to participate in the MRT process.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

All counties in New York State have rural areas with the exception of 7 downstate counties. Approximately 80% of LHCSAs and 86% of CHHAs are licensed to serve counties with rural areas.

Reporting, Record Keeping and Other Compliance Requirements and Professional Services:

There is one new requirement imposed on home care agencies as a result of these amendments, which is to include the need for palliative care in each patient's plan of care and medical orders. This requirement adds only a minimal recordkeeping burden on agencies, as plans of care and medical orders are already required for every patient serviced by a LHCSA or CHHA. No new professional staff is required to comply.

Costs:

It is not anticipated that there will be any increase in costs incurred by agencies as a result of these amendments. The amendments either remove existing obligations or add a minimal requirement that may be assumed with no increase in cost as part of current operations.

Minimizing Adverse Impact:

The MRT proposals were specific in their mandates. The Department has made only those changes required to implement the MRT proposals.

Rural Area Participation:

There is no impact specifically to rural areas as a result of these amendments, and the impact to all agencies is minimal.

JOB IMPACT STATEMENT

Nature of Impact:

The Department has determined that the proposed rules will not have a substantial adverse impact on jobs and employment opportunities.

Categories and Numbers Affected:

None

Regions of Adverse Impact:

None

Minimizing Adverse Impact:

Not applicable.

Self Employment Opportunities:

Not applicable.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 2800 and 2803 of the Public Health Law, Sections 405.2 and 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraphs (6) and (7) of subdivision (f) of section 405.2 are amended and a new paragraph (8) is added to read as follows:

(f) Care of patients. The governing body shall require that the following patient care practices are implemented, shall monitor the hospital's compliance with these patient care practices, and shall take corrective action as necessary to attain compliance:

* * *

(6) hospitals which conduct, or propose to conduct, or otherwise authorize human research on patients or other human subjects shall adopt and implement policies and procedures pursuant to the provisions of Public Health Law, article 24-A for the protection of human subjects; [and]

(7) hospitals shall have available at all times personnel sufficient to meet patient care needs[.];

and

(8) hospitals shall have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care as required by subdivision (a) of section 405.4 of this Part.

New paragraphs (4), (5), (6), (7) and (8) are added to subdivision (a) of section 405.4 to read as follows:

405.4 Medical staff.

- (a) Medical staff accountability. The medical staff shall be organized and accountable to the governing body for the quality of medical care provided to all patients.

* * *

- (4) The medical staff shall adopt, implement, periodically update and submit to the Department evidence-based protocols for the early recognition and treatment of patients with sepsis, severe sepsis and septic shock (“sepsis protocols”) that are based on generally accepted standards of care. Sepsis protocols must include components specific to the identification, care and treatment of adults and of children, and must clearly identify where and when components will differ for adults and for children. These protocols must include the following components:
- (i) a process for the screening and early recognition of patients with sepsis, severe sepsis and septic shock;
 - (ii) a process to identify and document individuals appropriate for treatment through severe sepsis protocols, including explicit criteria defining those patients who should be excluded from the protocols, such as patients with certain clinical conditions or who have elected palliative care;
 - (iii) guidelines for hemodynamic support with explicit physiologic and biomarker treatment goals, methodology for invasive or non-invasive hemodynamic monitoring, and timeframe goals;
 - (iv) for infants and children, guidelines for fluid resuscitation with explicit timeframes for vascular access and fluid delivery consistent with current,

evidence-based guidelines for severe sepsis and septic shock with defined therapeutic goals for children;

(v) a procedure for identification of infectious source and delivery of early antibiotics with timeframe goals; and

(vi) criteria for use, where appropriate, of an invasive protocol and for use of vasoactive agents.

(5) The medical staff shall ensure that professional staff with direct patient care responsibilities and, as appropriate, staff with indirect patient care responsibilities, including, but not limited to laboratory and pharmacy staff, are periodically trained to implement sepsis protocols required pursuant to paragraph (4) of this subdivision. Medical staff shall ensure updated training when the hospital initiates substantive changes to the protocols.

(6) Hospitals shall submit sepsis protocols required pursuant to paragraph (4) of this subdivision to the Department for review on or before July 1, 2013. Hospitals must implement these protocols no later than 45 days after receipt of a letter from the Department indicating that the proposed protocols have been reviewed and determined to be consistent with the criteria established in this Part. Hospitals must update protocols based on newly emerging evidence-based standards. Protocols are to be resubmitted at the request of the Department, not more frequently than once every two years unless the Department identifies hospital-specific performance concerns.

(7) Collection and Reporting of Sepsis Measures.

- (i) The medical staff shall be responsible for the collection, use, and reporting of quality measures related to the recognition and treatment of severe sepsis for purposes of internal quality improvement and hospital reporting to the Department. Such measures shall include, but not be limited to, data sufficient to evaluate each hospital's adherence rate to its own sepsis protocols, including adherence to timeframes and implementation of all protocol components for adults and children.
- (ii) Hospitals shall submit data specified by the Department to permit the Department to develop risk-adjusted sepsis mortality rates in consultation with appropriate national, hospital and expert stakeholders.
- (iii) Such data shall be reported annually, or more frequently at the request of the Department, and shall be subject to audit at the discretion of the Department.

(8) Definitions. For the purposes of this section, the following terms shall have the following meanings:

- (i) sepsis shall mean a proven or suspected infection accompanied by a systemic inflammatory response;
- (ii) severe sepsis shall mean sepsis plus at least one sign of hypoperfusion or organ dysfunction; and
- (iii) septic shock shall mean severe sepsis with persistent hypotension or cardiovascular organ dysfunction despite adequate IV fluid resuscitation.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (“PHL”) Section 2800 provides that “[h]ospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state . . ., the department of health shall have the central, comprehensive responsibility for the development and administration of the state’s policy with respect to hospital related services . . .”

PHL Section 2803 authorizes the Public Health and Health Planning Council (“PHHPC”) to adopt rules and regulations to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high quality health services at a reasonable cost.

Needs and Benefits:

Sepsis is a range of clinical conditions caused by the body's systemic response to an infection and affects about 750,000 people in the U.S. each year. The mortality rate is alarming – between 20 percent and 50 percent – and the rate largely depends on how quickly patients are diagnosed and treated with powerful antibiotics to battle the bacteria racing through their systems.

In New York State the number of **severe** sepsis cases increased from 26,001 in 2005 to 43,608 in 2011 - an increase of 68%. Similarly, the number of sepsis cases in New York State increased from 71,049 in 2005 to 100,073 in 2011, an increase of 41%. Sepsis mortality is significant and ranges widely from one hospital to another. In New York, sepsis mortality ranges between 15% and 37%. A patient may have a greater chance of dying from sepsis if care is provided by an institution ill-prepared to deal with this illness or from providers not thoroughly trained in identifying and treating sepsis.

The likelihood of death following initial diagnosis of sepsis is more than 20%, and the window for administering effective treatment is short. Mortality rates from severe sepsis are on a similar scale to lung, breast, and colon cancer, and it is one of the leading causes of death in the intensive care unit. Sepsis kills more people than HIV/AIDS, prostate cancer, and breast cancer combined.

The 28-day mortality rate in sepsis patients is comparable to the 1960s hospital mortality rate for patients of acute myocardial infarction (“AMI”). Over recent years, there has been an improvement in the awareness and management of AMI, resulting in a decline in mortality, while sepsis remains an unacknowledged killer.

The number of severe sepsis cases is expected to grow at a rate of 1.5% annually, adding an additional one million cases per year in the United States alone by 2020. This will increase total mortality and increase the burden on health care resources. The increase is mainly due to the growing use of invasive procedures, immune system modifying therapies and increasing numbers of elderly and high-risk individuals, such as those with diabetes, cancer and HIV. Older people are at an increased risk of sepsis as they are more vulnerable to infections due to aging, co-morbidities, use of invasive procedures, and problems associated with institutionalization. Individuals with diabetes, cancer, and HIV are at increased risk due to immune system and other dysfunction caused by their disease or its treatment.

Sepsis places a significant burden on health care resources, accounting for 40% of total ICU expenditures. Sepsis costs our health care system an estimated \$17 billion annually, and the average cost of treating the condition is \$50,000. (See http://www.nigms.nih.gov/Education/factsheet_sepsis.htm.)

The rapid diagnosis and management of sepsis is critical to successful treatment. The sepsis patient is usually already critically ill and requires immediate attention to avoid rapid deterioration; therefore, it is necessary to treat the patient at the same time as confirming the diagnosis. Due to the challenges of diagnosing and treating this complex condition, approximately 10% of sepsis patients do not receive prompt appropriate antibiotic therapy, which increases mortality by 10 to 15%.

In the absence of adoption of protocols as required by these regulations, it is estimated that New York will see dramatic increases in cases of sepsis and sepsis mortality as the numbers of persons who are at risk continue to increase.

Hospitals can significantly impact sepsis morbidity and mortality by adopting standard protocols. For example, since the implementation of Kaiser Permanente’s Northern California sepsis program mortality has been reduced for patients admitted to hospitals with sepsis, by more than 40 percent — and saved more than 1,400 lives. Similarly, Regions Hospital in Minnesota reports that initiatives launched in 2005 led to more than a 60 percent drop in sepsis mortality by 2011, and Intermountain Health Care reports a reduction in its sepsis mortality rate from 25% to 9%, saving 85 lives and \$38 million annually. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In particular, these regulations will promote the early identification and treatment of sepsis at general hospitals by focusing on the following areas:

- **Recognition** of risk factors, signs and symptoms of sepsis;
- **Resuscitation** with rapid intravenous fluids and administration of antibiotics upon diagnosis of sepsis;
- **Referral** to appropriate clinicians and teams as appropriate;
- **Measurement** and evaluation of current practices for purposes of informing future policy; and
- **Quality Improvement** measures that will permit development and dissemination of best practices through clinical and administrative information sharing.

The Department of Health (“the Department”) will publish guidance to assist facilities in developing protocols that include an appropriate process for screening all patients to ensure early recognition of patients with possible sepsis and, once possible sepsis has been documented,

establishing clear timeframes for administration of antibiotics and full protocol implementation. At a conference of stakeholders, including hospital systems, convened by the Department in 2012, it emerged that the current best practice is to pursue administration of antibiotics and fluid resuscitation within one hour of a diagnosis of sepsis, with full implementation of sepsis protocols within 3 hours for severe sepsis and six hours for septic shock. Given continual advancements in medical research and practice, these timeframes could change and accordingly will be set forth in guidance which will be updated as appropriate.

These regulations, requiring hospitals to adopt protocols to identify and treat sepsis, and another set of regulations requiring hospitals to provide patients and their parents or other medical decision-makers with critical information about the patient's care and to post a Parent's Bill of Rights, were inspired by the case of Rory Staunton, a 12-year-old boy who died of sepsis in April of 2012. Both sets of regulations, together known as "Rory's Regulations," will help New York State set a "gold standard" for patient care.

COSTS:

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Costs to the regulated entities are expected to be minimal and to be primarily associated with the following: (a) adoption of and compliance with evidence-based protocols; (b) reporting information to inform risk-adjusted sepsis mortality measures; and (c) training staff to implement the sepsis protocols. It is likely that hospitals will realize overall cost savings as a result of early identification and treatment (see below).

In fact, many hospitals throughout the State are currently implementing sepsis initiatives. The Greater New York Hospital Association (“GNYHA”) and the United Hospital Fund (“UHF”) have launched a joint program called the “Strengthening Treatment and Outcomes for Patients Sepsis Collaborative;” the North Shore-LIJ Health System recently launched an education program to train emergency and critical care nurses on how to identify sepsis at its earliest stages and provide treatment to improve patient outcomes; and the Healthcare Association of New York State (“HANY”) has organized a collaborative to improve the identification and management of sepsis and test the value of collaborative improvement projects versus traditional medical and clinical staff education. This regulation will build on and support these initiatives going forward.

Research conducted nationally suggests the possibility of a significant return on investment. As noted, Intermountain Health Care in Utah has reported savings of \$38 million per year due to its sepsis program, and reports more favorable reimbursement from insurers for identifying potential septic patients faster and treating them in the intensive care unit earlier. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In New York State, Stony Brook University Medical Center (“SBUMC”) reports that a recent campaign to reduce sepsis mortality was extremely successful, resulting in a 49 percent reduction in mortality and a decrease in length of stay for patients with severe sepsis. This resulted in a cost savings of more than \$740,000 for the 153 severe sepsis patients at SBUMC in 2010. (See <http://www.naph.org/Homepage-Sections/Explore/Innovations/Preventing-Hospital-Acquired-Conditions/Stony-Brook-Reduces-Sepsis-Mortality.aspx>.) Similarly, a recent sepsis initiative at South Nassau Communities Hospital resulted in a 44% reduction in sepsis

mortality (See HANYS Quality Institute, *Healthcare Association of New York State, Leading the Quest for Quality 2011 Profiles in Quality and Patient Safety*.) Similar savings to those reported by SBUMC are likely.

Costs to Local and State Government:

There is no anticipated fiscal impact to State or local government as a result of this regulation, except that hospitals operated by the State or local governments will incur minimal costs, offset by savings, as discussed above.

Costs to the Department of Health:

There will be minimal additional costs to the Department of Health associated with the following: review of protocols submitted by hospitals to the Department; general programmatic oversight; development of measures to evaluate the impact of these regulations as they relate to the adoption of evidence-based sepsis protocols; and creation of a data system for purposes of analysis and reporting.

Local Government Mandates:

Hospitals operated by State or local government will be affected and be subject to the same requirements as any other hospital licensed under PHL Article 28.

Paperwork:

Consistent with these regulations all hospitals will be required to submit evidence of the following:

- (a) adoption of an evidence-based sepsis protocol initially and then once every two years after that.
- (b) information sufficient to evaluate each hospital's adherence to its own sepsis protocol, including adherence to timeframes and implementation of all protocol components for adults and children;
- (c) data, as specified by the Department, to permit the evaluation of risk-adjusted severe sepsis mortality rates.

Duplication:

These regulations do not conflict with any State or Federal rules. Implementation of these regulations represents the first time New York State has required that facilities submit indication of adherence to evidence-based protocols for the early detection and treatment of sepsis and to report outcomes (risk-adjusted mortality). Thus, there is no duplication.

Alternative Approaches:

There are no viable alternatives. Implementation of these regulations is predicated on strong evidence indicating the effectiveness of implementing evidence-based protocols. In addition to requiring that all hospitals throughout the State develop and implement evidence-based sepsis

protocols, the regulations will require submission of data to the Department. This will allow the Department to monitor adherence to protocols, measure the impact of the protocols through risk-adjusted mortality statistics, and use the data and information obtained to inform the development of quality improvement initiatives.

Federal Requirements:

Currently there are no federal requirements regarding the adoption of sepsis protocols or for reporting adherence to protocols or risk adjusted mortality.

In December 2012, the National Quality Forum included a proposed measure of adherence to treatment bundles for patients treated for sepsis. This measure, which is currently under consideration, would focus on patients 18 years of age and older who present with symptoms of severe sepsis or septic shock who are eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle. The regulations proposed by the Department to measure adherence with established sepsis protocols will seek to be in alignment with the NQF measure when adopted.

Compliance Schedule:

These regulations will take effect upon publication of a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The provisions of these regulations will apply to the 228 general hospitals in New York State, including 18 general hospitals operated by local governments. Three general hospitals in the State are considered small businesses. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those three hospitals considered small businesses as well as the 18 hospitals operated by local governments. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

Professional Services:

Professional services are not anticipated to be impacted as a result of the following: (a) reporting the adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measure.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform risk-adjusted Sepsis mortality measures; and (c) training staff to implement the sepsis protocols. This will apply to those hospitals (three) defined as small businesses.

Economic and Technological Feasibility:

It is economically and technologically feasible for small businesses to comply with these regulations.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have a minimum of 90 days following adoption of these regulations to have sepsis protocols in place and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Small Business and Local Government Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are small businesses and operated by local governments, who are supportive of this initiative.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

The provisions of these regulations will apply to general hospitals in New York State, including 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals located in rural areas. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

Professional Services:

Professional services will not be impacted as a result of these regulations.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform

risk-adjusted Sepsis mortality measures; and (c) training staff to implement the sepsis protocols. This will apply to those hospitals located in rural areas of New York State.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have a minimum of 90 days following adoption of these regulations to have sepsis protocols in place and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Rural Area Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are located in rural areas, who are supportive of this initiative.

JOB IMPACT STATEMENT

Pursuant to the State Administrative Procedure Act (SAPA) section 201-a(2)(a), a Job Impact Statement for this amendment is not required because it is apparent from the nature and purposes of the proposed rules that they will not have a substantial adverse impact on jobs and employment opportunities.

SUMMARY OF EXPRESS TERMS

This proposal will amend Part 405 (Hospitals – Minimum Standards), primarily with respect to pediatric provisions and also to update various provisions to reflect current practice. Hospitals, for the purposes of Part 405, pertain to general hospitals.

Proposed amendments to Section 405.1 (Introduction) specify that the requirements of Part 405 relating to patient care and services will apply to patients of all ages, including newborns, pediatric and geriatric patients.

Proposed amendments to Section 405.3 (Administration), which currently requires hospitals to provide to the State Education Department (“SED”) a written report whenever enumerated professionals licensed by SED lose hospital employment or privileges for certain reasons, will require similar reporting to the Department of Health for certain individuals licensed by such Department.

Proposed amendments to Section 405.6 (Quality Assurance Program) will require hospital quality assurance processes to include a determination that the hospital is admitting only those patients for whom it has appropriate staff, resources and equipment and transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters or emergency surge that may require admissions to provide care to those patients.

A new subdivision (d) is added to Section 405.7 to require hospitals to post a Parent's Bill of Rights, setting forth the rights of patients, parents, legal guardians or other persons with decision-making authority to certain minimum protections required under other provisions of these regulations. In particular, the Parent's Bill of Rights would advise that patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a life-threatening or otherwise significant condition such that it requires immediate medical attention – are completed and reviewed by medical staff and communicated to the patient, his or her parents or other decision-makers, as appropriate

Proposed amendments to Section 405.9 (Admission/Discharge) specify that a hospital will be required to admit pediatric patients consistent with its ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients. If the hospital cannot meet these requirements, it will be required to develop criteria and policies and procedures for transfer of pediatric patients. This section also requires hospitals to develop policies and procedures enabling parents/guardians to stay with pediatric patients, and to permit at least one parent/guardian to remain with the patient at all times. Proposed amendments will also require hospitals to develop and implement written policies and procedures pertaining to review and communication of laboratory and diagnostic test/service results to the patient and, if the patient is not legally capable of making decisions, the patient's parent, legal guardian, health care agent or health care surrogate, as appropriate and subject to all applicable confidentiality laws and regulations. Such policies and procedures must

ensure that no discharge will occur while critical value tests are pending so as to assure appropriate care is provided to the patient. Further, all communication with the patient, parent, legal guardian, etc. must be clear and understandable to the recipient. In addition, the hospital must ask the patient or the patient's representative for the name of the patient's primary care provider, if any, and forward lab results to such provider.

This proposal also updates Section 405.12 (Surgical Services), which currently requires hospitals to develop and implement effective written policies and procedures, to provide that such policies and procedures include the performance of surgical procedures, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. The amendments will also require hospitals to assure that the privileges of each practitioner performing surgery are commensurate with his or her training and experience. Precautions must be clearly identified in written policies and procedures specific to the surgical service and post anesthesia care unit ("PACU") including appropriate resuscitation, airway and monitoring equipment including a resuscitation cart with age and size appropriate medications, equipment and supplies.

Updates to Section 405.13 (Anesthesia Services), which currently require hospitals to develop and implement effective written policies and procedures on matters such as the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital. Under the

amendments, such policies and procedures will have to be reviewed and updated at least biennially. In addition, hospitals will have to establish clinical competencies that are relevant to the care provided and, at a minimum, include instruction in safety precautions, equipment usage and inspections, infection control requirements and any patients' rights requirements pertaining to surgical/anesthesia consents. The amendments further provide that all equipment and services provided must be age and size appropriate.

Updates to Section 405.14 (Respiratory Care Services) will provide that orders for respiratory care services, in addition to specifying the type, frequency and duration of treatment, and as appropriate, the type and dose of medication, the type of diluent, and the oxygen concentration, must be consistent with generally accepted standards of care. The amendments further provide that all equipment and services provided must be age and size appropriate.

Updates to Section 405.15 (Radiologic and Nuclear Medicine Services) will specify that care must be provided in accordance with generally accepted standards of practice. The amendments will also require that policies and procedures regarding imaging studies for newborns and pediatric patients must include standards for clinical appropriateness, appropriate radiation dose and beam collimation, image quality and patient shielding. In addition, a policy and procedure must be developed to ensure that the practitioner's order for an imaging study is specific to the body part(s) that are to be imaged. Quality improvement audits must verify that these policies and procedures are being followed and must include a review of the adequacy of diagnostic images and

interpretations. Radiation safety principles must be adequate to ensure compliance with all generally accepted standards of practice as well as pertinent laws, rules and regulations. The amendments also provide that the chief of radiology, in conjunction with the radiation safety officer, must ensure that all practitioners who utilize ionizing radiation equipment within the hospital are properly trained in radiation safety procedures for patients of all ages.

The amendments to Section 405.1 also will update the megavoltage (“MEV”) requirements for therapeutic radiology or radiation oncology services to provide that they utilize six or more MEV unit with a source-axis distance of 100 or more centimeters as the primary unit in a multi-unit radiation oncology service. In addition, as amended, the regulations will require each therapeutic radiology service to have full time New York State licensed radiation therapists sufficient to meet the needs of the service and also a New York State licensed radiation therapy physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment. The amendments will also change a reference to an MEV unit so that it instead refers to a linear accelerator. A computed tomography (“CT”) scanner must be available within the radiation therapy program that is equipped for radiation oncology treatment planning or arrangements must be made for access to a CT scanner on an as needed basis. Provisions must be made for access to a magnetic resonance imaging (“MRI”) scanner for treatment planning purposes on an as needed basis.

Updates to Section 405.17 (Pharmaceutical Services) will require hospital pharmacy directors, in conjunction with designated members of the medical staff, to ensure that for patients of all ages, weight must be measured in kilograms and that resources relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration are available to the professional staff. Pediatric dosing resources must include age and size appropriate fluid and medication administration and dosing. Dosing must be weight based and not exceed adult maximum dosage, or in emergencies, length based, with appropriate references for pediatric dosing available. The amendments will further require the director to ensure that the pharmacy quality assurance program include monitoring and improvement activities to identify, measure, prevent and/or mitigate adverse drug events, adverse drug reactions and medication errors in accordance with generally accepted standards and practices in the field of medication safety and quality improvement. All drugs and biologicals must be controlled and distributed in accordance with written policies and procedures to maximize patient safety and quality of care.

Updates to Section 405.19 (Emergency Services) provisions will require at least one clinician on every shift to have the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate a child. The director of the hospital's emergency service, attending physicians, supervising nurses, registered professional nurses ("RNs"), physician assistants ("PAs") and nurse practitioners ("NPs") must satisfactorily complete and be current in Pediatric Advanced Life Support ("PALS") or have current training equivalent to PALS. Hospitals with less than 15,000 unscheduled

emergency visits per year do not need to have the supervising or attending physician present, but such supervising or attending physician must be available within 30 minutes of “patient presentation” provided that at least one physician, NP, or PA is on duty in the emergency service 24 hours a day, seven days a week.

In addition, the amendments will require hospitals to develop and implement protocols specifying when supervising or attending physicians must be present. In no event shall a patient be discharged or transferred to another hospital, unless evaluated, initially managed, and treated as necessary by an appropriately privileged physician, PA or NP. Specifically, no discharge should occur while critical value tests are pending so as to assure appropriate care is provided. The amendments will also require hospitals to develop and implement written policies and procedures pertaining to review and communication of laboratory and diagnostic test/service results ordered for a patient receiving emergency services to the patient and, if the patient is not legally capable of making decisions, the patient’s parent, legal guardian, health care agent or health care surrogate, as appropriate and subject to all applicable confidentiality laws and regulations. Further, policies and procedures must ensure that all communication with the patient, parent, legal guardian, etc. must be clear and understandable to the recipient. In addition, the hospital must ask the patient or the patient’s representative for the name of the patient’s primary care provider, if there is one, and lab results must be forwarded to such provider.

Section 405.20 (Outpatient Services) requires outpatient services, including ambulatory care services and extension clinics to be provided in a manner which safely and effectively meets the needs of all patients. Written policies must be in place for admission of patients whose postoperative status prevents discharge and necessitates inpatient admission to a hospital capable of providing the appropriate level of care.

Section 405.22 (Critical Care and Special Care Services) adds new provisions regarding Pediatric Intensive Care Unit (PICU) Services. A “PICU” is defined as a physically separate unit that provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill or injured. It must be staffed by qualified practitioners competent to care for critically ill or injured pediatric patients. “Qualified practitioners” are practitioners functioning within his or her scope of practice according to State Education Law and who meets the hospital’s criteria for competence, credentialing and privileging practitioners in the management of critically ill or injured pediatric patients. PICUs must be approved by the Department and the governing body must develop written policies and procedures for operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients. The PICU must have a minimum average annual pediatric patient number of 200/year. It must provide medical oversight for interhospital transfers of critically ill or injured patients during transfer to the receiving PICU.

The PICU must be directed by a board certified pediatric medical, surgical, anesthesiology or critical care/intensivist physician who must be responsible for the

organization and delivery of PICU care and has specialized training and demonstrated competence in pediatric critical care. Such physician in conjunction with the nursing leadership responsible for the PICU must participate in administrative aspects of the PICU. All hospitals with PICUs must have a physician, notwithstanding emergency department staffing, in-house 24 hours per day who is available to provide bedside care to patients in the PICU. PICU physician and nursing staff must successfully complete and be current in pediatric advanced life support (PALS) or have current training equivalent to PALS.

The hospital must have an organized quality performance improvement program for PICU services and include monitoring of volume and outcomes, morbidity and all case mortality review, regular multidisciplinary conferences including all health professionals involved in the care of PICU patients. Failure to meet one or more regulatory requirements or inactivity in a program for a period of 12 months or more may result in actions, including, but not limited to, withdrawal of approval to serve as a PICU. No PICU can discontinue operation without first obtaining written approval from the department and must give written notification, including a closure plan acceptable to other department at least 90 days prior to planned discontinuance of PICU services. A hospital must notify the department in writing within 7 days of any significant changes in its PICU services, including, but not limited to: (a) any temporary or permanent suspension of services or (b) difficulty meeting staffing or workload requirements.

Section 405.28 (Social Services) is updated to current standards that care be provided under the direction of a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), with the scope of practice defined in Article 154 of the Education Law.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by paragraph (2) of section 2803 of the Public Health Law, Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

Section 405.1 is amended to read as follows:

405.1 Introduction.

* * *

(e) The requirements of this Part relating to patient care and services shall apply to patients of all ages, including newborns, pediatric and geriatric patients.

Subdivision (e) of Section 405.3 is amended to read as follows:

405.3 Administration.

(e) Other reporting requirements.

* * *

(2) The hospital shall furnish to the Department of Education or the Department of Health for individuals licensed by the Department within 30 days of occurrence, a written

report of any denial, withholding, curtailment, restriction, suspension or termination of any membership or professional privileges in, employment by or any type of association with a hospital relating to an individual who is a health profession student serving in a clinical clerkship, an unlicensed health professional serving in a clinical fellowship or residency, or an unlicensed health professional practicing under a limited permit or a state licensee, such as an audiologist, [certified social worker,] licensed master social worker (LMSW), licensed clinical social worker (LCSW), dental hygienist, dentist, medical laboratory technologist, nurse, occupational therapist, ophthalmic dispenser, optometrist, pharmacist, physical therapist, podiatrist, psychologist, radiologic technologist, radiologist assistant, respiratory therapist, respiratory therapy technician or speech-language pathologist for reasons related in any way to any of the following reasons;

- (i) Alleged mental or physical impairment, incompetence, malpractice, misconduct or endangerment of patient safety or welfare;
- (ii) Voluntary or involuntary resignation or withdrawal of association, employment or privileges with the hospital to avoid imposition of disciplinary measure; and
- (iii) The receipt of information concerning a conviction of a misdemeanor or felony.

The report shall contain:

- (a) The name and address of the individual;

- (b) The profession and license number;

- (c) The date of the hospital's action;

- (d) A description of the action taken; and

- (e) the reason for the hospital's action or the nature of the action or conduct which lead to the resignation or withdrawal and the date thereof.

* * *

Section 405.6 is amended to read as follows:

405.6 Quality assurance program.

The governing body shall establish and maintain a coordinated quality assurance program which integrates the review activities of all hospital services to enhance the quality of patient care and identify and prevent medical, dental and podiatric malpractice.

* * *

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

(1) review of the care provided by the medical and nursing staff and by other health care

practitioners employed by or associated with the hospital[;]. Such review shall include a determination that the hospital is admitting only those patients for whom it has appropriate staff, resources and equipment and transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters and/or emergency surge that may require admissions to provide care to those patients;

* * *

A new subdivision (d) is added to Section 405.7 to read as follows:

(d) Each hospital shall be required to post in a conspicuous place a Parent's Bill of Rights advising that, at a minimum and subject to laws and regulations governing confidentiality, that in connection with every hospital admission or emergency room visit:

(i) The hospital must ask each patient or the patient's representative for the name of his or her primary care provider and shall document such information in the patient's medical record.

(ii) The hospital may admit pediatric patients only to the extent consistent with their ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients.

(iii) The hospital permits parents/guardians to stay with pediatric patients, and at least one parent/guardian may remain with the patient at all times.

(iv) All test results completed during the patient's admission or emergency room visit will be reviewed by a physician, physician assistant or nurse practitioner who is familiar

with the patient's presenting condition.

(v) Patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a life-threatening or otherwise significant condition such that it requires immediate medical attention – are completed and reviewed by medical staff and are communicated to the patient, his or her parents or other decision-makers, as appropriate.

(vi) Patients may not be discharged until they receive a written discharge plan, which will also be verbally communicated to patients, their parents or other medical decision-makers, which will identify critical value results of laboratory or other diagnostic tests ordered during the patient's stay and identify any other tests that have not yet been concluded.

(vii) The communication of critical value results and the discussion of the discharge plan must be accomplished in a manner that assures that the patient, their parents or other medical decision makers have the capacity to obtain, communicate, process, and understand the health information provided in order to make appropriate health decisions.

(viii) Hospitals shall provide all lab results to the patient's primary care provider, if known.

Subdivision (b) of Section 405.9 is amended to read as follows:

405.9 Admission/discharge.

(b) Admission.

* * *

(7) Pediatrics. (i) The hospital shall admit pediatric patients consistent with its ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients. The [facility] hospital shall establish a separate pediatric unit if the hospital regularly has 16 or more pediatric patients or if pediatric patients cannot be adequately and safely cared for in other than separately certified pediatric beds. If a hospital cannot meet these requirements the hospital must develop criteria and policies and procedures for transfer of pediatric patients.

(ii) Hospitals maintaining certified pediatric beds shall assure that admission to those beds is limited to patients who have not yet reached their 21st birthday except in instances when there are no other available beds within the hospital. In such instances, the hospital shall afford priority admission to the pediatric bed to patients 20 years of age or younger.

(iii) Children under the age of 14 shall not be admitted to a room with patients 21 years of age or over except with the knowledge and agreement of the child's attending practitioner and parent or guardian and the concurrence of the other patients occupying the room and their attending practitioners.

[(iv) Infants shall not be kept in the same nursery or room with older children or with any adult patient unless their own healthy mothers occupy the same room and the concurrence of the other patients and their attending practitioners has been

obtained.]

(iv) [(v)] In the event a separate pediatric unit is not available, arrangements for the admission of all children shall be made consistent with written policies and procedures to ensure the safety of each patient.

(v) The hospital shall develop policies and procedures enabling parents/guardians to stay with pediatric patients. To the extent possible given the patient's health and safety, the hospital shall allow at least one parent/guardian to remain with the patient at all times.

* * *

(16) The hospital shall ask each patient for the name of his or her primary care provider, if any, on admission and shall document such information in the patient's medical record.

* * *

(f) Discharge.

* * *

(10) The hospital shall develop and implement written policies and procedures pertaining to the review and communication of laboratory and diagnostic test/service results ordered for a patient while admitted or receiving emergency services to the patient. If the patient lacks medical decision-making capacity, the communication shall be to the patient's medical decision-maker. The results shall also be provided to the patient's primary care

provider, if any.. Such policies and procedures shall be reviewed and updated as necessary and at a minimum shall include:

- (i) a requirement that all laboratory and other diagnostic tests/service results be reviewed upon completion by a physician, physician assistant or nurse practitioner familiar with the patient’s presenting condition;
- (ii) a requirement that all laboratory and other diagnostic test services results be forwarded to the patient’s primary provider, if known, after review by a physician, physician assistant or nurse practitioner;
- (iii) provisions to include in the discharge plan information regarding the patient’s completed and pending laboratory and other diagnostic test/service results, medications, diagnoses, and follow-up care and to review such information with the patient or, if the patient is not legally capable of making decisions, the patient’s parent, legal guardian or health care agent, as appropriate, subject to all applicable confidentiality laws and regulations;
- (iv) a requirement that before a patient is discharged, any laboratory or other diagnostic tests that could reasonably be expected to yield “critical value” test results are completed and reviewed by a physician, physician assistant or nurse practitioner familiar with the patient’s presenting condition. A “critical value” test result is defined as one that represents a

pathophysiological state at such variance with normal as to be potentially life threatening or which requires immediate medical attention;

- (v) a requirement that before a patient is discharged, any critical laboratory test result are communicated to the patient or, if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations;

- (vi) a requirement that all information be presented to the patient or if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent, as appropriate, subject to all applicable confidentiality laws and regulations, in a manner that assures that the patient, their parents or other medical decision makers have the capacity to obtain, communicate, process, and understand the health information provided in order to make appropriate health decisions.

* * *

Section 405.12 is amended to read as follows:

405.12 Surgical services.

[If surgery is provided, the service shall be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of

medical practice.]

If surgical services are provided, the hospital shall develop and keep current and implement effective written policies and procedures regarding staff privileges consistent with provisions set forth in section 405.4 of this Part, the performance of surgical procedures, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. Such policies and procedures shall be reviewed and updated as necessary, but at a minimum biennially.

(a) *Organization and direction.* _The surgical service shall be directed by a physician who shall be responsible for the clinical aspects of organization and delivery of all in-patient and ambulatory surgical services provided to hospital patients. That physician or another individual qualified by training and experience shall direct administrative aspects of the service.

(1) The operating room shall be supervised by a registered professional nurse or physician who the hospital finds qualified by training and experience for this role.

(i) Nursing personnel shall be on duty in sufficient number for the surgical suite in accordance with the needs of patients and the complexity of services they are to receive.

(ii) A registered professional nurse qualified by the hospital and by training and

experience in operating room nursing shall be preset as the circulating nurse in any and each separate operating room where surgery is being performed for the duration of the operative procedure. Nothing in this section precludes a circulating nurse from leaving the operating room as part of the operative procedure, leaving the operating room for short periods; or, in accordance with employee rules or regulations, being relieved during an operative procedure by another circulating nurse assigned to continue the operative procedure.

(iii) Licensed practical nurses and surgical technologists may perform scrub functions and may assist in circulating duties under the supervision of the circulating nurse who is present in the operating room for the duration of the procedure, in accordance with policies and procedures established by the medical staff and the nursing service and approved by the governing body.

(2) Surgical privileges shall be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner as required by section 405.4 of this Part. The surgical service shall maintain a roster of practitioners specifying the surgical privileges of each practitioner. The hospital shall assure that the privileges of the practitioner are commensurate with his or her training and experience.

* * *

(6) Precautions shall be clearly identified in written policies and procedures specific to

the department and the post anesthesia care unit (PACU) and include but are not limited to:

- (i) safety regulations posted;
- (ii) routine inspection and maintenance of equipment;
- (iii) availability in the operating room suites and PACU of [a] appropriate resuscitation, airway and monitoring equipment [call-in system, cardiac monitor, resuscitator, defibrillator, aspirator,] including a resuscitation cart with age and size appropriate medications, equipment and supplies, [thoracotomy set and tracheotomy set]; and
- (iv) control of traffic in and out of the operating room suites and accessory services to eliminate through traffic.

(b) *Operation and service delivery.* Policies governing surgical services shall be designed to assure the achievement and maintenance of generally accepted standards of medical practice and patient care. The policies shall assure that service and equipment routinely available in the operating suite and PACU are age and size appropriate.

* * *

Section 405.13 is amended to read as follows:

405.13 Anesthesia services.

If anesthesia services are provided within a hospital, the hospital shall develop, implement and keep current effective written policies and procedures regarding staff privileges consistent with provisions set forth in section 405.4 of this Part, the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. Such policies and procedures shall be reviewed and updated as necessary, but at a minimum biennially.

(a) *Organization and direction.* Anesthesia services shall be directed by a physician who has responsibility for the clinical aspects of organization and delivery of all anesthesia services provided by the hospital. That physician or another individual qualified by education and experience shall direct administrative aspects of the services.

(1) The director shall be responsible, in conjunction with the medical staff, for recommending to the governing body privileges to those persons qualified to administer anesthetics, including the procedures each person is qualified to perform and the levels of required supervision as appropriate. Anesthesia shall be administered in accordance with their credentials, competencies and privileges by the following:

(i) anesthesiologists;

(ii) physicians granted anesthesia privileges;

(iii) dentists, oral surgeons, or podiatrists who are qualified to administer anesthesia under State law;

(iv) certified registered nurse anesthetists (CRNA's) under the supervision of an anesthesiologist who is immediately available as needed or under the supervision of the operating physician who has been found qualified by the governing body and the medical staff to supervise the administration of anesthetics and who has accepted responsibility for the supervision of the CRNA; or

(v) a student enrolled in a school of nurse anesthesia accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs may administer anesthesia as related to such course of study under the direct personal supervision of a certified registered nurse anesthetist or an anesthesiologist.

(2) Anesthesia service policies shall clearly outline requirements for orientation and continuing education programs for all staff, and staff compliance with such requirements shall be considered at the time of reappointment or performance evaluation. Such training, clinical competencies and continuing education programs shall be established that are relevant to care provided but must, at a minimum, include instruction in safety precautions, equipment usage and inspections, infection control requirements and any patients' rights requirements pertaining to surgical/anesthesia

consents.

(3) The director shall, in conjunction with the medical staff, monitor the quality and appropriateness of anesthesia related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved.

(b) Operation and service delivery. Policies governing anesthesia services shall be designed to ensure the achievement and maintenance of generally accepted standards of medical practice and patient care.

(1) All anesthesia machines shall be numbered and reports of all equipment inspections and routine maintenance shall be included in the anesthesia service records. Policies and procedures shall be developed and implemented regarding notification of equipment disorders/malfunctions to the director, to the manufacturer and, in accordance with section 405.8 of this Part, to the department.

(2) Written policies regarding anesthesia procedures shall be developed and implemented which shall clearly delineate pre-anesthesia and post-anesthesia responsibilities. These policies shall include, but not be limited to, the following elements:

(i) Pre-anesthesia physical evaluations shall be performed by an individual qualified to administer anesthesia and recorded within 48 hours, prior to surgery.

(ii) Routine checks shall be conducted by the anesthetist prior to every administration of anesthesia to ensure the readiness, availability, cleanliness, sterility when required, and working condition of all equipment used in the administration of anesthetic agents.

(iii) All anesthesia care shall be provided in accordance with generally accepted standards of practice and shall ensure the safety of the patient during the administration, conduct of and emergence from anesthesia. The following continuous monitoring is required during the administration of general and regional anesthetics. Such continuous monitoring is not required during the administration of anesthetics administered for analgesia or during the administration of local anesthetics unless medically indicated.

(a) An anesthetist shall be continuously present in the operating room throughout the administration and the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care. If there is a documented hazard to the anesthetist which prevents the anesthetist from being continuously present in the operating room, provision must be made for monitoring the patient.

(b) All patients must be attended by the anesthetist during the emergence from anesthesia until they are under the care of qualified post-anesthesia care staff or longer as necessary to meet the patient's needs.

(c) During all anesthetics, the heart sounds and breathing sounds of all

patients shall be monitored through the use of a precordial or esophageal stethoscope. Such equipment or superior equipment shall be obtained and utilized by the hospital.

(d) During the administration and conduct of all anesthesia services the patient's oxygenation shall be continuously monitored to ensure adequate oxygen concentration in the inspired gas and the blood through the use of a pulse oximeter or superior equipment that is age and size appropriate. During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm.

(e) All patients' ventilation shall be continuously monitored during the conduct of anesthesia. During regional anesthesia, monitored anesthesia care and general anesthesia with a mask, the adequacy of ventilation shall be evaluated through the continual observation of the patient's qualitative clinical signs. For every patient receiving general anesthesia with an endotracheal tube, the quantitative carbon dioxide content of expired gases shall be monitored through the use of endtidal carbon dioxide analysis or superior technology. In all cases where ventilation is controlled by a mechanical ventilator, there shall be in continuous use an alarm that is capable of detecting disconnection of any components of the breathing system.

(f) The patient's circulatory functions shall be continuously monitored during all anesthetics. This monitoring shall include the continuous display of the patient's electrocardiogram, from the beginning of anesthesia until preparation to leave the anesthetizing location, and the evaluation of the patient's blood pressure and heart rate at least every five minutes.

(g) During every administration of anesthesia, there shall be immediately available a means to continuously measure the patient's temperature.

(iv) All equipment and services provided shall be age and size appropriate.

[(iv)] (v) Intraoperative anesthesia records shall document all pertinent events that occur during the induction, maintenance, and emergence from anesthesia. These pertinent events shall include, but not be limited to, the following: intraoperative abnormalities or complications, blood pressure, pulse, dosage and duration of all anesthetic agents, dosage and duration of other drugs and intravenous fluids, and the administration of blood and blood components. The record shall also document the general condition of the patient.

[(v)] (vi) With respect to inpatients a post-anesthetic follow-up evaluation and report by the individual who administered the anesthesia or by an individual qualified to administer anesthesia shall be written not less than three or more than 48 hours after surgery and shall note the presence or absence of anesthesia related abnormalities or complications, and shall evaluate the patient for proper anesthesia recovery and shall document the general condition of the patient.

[(vi)] (vii) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff shall be documented for each patient prior to hospital discharge.

(3) Safety precautions shall be clearly identified in written policies and procedures specific to the department and include, but not be limited to:

- (i) safety regulations posted;
- (ii) routine inspection and maintenance of equipment;
- (iii) use and maintenance of shockproof equipment;
- (iv) proper grounding; and
- (v) infection control.

Section 405.14 is amended to read as follows:

405.14 Respiratory care services.

* * *

(b) *Operation and service delivery.* Respiratory care services shall be provided in manner which assures the achievement and maintenance of generally accepted standards of professional medical practice and patient care.

(1) Respiratory care services shall only be provided in accordance with specific hospital protocols/policies or upon the orders of members of the medical staff. The order for

respiratory care services shall specify the type, frequency and duration of treatment, and, as appropriate, the type and dose of medication, the type of diluent, and the oxygen concentration, consistent with generally accepted standards of care.

(2) All respiratory care services provided shall be documented in the patient's medical record, including the type of therapy, date and time of administration, effects of therapy, and any adverse reactions.

(3) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit shall meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control as set forth in section 405.16 of this Part.

(4) The service shall implement a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care and for the resolution of identified problems. The process shall involve the reporting of findings, conclusions and recommendations to the quality assurance committee in accordance with hospital policies and procedures.

(5) All equipment and services provided shall be age and size appropriate.

Section 405.15 is amended to read as follows:

405.15 Radiologic and nuclear medicine services.

(a) *General provisions for diagnostic and therapeutic radiologic services.* The hospital shall maintain or have available diagnostic radiologic services defined for purposes of this subdivision as imaging services utilizing diagnostic radiation equipment or devices which emit radiation by virtue of the application of high voltage. If therapeutic services are provided, they shall meet the requirements established in subdivision (b) of this section in addition to the requirements of this subdivision. In addition, the hospital shall meet the standards of Part 16 of the State Sanitary Code.

(1) The hospital shall maintain or have available radiologic services according to the needs of the patients as determined by the governing body in consultation with the medical staff and the administration.

(2) Radiologic services shall be provided in accordance with generally accepted standards of practice only on the order of physicians or, consistent with State law, of those other practitioners authorized by the medical staff and governing body to order such services. A practitioner's order for an imaging study shall be specific as to the body part(s) to be imaged.

(3) Safety for patients and personnel. [The radiologic services shall be free from hazards for patients and personnel.] Written policies and procedures shall be developed and

implemented and available for review [inspection.] The policies and procedures regarding imaging studies for newborns and pediatric patients shall include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. A policy and a procedure shall be developed to ensure that the practitioner's order for an imaging study is specific as to the body part(s) that are to be imaged.

Quality improvement audits shall verify that these policies and procedures are being followed. Quality improvement activities shall include a review of the adequacy of diagnostic images and interpretations.

(i) Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards and radiation hazards. This includes adequate shielding for patients and personnel, as well as appropriate storage, use and disposal of radioactive materials.

(ii) Any existing or potential hazards identified through periodic inspection by local or State health authorities shall be corrected promptly.

(iii) Personnel shall be instructed in radiation safety principles[;] and [radiation monitoring] practices. The radiation safety principles shall be adequate to ensure compliance with all [regulatory requirements] generally accepted standards of practice as well as pertinent laws, rules and regulations. Policies and procedures shall be developed

to minimize the radiation exposure that is necessary to produce high quality imaging studies on patients of all ages.

(iv) Radiologic procedures requiring the use of contrast media or fluoroscopic interpretation and control shall be performed with the active participation of a qualified specialist in diagnostic radiology or a physician qualified in a medical specialty related to the radiographic procedure. Emergency equipment and staff trained in its use shall be available for anaphylactic shock reactions from contrast media.

(4) Personnel. The hospital shall provide qualified personnel adequate to supervise and conduct the services. For radiologic tests, the following personnel standards shall apply for the purposes of this subdivision:

(i) a full-time or part-time radiologist who is a board certified or board admissible in radiology shall direct the clinical aspects of the organization and delivery of radiologic services. That radiologist or another individual qualified by education and experience shall direct the administrative aspects of the services;

(ii) radiologic tests shall be interpreted by a board certified or board admissible radiologist, except that radiologic tests may be interpreted by practitioners within their field of specialization who are granted privileges to interpret such test by the governing body and the medical staff in consultation with the director of radiologic services pursuant to the credentialing process in the hospital;

(iii) the services of qualified radiologists, qualified practitioners, and licensed radiologic technologists shall be sufficient and available to meet the needs of the patients. A licensed technologist shall be on duty or available at all times and function in accordance with Article 35 of the Public Health Law and Part 89 of this Title.

(iv) Use of the radiologic equipment and administration of radiologic procedures shall be limited to personnel who are currently licensed and designated as qualified by the hospital in accordance with any applicable licenses and regulations.

(v) The chief of radiology, in conjunction with the radiation safety officer, shall ensure that all practitioners who utilize ionizing radiation equipment within the hospital are properly trained in radiation safety procedures for patients of all ages.

(5) Records. Records of radiologic services including interpretations, consultations and therapy shall be filed with the patient's record, and duplicate copies shall be kept in the radiology department/service. All films, scans and other image records shall be referenced in the patient's medical record and retained in the patient's medical record, radiology department/service or in another central location accessible to appropriate staff. All electronic images shall have a duplicate storage either offsite or in another area of the hospital separate from the primary storage devices.

(i) Requests by the attending practitioner for x-ray examination shall contain a concise

statement of reasons for the examination which shall be authenticated by the requestor.

(ii) The radiologist or other practitioner who performs radiology services shall authenticate reports of his or her interpretations.

(iii) The hospital shall retain films, scans and other image records which have not been incorporated in the medical record for at least six years or three years after a minor patient reaches the age of majority.

(b) *Therapeutic radiology or radiation oncology.* Therapeutic radiology or radiation oncology services shall be provided in accordance with the following:

(1) no [facility] hospital providing the service shall refuse treatment of a patient on the basis of the referring practitioner or practitioner's hospital affiliation, if any;

(2) institutions shall provide services for patients who cannot attend treatment sessions during normal day shift working hours;

(3) therapeutic radiology or radiation oncology services shall utilize [four] six or more megavoltage (MEV) [or cobalt teletherapy] units with a source-axis distance of [80] 100 or more centimeters [and rotational capabilities] as the primary unit in a multi-unit [radiotherapy service or as the sole unit in a smaller radiotherapy unit;] radiation oncology service.

(4) a therapeutic radiology service shall be headed by a board admissible or board certified radiation therapist or a general radiologist who devotes at least 80 percent of his/her time to the practice of therapeutic radiology and who treats not fewer than 175 patients per year;

(5) a therapeutic radiology service shall have on staff:

(i) [one full-time New York State licensed radiation therapy technologist for every MEV unit; and] full time New York State licensed radiation therapists sufficient to meet the needs of the service; and

(ii) a full-time registered professional nurse with appropriate education and experience;

(6) a [facility] hospital with a therapeutic radiology service shall have on staff or through formal arrangements:

(i) a board admissible or board certified medical oncologist, hematologist or other specialist who devotes at least 80 percent of his/her practice to medical oncology and who treats not fewer than 175 oncology patients per year; and

(ii) A New York State licensed radiation therapy [a radiological] physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment. The

hospital shall provide for the services of a licensed radiation therapy physicist(s) in sufficient quantity to adequately meet the needs of its patients of all ages. [and who holds a degree in physics and who is either certified or admissible for certification by the American Board of Radiology or the American Board of Health Physicists; or]

(iii) A physicist in training must be supervised by a licensed radiation therapy physicist.

[(a) a person holding a degree in physics and having full-time radiation therapy experience; or]

[(b) a physicist in training or a dosimetrist supervised by a part-time radiological physicist;]

(7) the therapeutic radiology service shall be part of a multidisciplinary approach to the management of cancer patients, involving a variety of specialists in a joint treatment program, either through formal arrangement or in the hospital;

(8) each patient shall have a treatment plan in his/her medical records;

(9) each therapeutic radiology service shall have access, either through formal arrangements or in the hospital, to a full range of diagnostic services, including [ultrasound,] hematology, pathology, [CT scanners, nuclear medicine and diagnostic radiology] and medical imaging procedures;

(10) each hospital providing therapeutic radiology services shall have access to the full range of rehabilitation therapies, including but not limited to physical therapy, occupational therapy, vocational training, and psychological counseling services for its radiotherapeutic patients;

(11) a radiation therapy program operating [an MEV unit] a linear accelerator with photon or electron beam energies greater than 10 MEV's must be a part of a comprehensive program of cancer care which includes surgical oncology, medical oncology, pathology and diagnostic radiology, medical imaging and nuclear medicine. In addition such program shall meet the following standards:

(i) there shall be two full-time equivalent radiation oncologists on staff who are board-certified in radiation oncology or have equivalent training and experience and whose professional practices are limited to radiation oncology;

(ii) there shall be a full-time medical radiation physicist assigned to the radiation therapy program for the treatment planning of patients; and

(iii) [there shall be a simulator available within the radiation therapy program used for producing precise mock-ups of geometric relationships of treatment equipment to a patient and yielding high quality diagnostic radiographs of the treatment portals.] a CT scanner shall be available within the radiation therapy program that is equipped for

radiation oncology treatment planning or arrangements shall be made for access to a CT scanner on an as needed basis.

Provisions shall be made for access to an MRI scanner for treatment planning purposes on an as needed basis.

(c) *Nuclear medicine services.* If the hospital provides nuclear medicine services, those services shall meet the needs of the patients in accordance with generally acceptable standards of practice. Nuclear medicine services shall be ordered only by a physician whose Federal or State licensure and staff privileges allow such referrals.

(1) Organization and staffing. The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

- (i) The clinical aspect of the organization and delivery of nuclear medicine services shall be directed by a physician who is qualified in nuclear medicine and named in the hospital's New York State Health Department or New York City Health Department radioactive materials license as authorized to use radioactive materials in humans. The administrative aspects of these services shall be directed by that physician or another individual qualified for such duties by education and experience.

(ii) The qualifications, training, functions, and responsibilities of all nuclear medicine personnel shall be specified by the clinical service director in accordance with applicable regulations and approved by the medical staff and the hospital.

(2) Delivery of service. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with generally acceptable standards of practice and pertinent laws, rules and regulations.

(i) In-house preparation of radiopharmaceuticals shall be by, or under the direct supervision of, an appropriately trained registered pharmacist or a physician whose use of radioactive materials is authorized in the hospital's New York State Health Department or New York City Health Department radioactive materials license.

(ii) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control in accordance with the requirements of section 405.16 of this Part.

(3) Facilities. The hospital shall provide equipment and supplies which are appropriate for the types of nuclear medicine services offered and shall maintain such for safe and effective performance. The equipment shall be:

(i) maintained in safe operating condition; and

(ii) inspected, tested, and calibrated at least annually by qualified personnel and at the intervals specified in the hospital's quality assurance program.

(4) Records. The hospital shall maintain authenticated and dated reports of nuclear medicine interpretations, consultations and procedures.

(i) The hospital shall maintain copies of nuclear medicine reports which have not been incorporated into the patient's medical record for at least six years or three years after the patient reaches the age of majority.

(ii) Interpretation of the results of nuclear medicine procedures shall be made by a physician authorized in the hospital's New York State Health Department or New York City Health Department radioactive materials license, or a physician under his/her tutelage. Interpretations may be made in consultation with the referring practitioner or other practitioners. The authorized physician, or physicians in tutelage, shall authenticate and date the interpretations of these tests.

Section 405.17 is amended to read as follows:

405.17 Pharmaceutical services.

The hospital shall provide pharmaceutical services that are available at all times on the premises to meet the needs of patients. The hospital shall have a pharmacy that is registered and operated in accordance with article 137 of the New York State Education Law and is directed by a registered pharmacist trained in the specialized functions of hospital pharmacy.

(a) *Organization and direction.* The pharmacy shall be responsible, in conjunction with the medical staff, for ensuring the health and safety of patients through the organization, management and operation of the service in accordance with generally accepted professional principles and the proper selection, storage, preparation, distribution, use, control, disposal and accountability of drugs and pharmaceuticals.

(1) The director shall be employed on a full-time or part-time basis based on the needs of the hospital.

(2) The director, in conjunction with designated members of the medical staff, shall ensure that:

(i) for patients of all ages weight shall be measured in kilograms. [information] Resources relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration [is] are available to the professional staff. Pediatric dosing resources shall include age and size appropriate fluid and medication administration and dosing. Pediatric dosing must be weight based, and should not exceed adult maximum dosage, or in emergencies, length based, with appropriate references for

pediatric dosing available.

(ii) a formulary is established and reviewed at least annually and updated as necessary to meet the needs of the patients for use in the hospital to assure quality pharmaceuticals at reasonable costs;

(iii) standards are established concerning the use and control of investigational drugs and research in the use of recognized drugs;

(iv) clinical data are evaluated concerning new drugs or preparations requested for use in the hospital; and

(v) the list of floor stock medication is reviewed and recommendations are made concerning drugs to be stocked on the nursing unit floors and by other services.

* * *

(9) The director will ensure that there is a quality assurance program to monitor personnel qualifications, training performance, equipment and facilities.

(i) The director shall require and document the participation of pharmacy personnel in relevant education programs, including orientation of new employees as well as inservice and outside continuing education programs.

(ii) The quality assurance program shall include policies, [and] procedures and monitoring and improvement activities to identify, measure, prevent, [to] minimize

and/or mitigate adverse drug events, adverse drug reactions and medication errors in accordance with generally accepted standards and practices in the field of medication safety and quality improvement.

(iii) The director in conjunction with the medical staff shall ensure the monitoring and evaluation of the quality and appropriateness of patient services provided by the pharmaceutical service.

(10) The director shall participate in those aspects of the hospital's overall quality assurance program that relate to drug utilization and effectiveness.

(b) Operation and service delivery. All drugs and biologicals shall be controlled and distributed in accordance with written policies and procedures to maximize patient safety and quality of care.

(1) The compounding, preparation, labeling or dispensing of drugs shall be performed by a licensed pharmacist or pharmacy intern in accordance with applicable State and Federal laws, rules and regulations.

* * *

Section 405.19 is amended to read as follows:

405.19 Emergency services.

(a) *General.* (1) Emergency services shall be provided in accordance with this subdivision or subdivisions (b) through (e) of this section as appropriate.

(2) If emergency services are not provided as an organized service of the hospital, the governing body and the medical staff shall assure:

(i) prompt physician evaluation of patients presenting with emergencies;

(ii) initial treatment and stabilization or management; and

(iii) transfer, where indicated, of patients to an appropriate receiving hospital. The hospital shall have a written agreement with local emergency medical services (EMS) to accommodate the need for timely inter-hospital transfer on a 24 hours a day, 7 days a week, 365 days a year basis.

(b) *Organization.* (1) The medical staff shall develop and implement written policies and procedures approved by the governing body that shall specify:

(i) the responsibility of the emergency services to evaluate, initially manage and treat, or admit or recommend admission, or transfer patients to another facility that can provide definitive treatment. Such policies and procedures shall include a written agreement with one or more local emergency medical services (EMS) to accommodate the need for timely inter-facility transport on a 24 hours a day, 7 days a week, 365 days a year basis;

(ii) the organizational structure of the emergency service, including the specification of authority and accountability for services; and

(iii) explicit prohibition on transfer of patients based on their ability or inability to pay for services.

(2) At least one clinician on every shift must have the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate an infant or a child. The emergency service shall be directed by a licensed and currently registered physician who is board-certified or board-admissible for a period not to exceed five years after the physician first attained board admissibility in emergency medicine, surgery, internal medicine, pediatrics or family practice, and who is currently certified in advanced trauma life support (ATLS), or has current training and experience equivalent to ATLS. Such physician shall also have successfully completed a current course in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) or have had current training and experience equivalent to ACLS and PALS. A licensed and currently registered physician who is board-certified or board-admissible in psychiatry for a period not to exceed five years after the physician first attained board-admissibility, in psychiatry may serve as psychiatrist director of a separately operated psychiatric emergency service. Directors of separately operated psychiatric emergency services need not be qualified to perform [ACLS and] ATLS, ACLS and PALS or have current training and experience equivalent to ATLS, ACLS and PALS.

(3) An emergency service shall have laboratory and X-ray capability, including both fixed and mobile equipment, available 24 hours a day, seven days a week, to provide test results to the service within a time considered reasonable by accepted emergency medical standards.

(c) *General policies and procedures.* (1) The location and telephone number of the State Department of Health designated poison control center, shall be maintained at the telephone switchboard and in the emergency service.

(2) All cases of suspected child abuse or neglect shall be treated and reported immediately to the New York State Central Register of Child Abuse and Maltreatment pursuant to procedures set forth in article 6, title 6 of the Social Services Law.

(3) Domestic violence. The emergency service shall develop and implement policies and procedures which provide for the management of cases of suspected or confirmed domestic violence victims in accordance with the requirements of section 405.9(e) of this Part.

(4) The emergency service shall establish and implement written policies and procedures for the maintenance of sexual offense evidence as part of the hospital-wide provisions required by this Part. An organized protocol for survivors of sexual offenses, including medical and psychological care shall be incorporated into such policies and procedures.

These policies, procedures and protocols shall be consistent with the standards for patient care and evidence collection established in section 405.9(c) of this Part.

(5) The emergency service, in conjunction with the discharge planning program of the hospital, shall [establish and implement] develop and implement written policies and procedures, including written patient criteria and guidelines, for transfer of those patients for whom the hospital does not have the capability to care. Such policies and procedures shall [specifying]specify the circumstances, the actions to be taken, and the appropriate contact agencies and individuals to accomplish adequate discharge planning for persons in need of post emergency treatment or services, but not in need of inpatient hospital care.

(6) An admission and discharge register shall be current and shall include at least the following information for every individual seeking care:

(i) date, name, age, gender, ZIP code;

(ii) expected source of payment;

(iii) time and means of arrival, including name of ambulance service for patients arriving by ambulance;

(iv) complaint and disposition of the case; and

(v) time and means of departure, including name of ambulance service for patients transferred by ambulance.

(7) There shall be a medical record that meets the medical record requirements of this Part for every patient seen in the emergency service. Medical records shall be integrated or cross-referenced with the inpatient and outpatient medical records system to assure the timely availability of previous patient care information and shall contain the prehospital care report or equivalent report for patients who arrive by ambulance. On arrival to emergency services, a patient shall be asked for the name, if any, of his or her primary care provider, which shall be documented in the patient's medical record.

(8) The hospital shall develop and implement written policies and procedures pertaining to the review and communication of laboratory and diagnostic test/service results ordered for a patient while admitted or receiving emergency services to the patient. If the patient lacks medical decision-making capacity, the communication shall be to the patient's medical decision-maker. The results shall also be provided to the patient's primary care provider, if any. Such policies and procedures shall be reviewed and updated as necessary and at a minimum shall include:

(i) a requirement that all laboratory and other diagnostic tests/service results be reviewed upon completion by a physician, physician assistant or nurse practitioner familiar with the patient's presenting condition;

- (ii) a requirement that all laboratory and other diagnostic test services results be forwarded to the patient's primary provider, if known, after review by a physician, physician assistant or nurse practitioner;

- (iii) provisions to include in the discharge plan information regarding the patient's completed critical value laboratory and other diagnostic test/service results as well as other pending tests, medications, diagnoses, and follow-up care and to review such information with the patient and, if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent;

- (iv) a requirement that critical value laboratory test results or other test results as deemed necessary by the physician, physician assistant or nurse practitioner shall be promptly communicated on discharge to the patient and, if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent, or surrogate, as appropriate subject to all applicable confidentiality laws and regulations, and the patient's primary care provider, if known. A critical laboratory test result is defined as one that represents a pathophysiological state at such variance with normal as to be potentially life threatening or which requires immediate medical attention; and

- (v) a requirement that all information be presented to the patient or if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent, as appropriate, subject to all applicable confidentiality laws and regulations, in a manner that assures that the patient, their parents or other medical decision makers have

the capacity to obtain, communicate, process, and understand the health information provided in order to make appropriate health decisions.

[(8)](9) Review of the hospital emergency service shall be conducted at least four times a year as part of the hospital's overall quality assurance program. Receiving hospitals shall report to sending hospitals and emergency medical systems, as appropriate, all patients that die unexpectedly within 24 hours upon arrival at the receiving hospitals. These patient mortalities shall be included in both hospitals' quality assurance review.

(d) *Staffing.* The following requirements are applicable to all organized emergency services:

(1) Emergency service physician services shall meet the following requirements:

(i) The emergency services attending physician shall meet the minimum qualifications set forth in either clauses (a) or (b) of this subparagraph.

(a) The emergency services attending physician shall be a licensed and currently registered physician who is board-certified in emergency medicine, surgery, internal medicine, pediatrics or family practice and who is currently certified in advanced trauma life support (ATLS) or has current training and experience equivalent to ATLS. Such physician shall also have successfully completed a course and be current in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) or have had current training and experience equivalent to ACLS and PALS. A licensed and currently

registered physician who is board-certified in psychiatry may serve as psychiatrist attending in a separately operated psychiatric emergency service. A licensed and currently registered physician who is board-admissible in one of these specialty areas and is currently certified in ATLS or who has current training and experience equivalent to ATLS and has successfully completed a course and is current in ACLS and PALS or has had current training and experience equivalent to ACLS and PALS, may be designated as attending physician for a period not to exceed five years after the physician has first attained board-admissibility. [except that the] The requirement to be qualified to perform ATLS, [and] ACLS and PALS shall not be applicable to qualified psychiatrist attendings in a separately operated psychiatric emergency service. Physicians who are board-certified or admissible, for a period not to exceed five years after the physician first attained board-admissibility, in other specialty areas may be designated as attending physicians for patients requiring their expertise.

(b) The emergency services attending physician shall be a physician who:

(1) is licensed and currently registered;

(2) has successfully completed one year of postgraduate training;

(3) has, within the past five years, accumulated 7,000 documented patient contact hours or hours of teaching medical students, physicians in-training, or physicians in emergency medicine. Up to 3,500 hours of documented experience in hospital-based settings or other settings in the specialties of internal medicine, family practice, surgery or pediatrics may

be substituted for the required hours of emergency medicine experience on an hour-for-hour basis;

(4) has acquired in each of the last three years, an average of 50 hours or more per year of continuing medical education pertinent to emergency medicine or to the specialties of practice which contributed to meeting the 7,000 hours requirement specified in subclause (3) of this clause;

(5) is currently certified in ATLS or has current training and experience equivalent to ATLS; and

(6) has successfully completed a course and is current in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) or has had current training and experience equivalent to ACLS and PALS.

(ii) There shall be at least one emergency service attending physician on duty 24 hours a day, seven days a week. For hospitals that exceed 15,000 unscheduled visits annually, the attending physician shall be present and available to provide patient care and supervision in the emergency service. As necessitated by patient care needs, additional attending physicians shall be present and available to provide patient care and supervision.

Appropriate subspecialty availability as demanded by the case mix shall be provided promptly in accordance with patient needs. For hospitals with less than 15,000 unscheduled emergency visits per year, the supervising or an attending physician need not be present but shall be available within 30 minutes of patient presentation, provided

that at least one physician, nurse practitioner, or registered physician assistant shall be on duty in the emergency service 24 hours a day, seven days a week. The hospital shall develop and implement protocols specifying when physicians must be present.

(iii) Other medical staff practitioner services provided in the emergency service shall be in accordance with the privileges granted the individual.

(iv) Every medical-surgical specialty on the hospital's medical staff which is organized as a department or clinical service and where practitioner staffing is sufficient, shall have a schedule to provide coverage to the emergency service by attending physicians in a timely manner, 24 hours a day, seven days a week, in accordance with patient needs.

(2) Nursing services:

(i) There shall be at least one supervising emergency services registered professional nurse present and available to provide patient care services in the emergency service 24 hours a day, seven days a week.

(ii) Emergency services supervising nurses shall be licensed and currently registered and possess current, comprehensive knowledge and skills in emergency health care. They shall have at least one year of clinical experience, be able to demonstrate skills and knowledge necessary to perform basic life support measures, [have successfully completed a course] and be current in ACLS and PALS or have [had] current training and experience equivalent to ACLS and PALS;

(iii) Registered professional nurses in the emergency service shall be licensed and currently registered professional nurses who possess current, comprehensive knowledge and skills in emergency health care. They shall have at least one year of clinical experience, have successfully completed an emergency nursing orientation program and be able to demonstrate skills and knowledge necessary to perform basic life support measures. Within one year of assignment to the emergency service, each emergency service nurse shall [have successfully completed a course] be current in ACLS and PALS or have [had] current training and experience equivalent to ACLS and PALS[and shall maintain current competence in ACLS as determined by the hospital].

(iv) Additional registered professional nurses and nursing staff shall be assigned to the emergency service in accordance with patient needs. If, on average:

(a) the volume of patients per eight-hour shift is under 25, an additional registered professional nurse shall be available as needed to assist the supervising registered professional nurse with delivery of direct patient care; or

(b) the volume of patients per eight-hour shift is over 25, there shall be a minimum of two registered professional nurses per shift assigned to provide direct patient care. As patient volume and intensity increases, the total number of available registered professional nurses shall also be increased to meet patient care needs;

(3) Registered [physician's]physician assistants and nurse practitioners.

(i) Patient care services provided by registered [physician's]physician assistants shall be in accordance with section 405.4 of this Part.

(ii) Patient care services provided by certified nurse practitioners shall be in collaboration with a licensed physician whose professional privileges include approval to work in the emergency service and in accordance with written practice protocols for these services.

(iii) the registered physician assistants and the nurse practitioners shall meet the following standards:

(a) the registered physician assistants and the nurse practitioners in the emergency service shall [have successfully completed a course] be current in ACLS and PALS or have had current training and experience equivalent to ACLS and PALS when determined necessary by the hospital to meet anticipated patient needs or when a physician assistant or nurse practitioner is serving as the sole practitioner on duty in a hospital with less than 15,000 unscheduled emergency visits per year;

(b) registered physician assistants and nurse practitioners in the emergency service shall be current in ATLS or have had current training and experience equivalent to ATLS when determined necessary by the hospital to meet anticipated patient needs or when a physician assistant or nurse practitioner is serving as the sole practitioner on duty in a hospital with less than 15,000 unscheduled emergency visits per year.

(4) Support personnel. There shall be sufficient support personnel assigned to the emergency service to perform the following duties on a timely basis: patient registration, reception, messenger service, acquisition of supplies, equipment, delivery and label[ing] of laboratory specimens, responsible for the timely retrieval of laboratory reports, obtaining records, patient transport and other services as required.

(e) Patient care. (1) The hospital shall assure that all persons [arriving at the] presenting for emergency services [for treatment] receive emergency health care that meets generally accepted standards of practice [medical care].

(2) Every person [arriving at the] presenting for emergency services [for care] shall be promptly examined, diagnosed and appropriately treated in accordance with triage and transfer policies, procedures and protocols adopted by the emergency service and approved by the [hospital] governing body. Such policies, procedures and protocols must include written agreements with local emergency medical services (EMS) in accordance with subparagraph (b)(1)(i) of this section. All patient care services shall be provided under the direction and control of the emergency services director or attending physician. In no event shall a patient be discharged or transferred to another [facility] hospital, unless evaluated, initially managed, and treated as necessary by an appropriately privileged physician, physician assistant, or nurse practitioner. No later than eight hours after presenting in the emergency service, every person shall be admitted to the hospital, or assigned to an observation unit in accordance with subdivision (g) of this section, or transferred to another hospital in accordance with paragraph (6) of this subdivision, or

discharged to self-care or the care of a physician or other appropriate follow-up service. Hospitals which elect to use physician assistants or nurse practitioners shall develop and implement written policies, procedures and treatment protocols subject to approval by the governing body that specify patient conditions that may be treated by a registered physician assistant or nurse practitioner without direct visual supervision of the emergency services attending physician.

(3) Hospitals that have limited capability for receiving and treating patients in need of specialized emergency care shall develop and implement standard descriptions of such patients, and have triage and treatment protocols including consultation and formal written transfer agreements with hospitals that are designated as being able to receive and provide definitive care for such patients. Patients in need of specialized emergency care shall include, but not be limited to:

- (i) trauma patients and multiple injury patients;
- (ii) burn patients with burns ranging from moderate uncomplicated to major burns as determined by use of generally acceptable methods for estimating total body surface area:
- (iii) high risk maternity patients or neonates or pediatric patients in need of [intensive]higher level care
- (iv) head injured or spinal cord injured patients;
- (v) acute psychiatric patients;

- (vi) replantation patients;
- (vii) dialysis patients; and
- (viii) acute myocardial infarction patients including but not limited to patients with ST elevation.

(4) Hospitals shall verbally request ambulance dispatcher services to divert patients with life threatening conditions to other hospitals only when the chief executive officer or designee appointed in writing, determines that acceptance of an additional critical patient would endanger the life of that patient or another patient. Request for diversion shall be documented in writing and, if warranted, renewed at the beginning of each shift.

(5) Reserved.

(6) Patients shall be transferred to another hospital only when:

(i) the patient's condition is stable or being managed;

(ii) the attending practitioner has authorized the transfer; and

(iii) administration of the receiving hospital is informed and can provide the necessary resources to care for the patient; or

(iv) when pursuant to paragraph (2) of this subdivision, the patient is in need of specialized emergency care at a hospital designated to receive and provide definitive care

for such patients.

(7) Hospitals located within a city with a population of one million or more persons shall apply, and if accepted, participate to the full extent of their capability in the emergency medical service which is operated by such city or such city's health and hospitals corporation.

(f) Quality assurance. (1) Quality assurance activities of the emergency service shall be integrated with the hospital-wide quality assurance program and shall include review of:

(i) arrangements for medical control and direction of pre-hospital emergency medical services;

(ii) provisions for triage of persons in need of specialized emergency care to hospitals designated as capable of treating those patients;

(iii) emergency care provided to hospital patients, to be conducted at least four times a year, and to include pre-hospital care providers, emergency services personnel and emergency service physicians; and

(iv) adequacy of staff training and continuing education to meet the needs of patients of all ages presenting for emergency services.

* * *

Section 405.20 is amended to read as follows:

405.20 Outpatient services.

Outpatient services, including ambulatory care services and extension clinics, shall be provided in a manner which safely and effectively meets the needs of the patients.

(a) *General requirements.* As a minimum when provided, outpatient services shall comply with the rules and regulations set forth in this Part as well as the outpatient care provisions of Part 751, sections 752.1 and 753.1 and Parts 756, 757 and 758 of Subchapter C of this Title.

* * *

(d) *Hospital-based ambulatory service.* In a hospital maintaining an on-site hospital-based ambulatory surgery service, the following requirements supplement existing applicable requirements of sections 405.12 (Surgical services) and 405.13 (Anesthesia services) of this Part. Hospital-based ambulatory surgery services shall mean a service organized to provide surgical procedures which shall be performed for reasons of safety in an operating room on anesthetized patients requiring a stay of less than 24 hours duration. These procedures do not include outpatient surgical procedures which can be performed safely in a private physician's office or in an outpatient treatment room.

(1) The hospital-based ambulatory surgery service shall be directed by a physician found qualified by the governing body to perform such duties.

(2) The governing body and the medical staff shall develop, maintain and periodically review a list of surgical procedures which may be performed in the service. The medical staff shall assure that procedures performed in the service conform with generally accepted standards of professional practice, in accordance with the competencies of the medical and professional staff that have privileges in the hospital-based ambulatory surgery service, and are appropriate in the facilities and consistent with the equipment [available] necessary to meet the needs of all patients. The medical staff shall, based upon its review of individual medical staff qualifications, recommend to the governing body specific surgical procedures which each practitioner is qualified to perform in the hospital-based ambulatory surgery service.

(3) Hospital-based ambulatory surgery services may be located at the same site as the hospital (on-site) or apart from the hospital (off-site), pursuant to section 709.5 of this Title.

(i) Recovery rooms adequate for the needs of hospital-based ambulatory surgery patients, conveniently located to the operating room, shall be provided.

(ii) Waiting rooms adequate for the needs of patients and responsible persons accompanying patients shall be provided.

(4) Prior to surgery, each patient shall have a timely history and physical examination, appropriate to the patient's physical condition and the surgical procedure to be performed,

which shall be recorded in the patient medical record.

(5) Each postsurgery patient shall be observed for postoperative complications for an adequate time period as determined by the attending practitioner and the anesthesiologist.

The service shall have written policies for hospital admission of patients whose post-operative status prevents discharge and necessitates inpatient admission to a hospital capable of providing the appropriate level of care.

(6) Detailed verbal instructions understandable to the patient, or the patient's parent, legal guardian, or health care agent, confirmed by written instructions, and approved by the medical staff of the hospital-based ambulatory surgery service shall be provided to each patient, or the patient's parent, legal guardian, or health care agent, at discharge, to include at least the following:

(i) information about complications that may arise;

(ii) telephone number(s) to be used by the patient should complications or questions arise;

(iii) directions for medications prescribed, if any;

(iv) date, time and location of follow-up visit or return visit; and

(v) designated place to go for treatment in the event of emergency.

(7) The hospital-based ambulatory surgery service staff shall develop written policies, approved by the medical staff, for documentation of the patient's postoperative course of treatment. The policies must be reviewed and adopted by the governing [board] body of the hospital prior to implementation. The policies must provide a mechanism to assure that complications of surgery or anesthesia, which occur before and after discharge, are identified and documented in the patient's medical record.

(8) The hospital-based ambulatory surgery service shall have an organized system of quality assurance approved by the medical staff and the governing body which undertakes investigations into operative results of surgical procedures performed on the service and maintains statistics on operative failures and complications.

(9) Notwithstanding anything herein to the contrary, an off-site hospital-based ambulatory surgery service shall be operated in accordance with the provisions of Part 755 of this Title.

Section 405.22 is amended to read as follows:

405.22 Critical care and special care services.

(a) General provisions.

* * *

(b) Pediatric Intensive Care Unit (PICU) Services

(1) Definitions.

(1) PICU. A PICU is a physically separate unit that provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill or injured. A PICU must be staffed by qualified practitioners competent to care for critically ill or injured pediatric patients.

(2) Qualified practitioner. Qualified practitioner as referred to in this section shall mean a practitioner functioning within his or her scope of practice according to State Education Law who meets the hospital's criteria for competence, credentialing and privileging practitioners in the management of critically ill or injured pediatric patients.

(2) General. (i) A PICU must be approved by the Department. The governing body of a hospital that provides PICU services must develop written policies and procedures for operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients. The PICU shall:

(a) Provide multidisciplinary definitive care for a wide range of complex, progressive, and rapidly changing medical, surgical, and traumatic disorders occurring in pediatric patients;

(b) Have a minimum average annual pediatric patient number of 200/year;

(c) Have age and size appropriate equipment available in the unit; and

(d) Provide medical oversight for interhospital transfers of critically ill or injured patients during transfer to the receiving PICU.

(ii) Organization and Direction. The PICU shall be directed by a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who shall be responsible for the organization and delivery of PICU care and has specialized training and demonstrated competence in pediatric critical care. Such physician in conjunction with the nursing leadership responsible for the PICU shall participate in administrative aspects of the PICU. Such responsibilities shall include development and annual review of PICU policies and procedures, oversight of patient care, quality improvement activities, and staff training and development.

(a) All hospitals with PICUs must have a physician, notwithstanding emergency department staffing, in-house 24 hours per day who is available to provide bedside care to patients in the PICU. Such physician shall be at least a post graduate year three in pediatrics or anesthesiology. This physician must be skilled in and be credentialed by the hospital to provide emergency care to critically ill or injured children.

(b) The PICU shall have, at a minimum, a physician at the level of post graduate year two or above and/or mid-level practitioner (e.g., registered physician assistant and/or nurse practitioner) with specialized training in pediatric critical/intensive care assigned to the unit 24 hours/day, 7 days/week with an attending pediatric, medical, surgical or anesthesiology critical care/intensivist available within 60 minutes.

(c) An attending pediatric medical, surgical, or anesthesiology critical care/intensivist physician shall be responsible for the oversight of patient care at all times.

(d) The PICU shall provide registered professional nursing staffing sufficient to meet critically ill or injured pediatric patient needs, ensure patient safety and provide quality care.

(e) PICU physician and nursing staff shall have successfully completed a course and be current in pediatric advanced life support (PALS) or have current equivalent training and/or experience to PALS.

(iii) Quality Performance. The hospital shall have an organized quality assessment performance improvement (QAPI) program for PICU services. Such program shall require participation by all clinical members of the PICU team and include: monitoring of volume and outcomes, morbidity and all case mortality review, regular multidisciplinary conferences including all health professionals involved in the care of PICU patients.

(iv) Closure. Failure to meet one or more regulatory requirements or inactivity in a program for a period of 12 months or more may result in actions, including, but not limited to, withdrawal of approval to serve as a PICU.

(v) Voluntary closure. The hospital must give written notification, including a closure plan acceptable to the department, at least 90 days prior to planned discontinuance of PICU services. No PICU shall discontinue operation without first obtaining written approval from the department.

(vi) Notification of significant changes. A hospital must notify the department in writing within 7 days of any significant changes in its PICU services, including, but not limited to: (a) any temporary or permanent suspension of services or (b) difficulty meeting staffing or workload requirements.

(c) [(b)] Organ transplant center.

* * *

(d) [(c)] Burn unit/center.

* * *

(e) [(d)] Alternate level of care.

* * *

(f) [(e)] Acquired immune deficiency syndrome (AIDS) centers.

* * *

(g) [(f)] Comprehensive and extended screening and monitoring services for epilepsy.

* * *

(h) [(g)] Pediatric and maternal human immunodeficiency virus (HIV) services.

* * *

(i) [(h)] Secure units for tuberculosis patients including detainees.

* * *

(j) [(i)] Tuberculosis treatment center - for legally detained tuberculosis patients.

* * *

(k) [(j)] Live Adult Liver Transplantation Services.

* * *

Section 405.28 is amended to read as follows:

405.28 Social services.

The hospital shall provide appropriate supportive services to meet the psychosocial needs of its patients. The services shall be oriented to assist patients and their families with

personal and environmental difficulties which predispose to illness or interfere with obtaining maximum benefits from hospital care.

(a) Each patient shall be screened prior to or upon admission to determine the need for social services. All patients and families identified through such screening, and all patients and families subsequently identified as needing social services by medical, nursing or other clinical staff, shall be provided with the support they require.

(b)[Social services shall be provided under the direction of a qualified medical social worker or other person with appropriate training and experience.]

Social services shall be provided under the direction of a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), with the scope of practice defined in Article 154 of the Education Law.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (“PHL”) Sections 2800 and 2803 (2). PHL Article 28 (Hospitals), Section 2800 specifies that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state . . . , the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services”

PHL Section 2803(2) authorizes the Public Health and Health Planning Council (“PHHPC”) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

These amendments are promulgated to update various Part 405 pediatric and general hospital provisions including surgical, anesthesia, radiology and pharmacy services. Pediatrics is a unique, distinct part of medicine which is very different than adult medicine. Historically, children have often been seen as small adults. This has changed over time and it is now recognized that certain areas of pediatric care such as emergency, critical care and medication dosing require specialized knowledge, skills and equipment.

Part 405 of Title 10 NYCRR sets forth general hospital minimum standards. In 2010, the New York State Emergency Medical Services for Children (“EMS-C”) Advisory Committee recommended and the Department determined that Part 405 needed to be updated to address the unique needs of children. A comprehensive approach was necessary to make sure that hospitals are admitting children for whom it has appropriate staff, resources and equipment and that policies and procedures are in place for transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters and emergency surge situations. Many facilities that once had dedicated pediatric units have closed or reduced their units, resulting in a reduced focus on pediatric care. Currently, the pediatric provisions need

strengthening as they do not specifically address minimum standards for pediatric critical or emergency care. Pediatric care has become much more sophisticated and requires highly trained staff with expertise in the particular requirements for caring for children. In addition, various Part 405 subdivisions have been updated for all patients including surgical, anesthesia, radiologic and nuclear medicine, pharmaceutical and emergency services to reflect current practice.

The Department, in conjunction with the EMS-C Advisory Committee, carefully reviewed Part 405 of Title 10 and propose numerous updates and amendments. In particular, significant changes have been made to the Emergency, Radiology and Pharmacy provisions and new provisions are added regarding standards for Pediatric Intensive Care Units (PICUs). New provisions will require age appropriate equipment and supplies. The new provisions assure that personnel in the emergency department and pediatric intensive care unit have the skills to access and manage a critically ill or injured pediatric patient, including resuscitation. Changes in technology and equipment for diagnostic medical imaging and appropriate use of such equipment are addressed. Policies and procedures regarding imaging studies for newborns and pediatric patients are updated to include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. Pharmacy and equipment requirements for pediatric patients are revised to assure age and size appropriate dosing. The regulations clarify that pediatric dosing must be weight based and all patients must be weighed in kilograms. Current regulations require Advanced Cardiac Life Support (“ACLS”) training or current training equivalent to ACLS for adults but do not require

Pediatric Advanced Life Support (“PALS”) or current training equivalent to PALS for appropriate staff that will be caring for children within the hospital. These regulations address this inequity. This regulatory proposal attempts to strengthen minimum standards for the care of children that are flexible enough to fit the large tertiary care facilities as well as rural and community hospitals. This measure also requires that if laboratory and other diagnostic tests/services are ordered for a patient while receiving emergency services, the hospital must develop and implement written policies and procedures pertaining to the review and communication of the laboratory and diagnostic test/service results to the patient, the patient’s parent, legal guardian or health care agent, and the patient’s primary provider.

These regulations, requiring hospitals provide patients and their parents or other medical decision makers with critical information about the patient’s care and to post a Parent’s Bill of Rights, and another set of regulations requiring hospitals to adopt protocols to identify and treat sepsis, were inspired by the case of Rory Staunton, a 12-year old boy who died of sepsis in April of 2012. Both sets of regulations, together known as “Rory’s Regulations,” will help New York State set a “gold standard” for patient care.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Costs that may be incurred by the regulated parties could include PALS training, accommodations for parent(s) to stay with their child at all times, review and update of

various policies and procedures, pharmacy requirements regarding weight based dosing and the requirement of a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who has demonstrated competence in pediatric critical care to direct PICU services. Regulated parties must also ensure that their equipment is age and size appropriate.

PALS certification costs can range from \$0-\$300. Currently there are grant funded opportunities for PALS certification. Accommodations for parents may be able to be arranged with existing resources, but could also require additional furnishings. What accommodation costs would be incurred depends on the hospital involved. Review and update of the various policies and procedures and the pharmacy requirements could be accomplished with existing staff imposing little or no additional cost to the regulated parties. The “average” salary of a board certified medical, surgical, pediatric, or anesthesia intensivist to direct the PICU would be approximately \$187,192. Hospitals will need to inventory their equipment and supplies to ensure that they are size and age appropriate and provide accordingly. Pediatric dosing resources must include age and size appropriate fluid and medication administration dosing information if not already currently provided.

Cost to State and Local Government:

There is no anticipated fiscal impact to State or local government as a result of these regulations, except that hospitals operated by the State or local governments will incur minimal costs as discussed above.

Cost to the Department of Health:

There will be no additional costs to the Department associated with the implementation of this regulation. Existing staff will be utilized to conduct surveillance of the regulated parties and monitor compliance with these provisions.

Local Government Mandates:

Hospitals operated by State or local governments will be affected and be subject to the same requirements as any other hospital licensed under PHL Article 28.

Paperwork:

This measure will require facilities to develop various written policies and procedures with respect to: transfers of pediatric patients when unable to appropriately and safely care for them, enabling parents/guardians to stay with pediatric patients, assurance that staff privileges are commensurate with training and experience, assurance that various equipment is age and size appropriate, imaging studies and orders. In addition,

monitoring and improvement activities to identify, measure, prevent or mitigate adverse drug events, and for a hospital that provides PICU services policies and procedures for the operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients.

For hospitals with less than 15,000 unscheduled emergency visits per year, the hospital must develop and implement protocols specifying when supervising or attending physicians must be present. (Such facilities must have at least one physician, nurse practitioner, or registered physician assistant on duty in the emergency service 24 hours a day, seven days a week).

Duplication:

These regulations will not conflict with any state or federal rules.

Alternative Approaches:

There are no viable alternatives to this regulatory proposal. All general hospitals must be able to admit pediatric patients consistent with its ability to provide qualified staff, size and age appropriate equipment necessary for the unique needs of pediatric patients. If the hospital cannot meet these requirements, it will be required to develop criteria and policies and procedures for transfer of pediatric patients.

Consideration was made when developing the Pharmaceutical Services provisions in Section 405.17, that for pediatric patients only weight must be measured in kilograms. Upon further consideration it was determined that it was more appropriate to require that weight be measured in kilograms for patients of all ages.

When developing the Critical Care and Special Care Services for provisions for Pediatric Intensive Care Unit (PICU) services in Section 405.22 the Department initially considered a minimum bed standard of six beds. Upon further consideration it was determined that a minimum standard would not be a bed standard but instead require that a PICU must have a minimum average annual pediatric patient number of 200/per year.

Federal Requirements:

These regulations will not conflict with any state or federal rules.

Compliance Schedule:

These regulations will take effect upon publication of a Notice of Adoption in the New York State Register, but general hospitals will have 90 days from such date to comply with these provisions.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to the 228 general hospitals in New York State. A recent survey conducted by the Department determined that 32 hospitals in New York State currently have a pediatric intensive care unit (“PICU”). The proposed amendments will apply Statewide, including 18 general hospitals operated by local governments. These hospitals will not be affected in any way different from any other hospital. The operation of a PICU is not mandated by the State but is at the option of the hospital.

Compliance Requirements:

The literature supports the regulatory changes made to general hospital minimum standards with respect to pediatric care. These provisions specify that general hospitals in New York State must ensure that at least one clinician on every shift in the emergency department has the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate a child. This standard is supported by the American Academy of Pediatrics (*see Pediatrics* 1995; 96:526). This measure also states that policies and procedures regarding imaging studies for newborns and pediatric patients must include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. Medical imaging policies must provide age and

weight-appropriate dosing for children receiving studies involving ionizing radiation as supported by the American Academy of Pediatrics and the American College of Emergency Physicians (*Pediatrics* 2009; 124:1223). Pediatric pharmacy resources must include age and size appropriate fluid and medication administration and dosing. Dosing must be weight based and weight must be measured in kilograms as recommended by the American Academy of Pediatrics; (*Pediatrics* 2003;111:1120). Pediatric Advanced Life Support (PALS) or equivalent training will be required for appropriate staff that will be caring for children in the hospital, a practice supported by the American Academy of (*Pediatrics* 1995;96:526).

The PICU shall have a medical director who has received special training and has demonstrated competence in pediatric critical care as recommended by the American Academy of Pediatrics and Society of Critical Care Medicine (*Pediatrics* 2004; 114: 1114). PICU medical and nursing directors shall be responsible for promoting and verifying pediatric qualifications of staff, overseeing pediatric quality assurance and developing and reviewing PICU care policies consistent with recommendations of the American Academy of Pediatrics, Society of Critical Care Medicine, *Pediatrics* 2004; 114: 1114. PICUs must have a minimum average annual patient number of 200/year. This is consistent with the recommendation made in the American College of Surgeons' *Resources for Optimal Care of the Injured Patient, 2006*.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Professional Services:

The majority of facilities have in-house staff that could make any required changes to the policies and procedures. Small facilities may contract with outside professional staff from the various disciplines to assist them.

Compliance Costs:

A hospital that wants to provide PICU services must have an intensivist who has received special training and has demonstrated competence in pediatric care to direct the PICU. Currently, the majority of PICUs in New York State already have an intensivist in their

employ. According to Jobs-Salary.com, the average pediatric intensivist salary is \$187,712, with a range from \$100,651 to \$280,000. PALS training ranges from \$0-300.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

General hospitals will have 90 days from the effective date of these regulations to implement these provisions. In addition, at present, grant funding is available for PALS certification.

Small Business and Local Government Participation:

This proposal has been discussed and reviewed by the EMS-C Advisory Committee, the Greater New York Hospital Association (“GNYHA”), the Healthcare Association of New York State (“HANY”), the Iroquois Hospitals Association and the State Hospital Pharmacy Association.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

The provisions of these regulations will apply to general hospitals in New York State, including the 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals located in rural areas.

Compliance will require the admission of pediatric patients only if qualified staff and appropriate equipment are available. Further, compliance will require the adoption and implementation of policies and procedures tailored to the pediatric patient related to surgery, anesthesia, respiratory care, radiologic and nuclear medicine, pharmacy, emergency medicine, etc. ensuring the pediatric patient is appropriately cared for by skilled staff with the appropriate equipment in the appropriate location.

Professional Services:

Professional services for hospitals in rural areas are not expected to be impacted as a result of these regulations differently than other hospitals.

Compliance Costs:

Costs for general hospitals in rural areas will be the same as for general hospitals in nonrural areas. Cost that may be incurred by the regulated parties could include PALS training, accommodations for parent(s) to stay with their child at all times, review and update of various policies and procedures, pharmacy requirements regarding weight based dosing and the requirement of a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who has demonstrated competence in pediatric critical care to direct PICU services. Regulated parties must also ensure that their equipment is age and size appropriate.

PALS certification costs can range from \$0-\$300. Currently there are grant funded opportunities for PALS certification. Accommodations for parents may be able to be arranged with existing resources, but could also require additional furnishings. What accommodation costs would be incurred depends on the hospital involved. Review and update of the various policies and procedures and the pharmacy requirements could be accomplished with existing staff imposing little or no additional cost to the regulated parties. The “average” salary of a board certified medical, surgical, pediatric, or anesthesia intensivist to direct the PICU would be approximately \$187,192. Hospitals will need to inventory their equipment and supplies to ensure that they are size and age appropriate and provide accordingly. Pediatric dosing resources must include age and size appropriate fluid and medication administration dosing information if not already currently provided.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. Hospitals will have a minimum of 90 days following adoption of these regulations to adopt and implement sepsis protocols and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Rural Area Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are located in rural areas. The associations are supportive of this initiative.

JOB IMPACT STATEMENT

Nature of Impact:

These provisions will not have a significant impact on jobs. A PICU in any New York State general hospital must be directed by a board certified pediatric medical, surgical, anesthesiology or critical care/intensivist physician who must be responsible for the organization and delivery of PICU care. Such intensivist must have specialized training and demonstrated competence in critical care. Hospitals that want to provide PICU services may already have an intensivist to direct their unit.

Categories and Numbers Affected:

There are 32 hospitals in New York State the report that they have a PICU.

Regions of Adverse Impact:

There are no regions of adverse impact.

Minimizing Adverse Impact:

Hospitals will have 90 days from the effective date of these regulations to implement these provisions. In addition, at present, there is grant funding available for PALS certification.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 2 is amended to add a new section 2.59, as follows:

2.59 – Prevention of influenza transmission by healthcare and residential facility and agency personnel

(a) Definitions.

(1) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a healthcare or residential facility or agency, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with influenza, they could potentially expose patients or residents to the disease.

(2) “Healthcare and residential facilities and agencies,” for the purposes of this section, shall include:

(i) any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

- (ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies; and
- (iii) hospices as defined in section 4002 of the Public Health Law.

(3) “Influenza season,” for the purposes of this section, shall mean the period of time during which influenza is prevalent as determined by the Commissioner.

(b) All healthcare and residential facilities and agencies shall determine and document which persons qualify as “personnel” under this section.

(c) All healthcare and residential facilities and agencies shall document the influenza vaccination status of all personnel for the current influenza season in each individual’s personnel record or other appropriate record. Documentation of vaccination must include the name and address of the individual who ordered or administered the vaccine and the date of vaccination.

(d) During the influenza season, all healthcare and residential facilities and agencies shall ensure that all personnel not vaccinated against influenza for the current influenza season wear a surgical or procedure mask while in areas where patients or residents may be present. Healthcare and residential facilities and agencies shall supply such masks to personnel, free of charge.

(e) Upon the request of the Department, a healthcare or residential facility or agency must report the number and percentage of personnel that have been vaccinated against influenza for the current influenza season.

(f) All healthcare and residential facilities and agencies shall develop and implement a policy and procedure to ensure compliance with the provisions of this section. The policy and procedure shall include, but is not limited to, identification of those areas where unvaccinated personnel must wear a mask pursuant to subdivision (d) of this Section.

Subparagraph (v) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(v) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (4) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(4) Collects documentation of vaccination against influenza, or requires wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 751.6 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (5) of subdivision (c) of Section 763.13 is added to read as follows:

(5) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 766.11 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 793.5 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225 (5), 2800, 2803 (2), 3612 and 4010 (4). PHL 225 (5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL

Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies and providers of long term home health care programs. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Legislative Objectives:

The legislative objective of PHL 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. The requirement of surgical or procedure masks of unvaccinated healthcare and residential facility and agency personnel in these facilities will promote the health and safety of the patients and residents they serve and support efficient and continuous provision of services.

Needs and Benefits:

Transmission of influenza from healthcare and residential facility and agency personnel to patients and residents is a serious public health and patient safety issue. Influenza is a leading

cause of morbidity and mortality among hospitalized patients as well as persons admitted to or residing in other types of health care facilities. Healthcare and residential facility and agency personnel are at increased risk of acquiring influenza because of their contact with ill patients and residents, and personnel can transmit influenza to their patients and residents if they become ill. It is beyond dispute that vaccination is the most effective measure to prevent influenza, for health care facility personnel and their patients.

Accordingly, for the past two decades, the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) has strongly recommended that all healthcare personnel be vaccinated against influenza. With the Department's encouragement, some healthcare and residential facilities and agencies have voluntarily implemented strategies to increase influenza vaccination rates among their personnel; however, these efforts have met with limited success.

Despite ACIP recommendations and national and State efforts to increase voluntary influenza vaccination rates, vaccination rates among healthcare and residential agency personnel in New York State have remained unacceptably low. In the 2011-2012 influenza season, hospitals in New York State reported healthcare personnel vaccination rates ranging from 11.1% - 97.8%, with an average of 48.4%. Thirty-four hospitals reported vaccination rates of 50% or lower, and nine of these hospitals reported vaccination rates lower than 25%. Nursing homes reported an average personnel vaccination rate of 45.0%.

Now, like much of the rest of the nation, New York State is experiencing the worst seasonal influenza season in a decade. Notably, the 2012-13 influenza season is worse than in any season since ACIP set the national standard of medical care for influenza vaccination by recommending that all persons be vaccinated each year. The intensity of this year's influenza season is a reminder that influenza is unpredictable and may cause serious illnesses, deaths and healthcare disruption during any year. Additional steps must be taken to prevent the toll of influenza in health care facilities to the extent possible.

In response to this increased public health threat, New York State has taken active steps to prevent and control transmission of seasonal influenza, in addition to its annual promotional campaign encouraging influenza vaccination. On January 12, 2013 Governor Cuomo issued an Executive Order declaring a disaster emergency and temporarily modifying sections of the State Education Law to permit children ages 6 months to 18 years to be vaccinated by pharmacists. Yet the seriousness of the continuing influenza threat, and the failure of healthcare and residential facilities and agencies to achieve acceptable vaccination rates through voluntary programs, necessitates further action.

Although masks are not as effective as vaccination, evidence indicates that wearing a surgical or procedure mask will lessen transmission of influenza from patients experiencing respiratory systems. It is also known that persons incubating influenza may shed the influenza virus before they have noticeable symptoms of influenza. According to the CDC, the use of surgical or procedure masks by infectious patients may help contain their respiratory secretions and limit exposure to others. The CDC also recommends that patients who may have an

infectious respiratory illness wear a mask when not in isolation and that healthcare personnel wear a mask when in close contact with symptomatic patients. Further, the Infectious Disease Society of America recommends that healthcare personnel who are not vaccinated for influenza wear masks.

Accordingly, the Department is issuing these regulations to require all unvaccinated personnel in healthcare and residential facilities and agencies to wear surgical or procedure masks during the time when the Commissioner determines that influenza is prevalent. Requiring unvaccinated personnel to wear a mask is a reasonable step to lessen the risk of transmission to patients and residents, because unvaccinated personnel may be infectious before they are obviously ill, may contract a mild respiratory illness that is not recognized as influenza, and are at increased risk of becoming infected with influenza through patient or resident contact. All of these factors increase the risk of transmitting influenza to patients and residents.

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Healthcare and residential facilities and agencies must determine and document whether personnel have, or have not, been vaccinated against influenza for the current influenza season in each individual's personnel or other appropriate record. Those individuals who were not vaccinated for influenza must wear a surgical or procedure mask during the influenza season, as determined by the Commissioner. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from \$100 to \$250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the Public Health Law and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to document the influenza vaccination status of their personnel and, during the influenza season, provide surgical or procedure masks for those not vaccinated.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant, for several reasons. State and local facilities should already be providing masks for personnel who may come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, these entities are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of \$87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of \$47 annually per person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to the State and local governments, the savings will more than cover the cost of the program, and public health will be improved.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

There are no additional programs, services, duties or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district, except as they apply to facilities operated by local governments, except as noted above for local health departments.

Paperwork:

This measure will require healthcare and residential facilities and agencies to document whether personnel have, or have not, been vaccinated against influenza for the current influenza season. It will require these facilities and agencies to document the influenza vaccination status of all personnel for the current influenza season in each individual's personnel record or other appropriate record. Upon the request of the Department, a facility or agency must report the number and percentage of personnel that have been vaccinated against influenza for the current influenza season. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative to requiring a surgical or procedure mask for personnel unvaccinated for influenza would be to require all personnel to be vaccinated for influenza. The Department weighed these two options and, in balancing various factors related to each, determined that

promoting vaccination, but requiring unvaccinated personnel to wear a surgical or procedure mask, is the most effective and least burdensome way to immediately reduce the potential for transmission of influenza at this time.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any facility defined as a hospital pursuant to Article 28, a home services agency by PHL Article 36, or a hospice by PHL Article 40 will be required to comply. In New York State there are 228 general hospitals, 1198 hospital extension clinics, 1239 diagnostic and treatment centers, and 635 nursing homes. There are also 139 certified home health agencies (CHHAs), 97 long term home health care programs (LTHHCP), 19 hospices and 1164 licensed home care services agencies (LHCSAs).

Of those, it is known that 3 general hospitals, approximately 237 diagnostic and treatment centers, 40 nursing homes, 69 CHHAs, 36 hospices and 860 LHCSAs are small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule. Local governments operate 18 hospitals, 40 nursing homes, 42 CHHAs, at least 7 LHCSAs, and a number of diagnostic and treatment centers and hospices.

Compliance Requirements:

All facilities and agencies must document the vaccination status of each personnel member as defined in this regulation for influenza virus, in their personnel or other appropriate record. Each facility must develop a policy and procedure which requires all personnel who have not been vaccinated for influenza during the current influenza season to wear a surgical or procedure mask.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Facilities and agencies will need to provide surgical or procedure masks to those personnel not vaccinated for influenza during a current influenza season. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from \$100 to \$250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Although the cost to small businesses and local governments cannot be determined with precision, the Department does not expect this cost to be significant, for several reasons. Small businesses and local governments should already be providing masks for personnel who may

come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, small businesses and local governments are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of \$87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of \$47 annually per person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to small businesses and local governments, the savings will more than cover the cost of the compliance, and public health will be improved.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The requirement to wear a surgical mask does not impose any physical limitations on the wearer, as would be the case with wearing a respirator which would provide a higher level of protection. Because healthcare and residential facility and agency personnel often wear surgical or procedure masks for a variety of reasons, including both protecting patients and residents and

themselves from communicable disease risks, and because some healthcare facilities in the state already require unvaccinated personnel to wear masks during influenza season, this will not present an undue burden or stigma on healthcare and residential facilities and agencies, or their personnel.

Further, most of the healthcare facilities are already required by state law or soon will be required by federal law to maintain records of the influenza vaccination status of their personnel. Finally, the requirement is to be in effect only when influenza is prevalent as determined by the Commissioner. This enables the requirement to be tailored to the circumstances of any particular influenza season and to be in effect only when there is the greatest risk of influenza transmission.

For these reasons, these regulations do not impose an addition burden on the regulated parties.

Small Business and Local Government Participation:

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). The Department will be seeking local government input prior to proposing a permanent regulatory amendment.

This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

Any facility defined as a hospital pursuant to Article 28, a home services agency by PHL Article 36, or a hospice by PHL Article 40 will be required to comply. In New York State there are 228 general hospitals, 1198 hospital extension clinics, 1239 diagnostic and treatment centers, and 635 nursing homes. There are also 139 certified home health agencies (CHHAs), 97 long term home health care programs (LTHHCP), 19 hospices and 1164 licensed home care services agencies (LHCSAs). Of those, it is known that 47 general hospitals, approximately 90 diagnostic and treatment centers, 159 nursing homes, 92 certified home health agencies, 19 hospices, and 26 LHCSAs are in counties serving rural areas. These facilities and agencies will not be affected differently than those in non-rural areas.

Compliance Requirements:

All facilities and agencies must document the vaccination status of each personnel member as defined in this regulation for influenza virus, in their personnel or other appropriate record. Each facility must develop a policy and procedure which requires all personnel who have not been vaccinated for influenza during the current influenza season to wear a surgical or procedure mask.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Facilities and agencies will need to provide surgical or procedure masks to those personnel not vaccinated for influenza during a current influenza season. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from \$100 to \$250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Although the cost to facilities and agencies in rural areas cannot be determined with precision, the Department does not expect this cost to be significant, for several reasons. Facilities and agencies in rural areas should already be providing masks for personnel who may come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, facilities and agencies in rural areas are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of \$87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of \$47 annually per

person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to facilities and agencies in rural areas, the savings will more than cover the cost of the compliance, and public health will be improved.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The requirement to wear a surgical mask does not impose any physical limitations on the wearer, as would be the case with wearing a respirator which would provide a higher level of protection. Because healthcare and residential facility and agency personnel often wear surgical or procedure masks for a variety of reasons, including both protecting patients and residents and themselves from communicable disease risks, and because some healthcare facilities in the state already require unvaccinated personnel to wear masks during influenza season, this will not present an undue burden or stigma on healthcare and residential facilities and agencies, or their personnel.

Further, most of the healthcare facilities are already required by state law or soon will be required by federal law to maintain records of the influenza vaccination status of their personnel.

Finally, the requirement is to be in effect only when influenza is prevalent as determined by the Commissioner. This enables the requirement to be tailored to the circumstances of any particular influenza season and to be in effect only when there is the greatest risk of influenza transmission.

For these reasons, these regulations do not impose an addition burden on the regulated parties.

Public and Local Government Participation:

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE
FACILITIES**

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals,
Abstentions/Interests

CON Applications

Diagnostic and Treatment Center – Construction

Exhibit #4

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122161 C	East Harlem Council for Human Services, Inc. d/b/a Boriken Neighborhood Health Center (New York County)	Contingent Approval

Transitional Care Units - Construction

Exhibit #5

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122236 T	Upstate University Hospital at Community General (Onondaga County)	Contingent Approval
2.	122237 T	St. Joseph's Hospital (Chemung County)	Contingent Approval



Public Health and Health Planning Council

Project # 122161-C
**East Harlem Council for Human Services, Inc.
d/b/a Boriken Neighborhood Health Center**

County: New York (New York)
Purpose: Construction

Program: Diagnostic and Treatment Center
Submitted: September 28, 2012

Executive Summary

Description

East Harlem Council for Human Services, Inc. d/b/a Boriken Neighborhood Health Center (Boriken), an existing Article 28 diagnostic and treatment center (D&TC) that is designated as a Federally-Qualified Health Center (FQHC), requests approval to construction a 31,713 square foot replacement facility at 2265 Third Avenue, New York. This application amends and supersedes CON #102237-C, approved for \$14,997,465 in accordance with the administrative review provisions, and which is in the process of being constructed. This amendment is being submitted due to increases in project costs, changes in the proposed funding, and changes in facility design. Construction commenced on February 22, 2012, with a projected completion date revised to September 30, 2013.

The proposed facility will be located right across the street from where it has been operating since October 1978, in 14,000 square feet of leased space on the third floor of a subsidized housing development at 2253 Third Avenue (between 122nd and 123rd Street) in Manhattan. According to the applicant the current space configuration is not efficient and impedes patient flow along with having issues surrounding inadequate plumbing, air conditioning, heating, and vertical transportation.

Total project costs are estimated at \$28,574,905.

DOH Recommendation
Contingent approval.

Need Summary

Boriken currently provides 41,736 patient visits for the East Harlem Community, 55.9% of which are for Medicaid patients.

The proposed replacement facility will provide space for Boriken to increase its volume of visits by 39% in the first year of operation. This projected growth is in response to the demand for primary care services in Boriken's service area.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

Total project costs will be funded as follows: \$15,825,420 in awarded grant funds and \$250,000 in donations, plus a combination of loans totaling \$12,499,485. The loans consist of \$8,050,000 from the New Markets Tax Credit (NMTC) program administered by the US Treasury Department, (which is expected to be forgiven after the end of the seventh year) and a \$4,449,485 loan from the Primary Care Development Corporation.

Budget	<i>Revenues:</i>	\$ 14,711,832
	<i>Expenses:</i>	<u>14,090,890</u>
	<i>Gain/(Loss):</i>	\$ 620,942

Subject to the note contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed loan commitment for the New Markets Tax Credit program that is acceptable to the Department of Health. [BFA]
3. Submission of an executed loan commitment from the Primary Care Development Corporation that is acceptable to the Department of Health. [BFA]
4. Submission of a final executed Grant approval letters to be used as a source of financing acceptable to the Department of Health. [BFA]
5. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

Approval conditional upon:

1. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
2. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
3. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
4. The clinical space must be used exclusively for the approved purpose. [HSP]
5. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
6. The applicant shall complete construction by September 30, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

East Harlem Council for Human Services, Inc., d/b/a Boriken Neighborhood Health Center, is an existing Federally-Qualified Health Center (FQHC), which requests approval to construct a replacement facility to be located at 2265 Third Avenue, New York. This project amends and supercedes CON #102237-C.

Boriken Neighborhood Health Center has the following certified services:

Service	Certified Services	Requested Action	Certified Services Upon Completion
Audiology O/P	√		√
Certified Mental Health Services O/P	√	Delete	
Clinical Laboratory Service O/P	√		√
Dental O/P	√		√
Family Planning O/P	√		√
Health Fairs O/P	√		√
Medical Social Services O/P	√		√
Multiphasic Screening O/P	√		√
Nursing	√		√
Ophthalmology O/P		Add	√
Pediatric O/P	√		√
Podiatry O/P	√		√
Prenatal O/P	√		√
Primary Medical Care O/P	√		√
Psychology O/P	√		√
Radiology - Diagnostic O/P	√		√
Therapy - Respiratory O/P	√		√
Well Child Care O/P	√		√

Analysis

Boriken Neighborhood Health Center plans to relocate its main site and construct a replacement facility across the street from the existing center. Boriken is an FQHC that has served the residents of East Harlem since 1978.

Boriken is currently located in leased space at 2253 Third Avenue between 122nd and 123rd Streets in Manhattan. The existing site is over 30 years old, has frequent age-related problems, and cannot accommodate growth. The proposed site is across the street at 2265 Third Avenue in space that is owned by Boriken. Boriken's ownership of the space will provide control over the site's configuration and operation, while eliminating rental costs.

Boriken currently provides primary care services for children and adults, including pediatrics, internal medicine, dental, and obstetrics and gynecology. The facility also provides a range of on-site specialty services and programs, including

nutrition, dermatology, podiatry, social work services, and services for people living with asthma, diabetes, HIV/AIDS and Hepatitis C.

Utilization

Boriken Services and Utilization			
<i>Service</i>	<i>Current Utilization</i>	<i>1st Year Visits</i>	<i>3rd Year Visits</i>
Dental	6,942	9,615	15,490
Medical Social Services	3,618	5,011	8,073
Nutritional	867	1,201	1,935
Pediatrics	7,048	9,762	15,727
Podiatry	1,157	1,603	2,582
Primary Medical Care	22,104	30,617	49,326
Ophthalmology	N/A	1,664	2,080
Total	41,736	59,473	95,213

According to the NYC Department of Health and Mental Hygiene, the causes of premature death in East Harlem are heart disease (17 percent), HIV (16 percent), Cancer (15 percent), drug-related (7 percent), homicide (5 percent), and other causes (40 percent). Among “other causes” of premature death are certain Perinatal conditions (5 percent), diabetes (3 percent), diseases of the nervous system (2 percent), and chronic lower respiratory diseases (2 percent).

Boriken reports that 55.9 percent and 22.7 percent of their patient visits are for Medicaid and Indigent Clients, respectively.

Conclusion

This project for an updated and expanded D&TC will enable Boriken to significantly increase its volume of services in the East Harlem Community.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

East Harlem Council for Human Services, Inc. requests approval to construct a replacement facility for their Article 28 diagnostic and treatment center called Boriken Neighborhood Health Center. This proposal is an amendment to a previously approved project (CON 102237) that is required because of increased costs, changed financing, and architectural changes. Additionally, the facility would like to certify ophthalmology services and decertify certified mental health services at the center.

Staffing will consist of an additional 31 FTEs by the third year in the new facility.

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility’s enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Total Project Cost and Financing

Total project cost for the renovation and equipment is estimated at \$28,574,905, broken down as follows:

	Previously Approved under CON #102237-C	Incremental Project Costs	Revised Project Cost With NMTC Financing
Renovation & Demolition	\$10,303,719	\$4,125,575	\$14,429,294
Asbestos Abatement	63,000	344,200	407,200
Design Contingency	1,030,372	-916,372	114,000
Construction Contingency	1,030,372	-30,372	1,000,000
Fixed Equipment	0	200,000	200,000
Planning Consultant Fees	50,000	939,990	989,990
Architect/Engineering Fees	876,087	446,502	1,322,589
Construction Manager Fees	665,723	34,277	700,000
Other Fees (Consultant)	539,545	423,653	963,198
Movable Equipment	200,000	2,495,599	2,695,599
Telecommunications	<u>200,000</u>	<u>350,000</u>	<u>550,000</u>
Subtotal – Total Basic Cost of Construction	\$14,958,818	\$8,413,052	\$23,371,870
Financing Costs *	0		\$4,872,535
Interim Interest Expense	0		200,000
Con Application Fee	1,250		2,500
Added CON Processing Fee	<u>37,397</u>		<u>128,000</u>
Total Project Cost	<u>\$14,997,465</u>		<u>\$28,574,905</u>

**See attachment E for details of the Capital Financing Costs*

The project is currently under construction, pursuant to the approval under CON 102237 and according to the applicant this amendment is based on: increases in project costs; changes in the proposed project's funding mechanism; and changes in the facility's design.

The New Markets Tax Credit (NMTC) program was extended for the years 2012 and 2013 when President Obama signed the American Taxpayer Relief Act of 2012 on January 3, 2013.

The New Markets Tax Credit (NMTC) program created by the U.S. Federal Government in 2000, as part of the Community Renewal Tax Relief Act, encourages investment in low-income communities (LICs). Rather than being directly involved in how the benefits of this subsidy program are allocated, the U.S. Department of Treasury (through the Community Development Financial Institutions Fund or CDFI Fund) essentially deputizes this decision making process to the Community Development Entities (CDEs) which have demonstrated a track record of investing into low-income communities.

In essence, the tax credit created provides an incentive for an investor (typically a bank or financial institution) to purchase the tax credit, providing capital that can be used towards financing a real estate project or business in an low-income community (LIC). The credit is sufficient to repay the investor's capital over 7 years and provide a market-rate of return. At the end of seven years (provided facility continues operations within economically distressed area) through a put/call option the health center buys back the investor's interest for a nominal amount (\$1,000) and the health center owes the note to itself, so the note is liquidated and the principal balance becomes equity to the health center.

The applicant's financing plan appears as follows:

	Originally under CON <u>#102237-C</u>	Revised Project Cost With NMTC <u>Financing</u>
Equity		
Government Grants & Donation	\$14,997,465	\$16,075,420
New Markets Tax Credit (debt to be forgiven at the end of 7 years. Interest only during the 7years at 4.5%).		8,050,000
Primary Care Development Corporation with 10-year terms & amortization of 20 years. Fixed rate at the time of closing based on Treasury + 350 basic points (5.17% as of 9/10/12).	<u>0</u>	<u>4,449,485</u>
Total	\$14,997,465.	\$28,574,905

The applicant states that they qualify for the New Markets Tax Credit (NMTC) program as a "Qualified Active Low-Income Community Business." The qualifications include being located in a highly distressed census tract, which is defined by one or more of the following primary criteria:

- The area poverty level is above 30%. The applicant's poverty level in (census tract #36061019400) is 48.9%;
- The area median income is less then 60% of the benchmarked median income. The applicant's median income in (census tract #36061019400) is less then 22.2% of the benchmarked median income, or
- The unemployment rate in the area is at least 1.5 times the national average (which was 7.9% for the 2010 census). The applicant's unemployment rate in (census tract #36061019400) is 2.38 times the national average or 18.8%.

Primary Care Development Corporation (PCDC) has provided a letter of interest for construction and permanent financing, and they also indicated an interest in providing the New Markets Tax Credit.

Operating Budget

The applicant has submitted the operating budgets, in 2012 dollars, as summarized below:

	<u>Current Year</u>	<u>Incremental</u>	<u>Third Year</u>
Revenues-Outpatient:	\$4,349,955	\$6,038,047	\$10,388,002
Other Operating Income (A)	<u>2,716,390</u>	<u>1,607,440</u>	<u>4,323,830</u>
*Total Revenues	\$7,066,345	\$7,645,487	\$14,711,832
Expenses:			
Operating	\$7,468,225	\$5,273,425	\$12,741,650
Capital	<u>41,273</u>	<u>1,307,967</u>	<u>1,349,240</u>
*Total Expenses	\$7,509,498	\$6,581,392	\$14,090,890
Excess Revenue over Expenses	<u>(\$443,153)</u>	<u>\$1,064,095</u>	<u>\$620,942</u>
Utilization: (Visits)	41,736	53,477	95,213
Cost per visit	\$179.93		\$147.99

* Revenue and expenses are for Boriken Neighborhood Health Center

(A) Other operating revenues in year three of \$4,323,830 consist of: \$1,833,338 in Section 330 Grants, and an increase of \$322,930 from the current year; \$1,218,734 in Charity Care Pool, and an increase of \$684,510 from the current year; \$441,758 in HIV Early Intervention Grant, same as the current year; Other Grants of \$830,000, an increase of \$600,000 from the current year and they also included Women, Infants and Children (WIC), Meaningful Use and Patient-Centered Medical Home (PCMH) incentives and other federal and state grants.

Outpatient utilization by payor source is as follows:

	<u>Outpatient</u>
Medicaid Fee-for-Service	12.76%
Medicaid Managed Care	43.11%
Medicare Fee-for-Service	3.03%
Medicare Managed Care	4.29%
Commercial Manage Care	5.64%
Private Pay and All Other	8.44%
Charity	22.73%

Expenses are based upon historical experience adjusted for volume, investment and rising costs. Additionally staffing levels are expected to increase by 36.03 full time equivalent (FTE) employees, which includes 6.63 FTE physicians, going from 10.70 FTE to 17.33 FTE, and dentists and hygienists increasing by 2 FTE along with adding 1 FTE nutritionist, and 2 FTE social worker plus support staff. Utilization projects are based upon: need projections, the ability to efficiently handle projected volume in the 37 new exams rooms and 10 dental chairs, representing an increase of 23 exams rooms and 5 dental chairs. Additionally, the new facility will have greater exposure to the local population and will be easier for them to access. The breakeven point at the proposed facility is approximately 88,540 visits, which the applicant projects reaching by the second year of operating at the new replacement facility.

Capability and Feasibility

The total project cost of \$28,574,905 is presented under a financing plan which utilizes the New Markets Tax Credit (NMTC) program administered by the US Treasury Department. The project will be funded with \$16,075,420 in grants and a contribution, a loan of \$4,449,485 for which a letter of interest has been provided by Primary Care Development Corporation (PCDC) at the above stated terms. The remaining balance of \$8,050,000 will be provided through the New Markets Tax Credit (NMTC) program, at the above stated terms. As previously stated under the New Markets Tax Credit program, it is expected that approximately \$8,050,000 in debt will be forgiven at the end of the seventh year.

Presented as Attachments A and B are East Harlem Council for Human Services, Inc certified financial summary for June 30, 2010 and June 30, 2011 and their Internal financial summary as of June 30, 2012. Presented as Attachment C, is a list of Grant Funding Sources plus a contribution, which indicates the availability of sufficient resources for this project.

Working capital requirements are estimated at \$1,096,899, which appear reasonable based on two months of third year budgeted expenses. Presented as Attachment D is Boriken Neighborhood Health Center projected cash flow which indicates working capital requirements can be met from operations.

The operating budget projects a first year loss of \$1,306,496 and a surplus of \$620,942 by the third year. Review of Attachments A and B, shows East Harlem Council for Human Services, Inc. had an average excess of revenues over expenses of \$1,013,427, a positive average work capital position of \$3,321,806 and positive net asset position of \$6,092,580 as of June 30, 2012. Revenues are based on prevailing reimbursement methodologies and current rate schedules. The budget appears reasonable.

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Financial Summary as of June 30, 2010 and June 30, 2011, East Harlem Council for Human Services, Inc.
BFA Attachment B	Internal Financial Summary as of June 30, 2012, East Harlem Council for Human Services, Inc.
BFA Attachment C	List of Grant Funds
BFA Attachment D	Cash Flow
BFA Attachment E	Capital Financing Costs



Public Health and Health Planning Council

Project # 122236-T UPSTATE University Hospital at Community General

County: Onondaga (Syracuse)
Purpose: Demonstration

Program: Transitional Care Unit
Submitted: November 15, 2012

Executive Summary

Description

Upstate Medical University is a 715-bed public State-owned hospital which operates two hospital campuses, Upstate University Hospital downtown campus (409 beds) and the Upstate University Hospital - Community General campus (306 beds) located at 750 East Adams Street, Syracuse and 4900 Broad Road, Syracuse, respectively. Upstate Medical University requests approval to create a 20-bed skilled nursing facility to function as a Transitional Care Unit (TCU), to bridge the gap between the hospital's acute-care setting and post-acute care to ensure a smooth transitional care continuum, at the Community General campus, which will serve patients cared for at both facilities.

On October 16, 2012, the Department of Health requested applications in accordance with the provisions of Section 2802-a, of the Public Health Law for a TCU Demonstration Program.

The TCU will be designed to achieve the following objectives:

- Provide an interdisciplinary evaluation of each patient to optimize cognitive and physical function with the goal of discharge to the lowest, most cost effective level of care that meets patient needs.
- Reduce the occurrence of iatrogenic events that can increase length of stay (example: falls, polypharmacy, skin breakdown, delirium, prolonged immobility, hospital acquired infections, among other conditions).
- Provide patient centered care to meet individualized care plans and therapeutic goals, including evaluation of social supports, to reduce rate of readmission for the same or related medical or surgical condition.
- Provide coordinated care that optimizes communication with patient's primary care physician to maintain continuity of care after discharge.

- Provide educational services to patient and his/her family to assist in preparing patients for discharge home.
- Provide ongoing quality improvement oversight to assure objectives are achieved and a process for continual improvement exists in measuring key aspects of care.

Total project costs are estimated at \$2,842,287.

DOH Recommendation
Contingent approval.

Need Summary

Section 2802-a of the Public Health Law was amended by Chapter 58 of 2010, authorizing the Commissioner to approve an additional 13 general hospitals to operate TCUs on a demonstration basis.

Program Summary

The TCU program will provide access to rehabilitation therapies – individualized physical therapy, structured occupational therapy, speech language pathology, recreational therapy, and psychosocial therapy. The 20-bed TCU unit will be located and self-contained on the fifth floor east wing of the hospital.

Financial Summary

Project costs will be met with \$337,775 in accumulated funds from Upstate Medical University, and a mortgage loan of \$2,504,512 (30 yrs. @ 3%).

Incremental Budget:	<i>Revenues:</i>	\$ 3,717,054
	<i>Expenses:</i>	<u>1,487,153</u>
	<i>Gain/(Loss):</i>	\$ 2,229,901

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

The Central New York HSA recommends approval of this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a commitment for a permanent mortgage for the project, to be provided from a recognized lending institution at a prevailing rate of interest, determined to be acceptable by the Department of Health. This is to be provided within 120 days of receipt from the Department of Health, Bureau of Architectural and Engineering Facility Planning of approval of final plans and specifications, and before the start of construction. Included with the submitted permanent mortgage commitment must be a Sources and Uses Statement and a Debt Amortization Schedule, for both new and refinanced debt. [BFA]

Council Action Date

February 7, 2013.

Need Analysis

Background

Section 2802-a of the Public Health Law was amended by Chapter 58 of 2010 authorizing the Commissioner to approve an additional 13 general hospitals to operate transitional care units (TCUs) on a demonstration basis. The original TCU enabling legislation of 2005 authorized five demonstration projects.

Transitional Care Unit Purpose

Section 2802-a of PHL defines "transitional care" as sub-acute care services provided to inpatients of a general hospital who no longer require acute care inpatient services, but continue to need specialized medical, nursing and other hospital ancillary services and are not yet ready for discharge. TCUs should be limited in length of stay and designed to meet and resolve patients' specific sub-acute medical care needs. Discharges from these units are to be timely and appropriate.

The improvement of quality outcomes for the TCU population through the provision of appropriate services, delivered in the most efficient manner, is the primary goal of the TCU demonstration program. Hospitals selected for this program are required to demonstrate an overall decrease in length of stay, quantify the clinical benefits of the program for TCU patients, and illustrate a synergistic relationship with long term care providers in the community. Collaboration between hospitals and nursing homes in local service areas will help bring about more efficient allocation of patients between the two settings.

In accordance with Section 2802-a of PHL, all providers in this demonstration program must meet all Conditions of Participation (CoP) for skilled nursing facilities (SNFs) as defined under Title XVIII of the Federal Social Security Act (Medicare). In order to qualify for Medicare certification, providers must comply with Part 415 of Title 10 of the New York Compilation of Codes, Rules and Regulations (10 NYCRR). In this demonstration, providers not currently licensed to operate nursing home beds will not be required to obtain Public Health and Health Planning Council establishment approval. Additionally, TCU units are not recognized as RHCf beds as defined in 10 NYCRR Section 709.3.

As part of this demonstration program, specific State SNF regulations that may impede the development of TCUs or their ability to provide appropriate services to patients may be subject to waiver, at the discretion of the Department. Such issues will be reviewed on an individual basis.

Applicants must demonstrate the need for any services proposed within the TCU and emphasize the benefits of such a program to a specific community, including, but not limited to, addressing the absence of sufficient post-discharge services in nursing homes and community-based care.

Transitional care units should be limited in length of stay and designed to meet and resolve specific sub-acute medical care needs. The average length of stay for patients served in a TCU ranges from 5 to 21 days, following a qualifying acute care stay. TCU services will be reimbursed at the applicable Medicare per diem SNF rate.

Transitional Care Unit Criteria and Requirements

Section 2802-a requires all providers applying to participate in this demonstration program to meet all applicable requirements as defined under Title XVIII of the Federal Social Security Act (Medicare). Additionally, Transitional Care Units must:

- Have a length of stay of not less than 5 days and not in excess of 21 days;
- Have a pre-opening survey, separate Medicare Number, and SNF certification;
- Be staffed by qualified staff dedicated to the TCU;
- Serve patients who will benefit from active rehabilitation. (It is expected that patients will actively participate in three hours or more of Occupational Therapy/Physical Therapy/Speech Therapy, every day, either three hours consecutively or in combination between rehabilitative sessions); and

- Collect information and submit reports to the Department on an annual basis to demonstrate an overall decrease in length of stay; quantify the clinical benefits of the program for TCU residents and illustrate a synergistic relationship with long term care providers.

Applications must address the configuration of the Transitional Care Unit. However, the applicant must adhere to the following requirements:

- Beds must be located at one geographic location; and
- Beds must be located contiguously within a distinct unit/space within the hospital.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

The principal elements of the proposed TCU program are:

- A 20-bed unit to provide services to medically complex patients in need of services not generally provided in the community. These include, but are not limited to patients requiring infectious disease, wound, respiratory TPN and other nutrition care.
- Location in Upstate University Hospital at Community General and also serving the affiliated University Hospital SUNY Health Science Center hospital, both with above average lengths of stay in part attributable to difficulties in discharging patients requiring more complex medical care.
- Operation by a facility with dedicated staff with prompt access to specialist acute care professionals and related services.
- Single-bedded and double-bedded rooms with dining/activities/lounge space in a unit to be renovated unit on an acute care floor. Therapy space is located adjacent to the unit.

Analysis

The TCU will focus on patients that if not discharged to the TCU would otherwise, continue to be served in a Med/Surg bed. These patients will remain in the TCU for a short stay of not less than 5 and no more than 20 days. The target patient focus is on medically complex elderly patients who while clinically stable still require on-going physician oversight and the specialized services of hospital staff.

The TCU will be under the direct responsibility of the hospital's senior leadership and quality council and will include a management team consisting of a part time Licensed Nursing Home Administrator and Medical Director, Upstates's Director of Geriatrics, and, a Nurse Administrator RN with hospital experience. The team will also include an MDS Coordinator, Register Nurses, Aides, a Social Worker, and Activities and Therapy staff.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Total Project Costs

Total project costs for renovations and the acquisition of moveable equipment is estimated at \$2,842,287, itemized as follows:

Renovation & Demolition	\$1,528,723
Asbestos Abatement	95,077
Construction Contingency	243,570
Architect/Engineering Fees	186,600
Other Fees	20,000
Movable Equipment	383,213
Telecommunications	330,000
Interim Interest Expense	37,568
Application Fee	2,000
Additional Processing Fee	<u>15,536</u>
Total Project Cost	<u>\$2,842,287</u>

Project costs are based on a July 1st, 2013 construction start date and a six month construction period.

The applicant has submitted an incremental operating budget in 2012 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$3,717,054	\$3,717,054
Expenses:		
Operating	\$1,264,321	\$1,264,321
Interest	75,135	71,929
Depreciation and Rent	<u>150,903</u>	<u>150,903</u>
Total Expenses	\$1,490,359	\$1,487,153
Net Income	<u>\$2,226,695</u>	<u>\$2,229,901</u>
Utilization: Patient Days	6,570	6,570

Utilization for the first year is 100% Medicare, and 97% Medicare and 3% Commercial for the third year.

Expense and utilization assumptions are based on the historical experience of inpatients.

Capability and Feasibility

Project cost will be satisfied by accumulated funds from Upstate Medical University and a mortgage of \$2,504,512 from DASNY at 3% interest for 30 years. Presented as BFA Attachment A is the financial summary of Upstate Medical University showing sufficient funds available.

Working capital of \$247,859 based on two months of third year expenses will come from hospital operations. As shown on BFA Attachment A, the facility has sufficient assets to cover the working capital requirements.

The submitted incremental budget indicates a net income of \$2,226,695 and \$2,229,901 during the first and third years of operation, respectively. The budget appears reasonable.

As shown in BFA Attachment A, Certified Financial Summary for Upstate Medical University maintained positive net asset and working capital positions, and experienced an average net loss of \$12,330,045 for the period 2010-2011. The applicant indicates that the loss was caused by declining rates of government reimbursement for both inpatient

and outpatient services, and lack of appropriate funding for graduate medical education specific to teaching hospitals (over 300 residents annually).

The facility must also deal with fiscal requirements associated with being part of the SUNY system, with significant declines in overall state support, while fringe benefit costs for employees have grown exponentially.

In order to rectify these conditions, the applicant has implemented a number of initiatives intended to increase efficiencies and patient throughput, as well as decrease overall operating expenses. The facility has focused on expense management and revenue cycle improvements in their overall initiatives. They have also limited new hiring to essential personnel, and have placed restrictions on many non-personnel expenditures. The applicant is also actively pursuing additional state support to assist in the funding of escalating fringe benefit costs. The applicant indicates that implementation of this TCU project is a step towards increasing the facility's operational efficiencies.

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A

Financial Summary of Upstate Medical University 2010-2011



Public Health and Health Planning Council

Project # 122237-T
St. Joseph's Hospital

County: Chemung (Elmira)
Purpose: Demonstration

Program: Transitional Care Unit
Submitted: November 16, 2012

Executive Summary

Description

St. Joseph's Hospital, a 224-bed not-for-profit hospital located in Chemung County, requests approval to create a 26-bed Transitional Care Unit (TCU) designed to meet the needs of seriously ill, but medically stable patients who require continuous skilled nursing care, as well as rehabilitative and/or technological treatment and support. The TCU beds will be located on the 4A and 4B units of the hospital.

The applicant is a member of the Arnot Health, Inc. System (AHI), which consists of three acute care hospitals: Arnot Ogden Medical Center, Ira Davenport Memorial Hospital, St. Joseph's Hospital; and three residential health care facilities (RHCFS) at each respective hospital. The consolidation of these hospitals occurred in the fall of 2011.

Once the renovations are completed at St. Joseph's Hospital and the TCU is established, Arnot Health will implement the next step in its restructuring plan by decertifying the 40-bed RHCFS on the Arnot Ogden Medical Center campus through the closure of 26 RHCFS beds and transfer of the remaining 14 beds to the St. Joseph's campus. The creation of the TCU and decertification and transfer of RHCFS beds will result in the consolidation of all hospital-based long term care services at the St. Joseph's campus, consistent with Arnot Health's restructuring plan for all Elmira Hospitals.

On October 16, 2012, the Department of Health requested applications in accordance with the provisions of Section 2802-a, of the Public Health Law for a TCU Demonstration Program. There is currently no TCU in the service area.

Total project costs are estimated at \$4,984,253.

DOH Recommendation

Contingent approval.

Need Summary

Section 2802-a of the Public Health Law was amended by Chapter 58 of 2010, authorizing the Commissioner to approve an additional 13 general hospitals to operate TCUs on a demonstration basis.

Program Summary

The establishment of a TCU will help bring about more efficient delivery of care in the relevant service area by providing an alternative level of service to patients who no longer require acute inpatient care, but continue to need specialized medical, nursing and ancillary treatments prior to discharge. Patients admitted to the TCU will be expected to have a reduced overall length of stay as nursing, rehabilitative, and educational services are provided to the patient in preparation of discharge. The program will be coordinated with existing nursing homes in the area, including the AHI's system RHCFS's.

Financial Summary

Project costs will be met as follows: Equity of \$1,484,253 and HEAL 21 Grant Funds of \$3,500,000.

Incremental Budget:	<i>Revenues:</i>	\$ 3,355,644
	<i>Expenses:</i>	<u>2,439,295</u>
	<i>Gain/(Loss):</i>	\$ 916,349

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

The Finger Lakes HSA recommends approval of this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed HEAL 21 grant contract that is acceptable to the Department of Health. [BFA]

Council Action Date

February 7, 2013.

Need Analysis

Background

Section 2802-a of the Public Health Law was amended by Chapter 58 of 2010 authorizing the Commissioner to approve an additional 13 general hospitals to operate transitional care units (TCUs) on a demonstration basis. The original TCU enabling legislation of 2005 authorized five demonstration projects.

Transitional Care Unit Purpose

Section 2802-a of PHL defines "transitional care" as sub-acute care services provided to inpatients of a general hospital who no longer require acute care inpatient services, but continue to need specialized medical, nursing and other hospital ancillary services and are not yet ready for discharge. TCUs should be limited in length of stay and designed to meet and resolve patients' specific sub-acute medical care needs. Discharges from these units are to be timely and appropriate.

The improvement of quality outcomes for the TCU population through the provision of appropriate services, delivered in the most efficient manner, is the primary goal of the TCU demonstration program. Hospitals selected for this program are required to demonstrate an overall decrease in length of stay, quantify the clinical benefits of the program for TCU patients, and illustrate a synergistic relationship with long term care providers in the community. Collaboration between hospitals and nursing homes in local service areas will help bring about more efficient allocation of patients between the two settings.

In accordance with Section 2802-a of PHL, all providers in this demonstration program must meet all Conditions of Participation (CoP) for skilled nursing facilities (SNFs) as defined under Title XVIII of the Federal Social Security Act (Medicare). In order to qualify for Medicare certification, providers must comply with Part 415 of Title 10 of the New York Compilation of Codes, Rules and Regulations (10 NYCRR). In this demonstration, providers not currently licensed to operate nursing home beds will not be required to obtain Public Health and Health Planning Council establishment approval. Additionally, TCU units are not recognized as RHCf beds as defined in 10 NYCRR Section 709.3.

As part of this demonstration program, specific State SNF regulations that may impede the development of TCUs or their ability to provide appropriate services to patients may be subject to waiver, at the discretion of the Department. Such issues will be reviewed on an individual basis.

Applicants must demonstrate the need for any services proposed within the TCU and emphasize the benefits of such a program to a specific community, including, but not limited to, addressing the absence of sufficient post-discharge services in nursing homes and community-based care.

Transitional care units should be limited in length of stay and designed to meet and resolve specific sub-acute medical care needs. The average length of stay for patients served in a TCU ranges from 5 to 21 days, following a qualifying acute care stay. TCU services will be reimbursed at the applicable Medicare per diem SNF rate.

Transitional Care Unit Criteria and Requirements

Section 2802-a requires all providers applying to participate in this demonstration program to meet all applicable requirements as defined under Title XVIII of the Federal Social Security Act (Medicare). Additionally, Transitional Care Units must:

- Have a length of stay of not less than 5 days and not in excess of 21 days;
- Have a pre-opening survey, separate Medicare Number, and SNF certification;
- Be staffed by qualified staff dedicated to the TCU;
- Serve patients who will benefit from active rehabilitation. (It is expected that patients will actively participate in three hours or more of Occupational Therapy/Physical Therapy/Speech Therapy, every day, either three hours consecutively or in combination between rehabilitative sessions); and

- Collect information and submit reports to the Department on an annual basis to demonstrate an overall decrease in length of stay; quantify the clinical benefits of the program for TCU residents and illustrate a synergistic relationship with long term care providers.

Applications must address the configuration of the Transitional Care Unit. However, the applicant must adhere to the following requirements:

- Beds must be located at one geographic location; and
- Beds must be located contiguously within a distinct unit/space within the hospital.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

The principal elements of the proposed TCU program are:

- A 26-bed unit to provide services to post-acute patients in need of clinically complex skilled nursing services not generally provided in the community. These include, but are not limited to, CHF COPD, diabetes and post-surgical orthopedic cases in need of early intervention rehabilitation, wound management and nutritional services.
- Location in St Joseph's Hospital, Elmira, Chemung County, an area not currently served by a TCU, with the goal of expanding the continuum of care and reducing average hospital lengths of stay at this and surrounding area hospitals.
- Operation by a facility with dedicated staff with prompt access to specialist acute care professionals and related services.
- Single-bedded and double-bedded rooms with dining/activities/lounge space in an area to be renovated unit on an acute care floor. Therapy space is located on the unit.

The TCU will focus on patients that if not discharged to the TCU would otherwise, continue to be served in Med/Surg beds at this and other local hospitals. These patients will remain in the TCU for a short stay of not less than 5 and no more than 20 days. The target patient focus is on medically complex elderly patients, who, while clinically stable, still require on-going physician oversight and the specialized services of hospital staff.

The TCU will be under the direct responsibility of a full time licensed nursing home administrator operating within the Arnot Ogden systems LTC branch. In addition to the nursing home administrator the TCU will employ a fulltime Director of Nursing and fulltime physician/Medical Director. Employees will also include RNs, LPNs, Aides, Social Worker, Activities Director and Therapy staff.

The applicant will submit an annual progress report on TCU operations to the Department of Health.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Total Project Cost and Financing

Total project cost, which is for renovations and the acquisition of moveable equipment, is estimated at \$4,984,253, itemized below:

Renovation and Demolition	\$3,600,000
Asbestos Abatement or Removal	100,000
Design Contingency	360,000
Construction Contingency	360,000
Planning Consultant Fees	5,000
Architect/Engineering Fees	210,000
Other Fees (Consultant)	10,000
Moveable Equipment	300,000
Telecommunications	10,000
CON Fee	2,000
Additional Processing Fee	<u>27,253</u>
Total Project Cost	\$4,984,253

Project costs are based on a May 1, 2013 construction start date and a twelve month construction period.

The applicant's financing plan appears as follows:

Equity	\$1,484,253
HEAL 21 Grant	3,500,000

Operating Budget

The applicant has submitted an incremental operating budget, in 2013 dollars, for the first and third years, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,098,381	\$3,355,644
Expenses:		
Operating	\$1,560,020	\$2,241,095
Capital	<u>198,200</u>	<u>198,200</u>
Total Expenses	\$1,758,220	\$2,439,295
 Excess of Revenues over Expenses	 \$340,161	 \$916,349
 Utilization: (patient days)	 4,745	 7,592

Utilization for the TCU beds will be 100% Medicare.

Capability and Feasibility

The applicant will meet the total project cost via the following: HEAL 21 Grant of \$3,500,000 and Equity via operations of \$1,484,253. As a contingency of approval, the applicant must provide an executed HEAL 21 Grant contract that is acceptable to the Department of Health. The remainder, \$1,484,253, will be provided by Arnot Health, Inc. via operations. Presented as BFA Attachment, A is the September 30, 2012 internal financial statements of Arnot Health, Inc., which indicates the availability of sufficient funds for the equity contribution.

The submitted budget projects an excess of revenues over expenses of \$340,161 and \$916,349 during the first and third years, respectively. The Medicare revenues were based on current reimbursement methodologies for TCU

patients with St. Joseph's Hospital medically complex patients and excess days these patients spent in the hospital. The budget appears reasonable.

As shown on Attachment A, Arnot Health, Inc. had an average positive working capital position and an average positive net asset position for the period through September 30, 2012. Also, the entity incurred losses of operations of \$1,343,143 for the period through September 30, 2012.

The applicant has indicated that the reasons for the losses are the result of the following: system wide admissions were down 471 cases, or 3.7%, volumes are lower in the emergency room and radiation therapy and bad debts are up 16%.

The applicant has indicated that they implemented the following steps to improve operations: administrative services, including human resources, information technology and financial services have been consolidated, support services, including dietary, housekeeping and laundry services have been centralized, clinical services are being realigned, excess capacity is being eliminated, new services are being developed where community need is identified, and reduction of FTE's and reduced drug and supply expenses.

Presented as BFA Attachment B are the 2010 and 2011 certified financial statements of St. Joseph's Hospital. As shown on Attachment B, the hospital had an average positive working capital position and an average positive net asset position. Also, the hospital incurred an average loss of operations of \$3,427,560 from 2010 through 2011. The applicant has indicated that the reason for the losses are a result of the following: expenses rose by 10% with revenue growing by 7%; acquired a large physician practice in the fourth quarter of 2010, which dramatically increased bad debts, wages, fringe benefits and other expenses; inpatient volumes fell by almost 16% in 2011; behavioral science and physical rehab patient days declined by over 10% in 2011; the sole oncologist working at SJH campus left the community abruptly; ER volume declined by 10%; there were one-time expenses associated with standardizing accounting policies with those of AHI, and new physician contracts and union contracts drove up wages by almost 15%.

The applicant implemented the following steps to improve operations: consolidation of the physician practices affiliated with SJH by combining their operations and management in Arnot Medical Services under AHI; moved all infusion services to SJH campus; consolidated management personnel for all of AHI; invested in refurbishing and expanding rehabilitation services at SJH, supported by a HEAL NY 15 grant; began renegotiating single contracts with commercial payers; recruited physicians for rehab and behavioral science units; contracted for new clinical information system in order for SJH to qualify for the federal meaningful use requirements, and paid off bond debt and reduced other external debts of the organization, and support through a HEAL NY 19 grant.

Presented as BFA Attachment C, is the October 31, 2012 internal financial statements of St. Joseph's Health System and Subsidiaries. As shown on Attachment C, the hospital incurred loss from of operations of \$2,559,601 through October 31, 2012. The applicant has indicated that the reason for the losses were the result of continued erosion of market share. The applicant has indicated that they implemented the following steps to improve operations: submitted an application for TCU beds and they are planning for an aggressive contract negotiation in 2013 to allow staffing to better flex with patient demand.

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	September 30, 2012 internal financial statements of Arnot Health
BFA Attachment B	Financial Summary- 2010 and 2011 certified financial statements of St. Joseph's Hospital
BFA Attachment C	October 31, 2012 internal financial statements of St. Joseph's Hospital

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE
FACILITIES**

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Ambulatory Surgery Center – Construction

Exhibit #6

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122085 C	Gramercy Surgery Center, Inc. (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval



Public Health and Health Planning Council

Project # 122085-C
Gramercy Surgery Center, Inc.

County: Queens (Flushing)
Purpose: Construction

Program: Ambulatory Surgery Center
Submitted: August 14, 2012

Executive Summary

Description

Gramercy Surgery Center, Inc., a proprietary corporation that operates a multi-specialty freestanding ambulatory surgery center (ASC) at 380 Second Avenue, New York, is requesting approval to certify and construct an extension clinic to be located at 59-25 Kissena Boulevard, Flushing. The proposed ASC extension clinic will be known as Gramercy Surgery Center – Queens, and will lease approximately 11,050 square feet to accommodate three Class B procedure rooms, one Class C operating room, four pre-operating bays, and ten recovery bays, along with requisite support areas.

Gramercy Surgery Center, Inc. ownership is as follows: 91% by Katy Chiang, and 9% by her husband Tung Cheng.

No responses were received to the Department’s inquiry to local hospitals regarding the impact of the proposed ASC in the service area.

Total project costs are estimated at \$4,862,951.

DOH Recommendation
Contingent approval.

Need Summary

Gramercy Surgery Center – Queens will serve the facility’s patients that reside in Queens County but travel into New York County for ambulatory surgery care. From 2009 through 2011, the number of patients from Queens County who traveled to Gramercy Surgery Center’s New York County facility for care increased by 20 percent. The approval of this clinic will allow the facility to provide health care services

closer to home for its Queens patients, and in an area of Queens not served by other ASCs.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility’s current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

Total project costs will be met from \$492,951 in cash and a 10-year self-amortizing loan of \$4,370,000 from Country Bank at a 6.5% interest rate.

Incremental Budget:	<i>Revenues:</i>	\$ 5,071,626
	<i>Expenses:</i>	<u>4,125,029</u>
	<i>Gain/(Loss):</i>	946,597

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a plan and signed agreement, acceptable to the Department, to provide services to the Medicaid eligible population that supports the projected payor mix as indicated in the CON application. [RNR]
3. Submission of a project loan commitment that is acceptable to the Department of Health. [BFA]
4. Submission of a working capital loan commitment that is acceptable to the Department of Health. [BFA]
5. Submission of a executed building lease that is acceptable to the Department of Health. [BFA]
6. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

Approval conditional upon:

1. The submission of annual reports for a period of no less than five years, acceptable to the Department, demonstrating that actual utilization and payor mix experience is substantially consistent with that projected in the CON application with respect to Medicaid and charity care. [RNR]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by December 31, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Gramercy Surgery Center, Inc. (GSC) located at 380 Second Avenue, Manhattan, seeks CON approval to certify a multi-specialty ambulatory surgery center (ASC) extension clinic at 59-25 Kissena Flushing, 11355, in Queens County.

Analysis

Gramercy Surgery Center – Queens proposes to offer surgery in the following specialties:

Podiatry General Surgery Pain Management Urology

It is estimated that Gramercy Surgery Center – Queens will perform 1,500 and 2,000 surgeries during the first and third years of operation, respectively.

The anticipated hours of operation of the proposed site are 8 am to 6 pm Monday through Friday. The hours and days of operation may be modified to accommodate patient demand and convenience.

Gramercy Surgery Center, Inc. intends to provide a portion of its services to medically indigent patients and anticipates that at least 3 percent of its care will be charity care.

In 2009, Gramercy Surgery Center, Manhattan, performed 6,347 ambulatory surgery procedures. By 2011 these cases increased by 29.4 percent to 8,215. During the period, approximately 17 percent of these cases originated in Queens. In 2009, Gramercy Surgery Center had 1,093 cases from Queens County. By 2011, Queens County cases increased by 20 percent to 1,312.

Distribution of Ambulatory Surgery Cases by Patient County of Origin: Gramercy Surgery Center				
<i>County of Residence</i>	<i>2009</i>	<i>2010</i>	<i>2011</i>	<i>Percent Change 2009 vs. 2011</i>
New York	2,743	3,405	3,637	32.6
Queens	1,093	1,252	1,312	20.0
Total	6,347	7,494	8,215	29.4

Source: SPARCS 2009 – 2011.

Currently, there are six Ambulatory Surgery Centers in Queens County; none are located in the proposed service area of Gramercy Surgery Center – Queens. The type of ambulatory surgery service and the number of cases performed at the centers are listed below.

Distribution of Ambulatory Surgery Procedures at Existing Queens County Facilities		
<i>ASC Type</i>	<i>Name</i>	<i>2010</i>
Multi-Specialty	New York Surgery Center Queens, LLC	1,505
Single - Ophthalmology	The Mackool Eye Institute LLC	7,024
Multi-Specialty	Queens Surgi-Center	6,169
Multi-Specialty	Hillside Diagnostic and Treatment Center, LLC	2,863
Multi-Specialty	Choices Women's Medical Center Inc	9,231
Multi-Specialty	Physicians Choice Surgicenter	962
	<i>Total</i>	<u>27,754</u>

Source: SPARCS, 2010

Gramercy Surgery Center is committed to serving all persons in need of ambulatory surgery service without regard to race, sex, age, religion, creed, sexual orientation, source of payment, ability to pay, or other personal characteristics. The applicant understands that it must provide its fair share of charity care and proposes to do it.

Conclusion

Gramercy Surgery Center – Queens will serve the facility’s patients that reside in Queens County but travel into New York County for ambulatory surgery care. From 2009 through 2011, the number of patients from Queens County who traveled to GSC’s New York County facility for care increased by 20 percent. The approval of this clinic will allow the facility to provide health care services closer to home for its Queens patients, and in an area of Queens not served by other ASCs.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

Construct an extension clinic to operate as a multi-specialty ambulatory surgery center.

Proposed Operator	Gramercy Surgery Center, Inc.
Site Name	Gramercy Surgery Center - Queens
Site Address	59-25 Kissena Boulevard, Flushing
Surgical Specialties	Multi-Specialty including: Oncology Urology Podiatry Pain Management
Operating Rooms	1
Procedure Rooms	3
Hours of Operation	Five days per week from 8:00am to 6:00pm (Modified as necessary for patient needs).
Staffing (1st Year / 3rd Year)	13 FTEs / 18 FTEs
Medical Director(s)	Benjamin Chang-Hwa Peng
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Flushing Hospital Medical Center
On-call service	Access to the facility’s on-call physician during hours when the facility is closed.

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility’s enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Lease Rental Agreement

The applicant has submitted a draft lease for the proposed site, the terms of which are summarized below:

Premises: 11,050 gross square feet located at 59-25 Kissena Boulevard, Flushing, New York 11355

Landlord: Queens Kissena, LLC
Lessee: Gramercy Surgery Center, Inc.
Term: 10 years at \$360,000 (\$32.58 sq. ft.)
 Renewal option of one 5-year term plus a 3% increase each year after the tenth year.
Provisions: Utilities, Taxes, Maintenance and Insurance

The applicant has provided an affidavit stating that the lease is a non-arms length arrangement. Katy Chiang and her husband Tung Cheng are equal members of the landlord (Queens Kissena, LLC) and stockholders of the applicant (Gramercy Surgery Center, Inc.). Realtor letters have been provided attesting to the rental rate being of fair market value.

Total Project Costs and Financing

Total project cost for the renovation and acquisition of moveable equipment is estimated at \$4,862,951, broken down as follows:

Renovation & Demolition	\$2,156,310
Design Contingency	215,631
Construction Contingency	215,631
Architect/Engineering Fees	175,000
Other Fees	80,000
Movable Equipment	1,770,490
Telecommunications	221,300
CON Application Fee	2,000
CON Processing Fee	<u>26,589</u>
Total Project Cost	\$4,862,951

Project costs are based on a March 1, 2013 start date with a ten month construction period.

The applicant's financing plan appears as follows:

Cash Equity (Applicant)	\$492,951
Project Loan (10-year term, 6.50%)	<u>4,370,000</u>
Total	\$4,862,951

A letter of interest has been provided by Country Bank.

Operating Budget

The applicant has submitted the first and third years operating budgets, in 2012 dollars, as summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$3,806,317	\$5,071,626
Expenses:		
Operating	\$2,233,980	\$3,037,500
Capital	<u>1,139,451</u>	<u>1,087,529</u>
Total Expenses	\$3,373,431	\$4,125,029
Net Income or (Loss)	\$432,886	\$946,597
Utilization: (procedures)	1,500	2,000
Cost Per Procedure	\$2,248.95	\$2,062.51

Utilization by payor source for the first and third years is anticipated as follows:

Medicaid Fee-for-Service	3.4%
Medicaid Managed Care	11.0%
Medicare Fee-for-Service	29.7%
Commercial Manage Care	44.3%
Private Pay & Other	8.4%
Charity	3.2%

Utilization assumptions are based upon estimates from the proposed practicing physicians. The applicant estimates that 20% of budgeted procedures will be transfers from Gramercy Surgery Center's main site in Manhattan, and another 75% from other ASCs or office based practices. Expense assumptions are based on utilization projections in combination with the applicant's experience. The applicant has calculated the breakeven point to be 89% and 81% of budgeted procedures for the first and third years, respectively.

Capability and Feasibility

The total project cost of \$4,862,951 will be provided from \$492,951 in accumulated funds, with the balance of \$4,370,000 being financed through Country Bank at the above stated terms.

Working capital requirements are estimated at \$687,506, which appears reasonable based on two months of third year expenses. Half of the working capital or \$343,753 will be provide from accumulated funds, with the remaining \$343,753 being borrowed from Country Bank for five years at a 6.5% rate of interest. Presented as BFA Attachments A and B are 2010 and 2011 financial summaries and a net worth statement for the applicant's owners.

The major stockholder (Katy Chiang) has provided an affidavit stating that by December 31, 2012, she will repay Gramercy Surgical Center, Inc., \$1,200,000 of the \$2,760,850 she borrowed. Katy Chiang has attested she will repay the remaining note balance of \$1,560,850 by the end of 2013. The applicants' owners have provided an affidavit stating, if necessary, they will contribute additional personal funds to support this project. In light of the above, the applicant appears to have sufficient liquid assets to meet the requirements.

Gramercy Surgery Center-Queens projects an operating excess of \$432,886 and \$946,597 in the first and third years, respectively. Revenues are based on current federal and state governmental reimbursement methodologies, while commercial payers are based on current rate schedules. The budget appears reasonable.

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Financial summary for 2010 and 2011, Gramercy Surgery Center, Inc.
BFA Attachment B	Personal Net Worth Statement for the Stockholders of Gramercy Surgery Center, Inc.
BHFP Attachment	Map

Supplemental Information

Outreach

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant's response to DOH's request for information on the proposed facility's volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Facility: Forest Hills Hospital
102-01 66th Road
Forest Hills, New York 11375

No response.

Facility: Flushing Hospital Medical Center
4500 Parsons Boulevard
Flushing, New York 11355

No response.

Facility: Queens Hospital Center
82-68 164th Street
Jamaica, New York 11432

No response.

Facility: New York Hospital Medical Center
of Queens
56-45 Main Street
Flushing, New York 11355

No response.

Supplemental Information from Applicant

- Need and Sources of Cases

The applicant states that 20 percent of the procedures projected for the facility will be from cases that currently go to the applicant's main site in Manhattan. The remaining cases will come from the existing practices of the applicant physicians, both from office-based sites and from existing ASC's. The proposed ASC will address the needs of patients by reducing the current scheduling backlogs. It will also attract patients through its improved efficiencies and as a modern facility with up-to-date equipment. The applicant also states that the ASC will allow the provision of charity care and outreach programs not currently feasible through the participating physicians' private practices.

- Staff Recruitment and Retention

Measures to recruit and retain skilled staff and counter staff turnover will include attractive compensation and benefits packages, continuing education opportunities, recognition and appreciation programs to reward high performers, and an open work atmosphere that encourages staff involvement and continuous improvement.

- Office-Based Cases

The applicant states that approximately 80 percent of the cases projected for the ASC are now provided in either office-based settings or non-hospital affiliated ambulatory surgery settings. None of the projected cases are currently being performed in the ambulatory surgical programs of area hospitals.

OHSM Comment

There were no hospital comments submitted in opposition to this application. Therefore, the Department finds no reason to consider reversal or modification of the recommendation for contingent approval of the proposed ASC based on public need, financial feasibility and operator character and competence.

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE
FACILITIES**

CATEGORY 6: Applications for Individual Consideration/Discussion

Acute Care – Construction

Exhibit # 7

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	131015 C	Montefiore Medical Center – Henry and Lucy Moses Division (Bronx County)	To be presented at the Special Establishment/Project Review Committee on 2/7/13 No Recommendation



Public Health and Health Planning Council

Project # 131015-C Montefiore Medical Center – Henry & Lucy Moses Division

County: Bronx (Bronx)
Purpose: Construction

Program: Acute Care Services
Submitted: January 8, 2013

Executive Summary

Description

Montefiore Medical Center – Henry & Lucy Moses Division (Montefiore), a 767-bed not-for-profit hospital located at 111 East 210th Street, Bronx, requests approval to acquire the assets of New York Westchester Square Medical Center's (NYWSMC) real property, building, and certain equipment. NYWSMC, a 140-bed not-for-profit hospital located in Bronx County, is in Chapter 11 bankruptcy and Montefiore has been selected as the winning bidder at bankruptcy auction.

Montefiore will maintain the services currently provided at NYWSMC, with the exception of inpatient services. The applicant will not acquire the beds of the hospital; these beds will be decertified. As a result, there will be no change in total bed capacity for Montefiore Medical Center.

This site will be operated as a clinically-integrated hospital extension of Montefiore, to include a provider-based off-campus emergency department (ED). This site will be known as Montefiore Medical Center - Westchester Square Campus, and will be comprised of a full-time service provider-based off-campus ED, ambulatory surgery center, imaging services, and ambulatory programs, including primary care. The services provided will be all outpatient services. The purpose of the project is:

- To preserve the most vital of the health care services provided by New York Westchester Square Medical Center and create a more progressive, ambulatory care center that expands needed primary care in the community and manages the health of the community.
- To ensure the health care needs of the community are addressed in accordance with the Community Health Needs Assessment and the State Health Improvement Plan.

The purchase price and the total project cost is estimated at \$20,000,000.

DOH Recommendation

Because an off-site ED without inpatient beds is a new model of care in New York State, the Department recommends a five-year limited life approval for the proposed ED. During this period, the facility will be required to report operational and quality measures to the Department to aid in evaluation of this model of care.

Need Summary

In 2011, NYWSMC had 21,846 ED visits, 23% of which resulted in admission. NYWSMC's ambulatory surgery cases totaled 5,308 in 2010. Montefiore Medical Center's Weiler Division and its Moses Division are expected to absorb a portion of Westchester Square's former inpatient cases, which are expected to average between 25 patients per day at each division.

Program Summary

An off-campus ED is acceptable on the federal level as long as the facility meets the applicable conditions of participation. Montefiore has worked with the Centers for Medicare and Medicaid Services (CMS) and is aware of the requirements and provisions with which they must comply. The Department will also work with CMS to ensure that the program is in compliance with these standards.

Financial Summary

The purchase price and the total project cost totals will be met via HEAL 21 grant. The applicant submitted an incremental operating budget, in 2012 dollars, for the third year subsequent to the change in operator, which is summarized below.

Incremental Budget: (Year 3)	<i>Revenues:</i>	\$ 40,217,985
	<i>Expenses:</i>	39,271,019
	<i>Excess</i>	\$ 946,966

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval for a limited life of 5 years from the date of issuance of an operating certificate is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed HEAL 21 grant contract that is acceptable to the Department of Health. [BFA]
3. Submission of an original affidavit from the applicant, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. [BFA]

Approval conditional upon:

1. Compliance with 10 NYCRR 405.19 (Emergency Services), as well as additional Part 405 sections, including those for the governing body, quality assurance, and medical records. [HSP]
2. Compliance with applicable CMS Conditions of Participation (CoPs), including those for governing body, medical staff, nursing staff, laboratory services, quality assurance, medical records, infection control. [HSP]
3. Full integration of all operations with the Montefiore main site hospital. Medical staff of the freestanding ED should be part of the single medical staff of Montefiore. [HSP]
4. Compliance with all EMTALA obligations. [HSP]
5. Employment of a triage system of care, one linked to the community's primary care delivery system. [HSP]
6. Linkage of the ED to a primary care "medical home," with protocols for referral, enrollment and tracking. [HSP]
7. Use of a health information exchange (HIE) to enhance clinical decision-making by providing appropriately private and secure patient encounter history at the time and point of care, creating a platform for community-wide coordination of care. [HSP]
8. Establishment of agreements and protocols with the EMS community to provide transfer to the freestanding ED for appropriate patients. [HSP]
9. Establishment of an agreement with an ambulance company to provide timely transportation to the main site ED or closest hospital that meets the needs of the patient. [HSP]
10. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health to provide annual reports to the Department beginning in the second year of operation. These reports shall include:
 - Data showing utilization, including emergency and non-emergency cases;
 - Data showing number of transfers to hospitals and subsequent inpatient admissions from the ED;
 - Data showing number of referrals to primary care, including to the primary care health home;
 - Data on efforts in patient education regarding appropriate conditions for ED treatment;
 - Data showing a breakdown of visits by payor source; and
 - Data showing percentage of charity care provided. [HSP]

Council Action Date

February 7, 2013.

Need Analysis

Background

Montefiore Medical Center – Henry & Lucy Moses Division, a 767-bed acute care hospital located at 111 East 210th Street, Bronx, 10467, in Bronx County, seeks approval to certify New York Westchester Square Medical Center (NYWSMC) as a division of Montefiore Medical Center (Montefiore). The site will be known as Montefiore Medical Center – Westchester Square Campus and will be certified as an ambulatory extension site to include provider based off-campus emergency department services.

Freestanding Emergency Departments

Between 1990 and 2010, the number of hospital-based emergency departments (EDs) declined by 27 percent nationwide.¹ At the same time, there has been an increase in the use of the “freestanding” ED, i.e., one operated away from a main hospital site and run either by a sponsoring hospital or a non-hospital provider. Freestanding EDs originally emerged to serve rural areas, bringing emergency-level services to communities that could not support full-service hospitals. However, the growing volume of ED use nationwide has led to the establishment of freestanding EDs in urban and suburban areas, where they may serve not only to expand access to emergency services in particular service areas but to relieve ED overcrowding at main hospital sites as well.

In New York State, the Department to date has approved four hospitals that primarily function as EDs, in suburban Buffalo, Lake Placid, Manhattan and Sidney (Delaware County). Three of the four operate as divisions of their sponsoring hospitals. The fourth, in Sidney, operates as a hospital with four inpatient beds (the other sites each have two). As defined in PHL Section 2801(10), a “general hospital” is a facility

engaged in providing medical or medical and surgical services primarily to in-patients by or under the supervision of a physician on a twenty-four hour basis with provisions for admission or treatment of persons in need of emergency care. . . .

Adherence to this definition requires that the four ED-focused facilities operate inpatient beds. Accordingly, each maintains inpatient beds on site.

Although the need to promote efficiency and improve quality in health care demands the consideration of new approaches to service organization and delivery, such innovations must be fully evaluated for cost-effectiveness, efficacy and sustainability. Montefiore Medical Center proposes to operate a freestanding ED at the site of the former Westchester Square Medical Center, without inpatient beds. Because this arrangement would not meet the definition of a “general hospital” set forth in PHL Section 2801(10), it is to be operated as an extension site of Montefiore, certified to operate an emergency department.

Terms of Approval

As a new model of care, the proposed freestanding ED should be monitored for its potential to deliver emergency care in keeping with existing regulatory requirements. It should be further evaluated for its capacity to improve efficiency and control health care costs in a sustainable manner. In regard to the latter concern, the facility may be prone to overutilization for non-emergency services, especially since its freestanding location and absence of inpatient beds may cause the public to perceive it as an “urgent care” clinic – a type of provider not defined in regulation but one that typically offers a broad range of primary and non-emergency care and extended hours of operation. This could lead to overcrowding of the proposed ED and could perpetuate existing inefficiencies in the delivery of both emergency and non-emergency services within the Montefiore/Westchester Square service area.

In view of these concerns surrounding the operation of a new type of ED in accordance with regulatory requirements and its susceptibility to inappropriate utilization, the Department recommends that the proposed freestanding ED be

¹ Hsia, R. Y., Kellermann, A., and Shen, Y-C. Factors Associated with Closures of Emergency Departments in the United States. JAMA, May 18, 2011. Vol. 305, No. 19.

approved initially for a limited life of five years from the date of issuance of the operating certificate; and that it be operated subject to the following conditions:

- Compliance with 10 NYCRR 405.19 (Emergency Services), as well as additional Part 405 sections, including those for the governing body, quality assurance, and medical records;
- Compliance with applicable CMS Conditions of Participation (CoPs), including those for governing body, medical staff, nursing staff, laboratory services, quality assurance, medical records, infection control;
- Full integration of all operations with the Montefiore main site hospital. Medical staff of the freestanding ED should be part of the single medical staff of Montefiore;
- Compliance with all EMTALA obligations;
- Employment of a triage system of care, one linked to the community's primary care delivery system;
- Linkage of the ED to a primary care "health home," with protocols for referral, enrollment and tracking;
- Use of a health information exchange (HIE) to enhance clinical decision-making by providing appropriately private and secure patient encounter history at the time and point of care, creating a platform for community-wide coordination of care;
- Establishment of agreements and protocols with the EMS community to provide transfer to the freestanding ED for appropriate patients;
- Establishment of an agreement with an ambulance company to provide timely transportation to the main site ED or closest hospital that meets the needs of the patient; and
- Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health to provide annual reports to the Department beginning in the second year of operation. These reports shall include:
 - Data showing utilization, including emergency and non-emergency cases; ,
 - Data showing number of transfers to hospitals and subsequent inpatient admissions from the ED;
 - Data showing number of referrals to primary care, including to the primary care health home;
 - Data on efforts in patient education regarding appropriate conditions for ED treatment;
 - Data showing a breakdown of visits by payor source; and
 - Data showing percentage of charity care provided.

Analysis

Montefiore operates three acute care hospitals, a certified home health agency, a diagnostic and treatment center, a long term home health care program, and hospital extension clinic and school based health centers.

Montefiore will provide the following services at the Westchester Square Campus:

- Provider-based off-campus emergency department;
- Ambulatory Surgery;
- Imaging;
- Ambulatory Programs; and
- Primary Care

**Certified Services:
Montefiore Medical Center - Westchester Square Division 2475 St Raymond Avenue Bronx, 10461**

<i>Service</i>	<i>Requested Action</i>	<i>Services Upon Completion</i>
Ambulatory Surgery – Multi Specialty	Add	√
CT Scanner	Add	√
Emergency Department	Add	√
Health Fairs O/P	Add	√
Hyperbaric Chamber	Add	√
Lithotripsy	Add	√
Magnetic Resonance Imaging	Add	√
Medical Social Services	Add	√
Nuclear Medicine – Diagnostic	Add	√
Nutritional	Add	√
Podiatry	Add	√
Primary Medical Care O/P	Add	√
Radiology – Diagnostic	Add	√
Therapy – Physical	Add	√

The Emergency Department will provide services 24 hours a day, seven days a week. The facility will have two to four non-acute care holding beds for assessment and monitoring of patients. Other ambulatory services at the Westchester Square Campus will be provided Monday through Friday from 7:00 am to 7:00 pm.

Montefiore Medical Center hospitals have the following New York State designations:

Montefiore Medical Center - Jack D Weiler:
Regional Perinatal Center; and
Stroke Center.

Montefiore Medical Center - North Division:

Level 3 Perinatal Center.

Montefiore Medical Center - Henry & Lucy Moses:

AIDS Center; and
Stroke Center.

The inpatient utilization statistics for MMC's three (3) acute care hospitals are shown below:

Montefiore Hospitals: Inpatient Utilization by Major Service Category				
<i>Service</i>	<i>Discharges</i>	<i>Average Daily Census</i>	<i>Occupancy Based on Current Beds</i>	<i>Current Beds</i>
MMC - North (1168)				
Medical/Surgical	8,297	132	58.8	224
Subtotal	13,625	207	64.6	321
Healthy Newborns	2,318	16		
<i>Grand Total</i>	<i>15,943</i>	<i>224</i>		
MMC - Moses (1169)				
Medical/Surgical	37,748	616	98.6	625

Montefiore Hospitals: Inpatient Utilization by Major Service Category				
<i>Service</i>	<i>Discharges</i>	<i>Average Daily Census</i>	<i>Occupancy Based on Current Beds</i>	<i>Current Beds</i>
<i>Total</i>	44,768	720	93.9	767
MMC- Weiler (3058)				
Medical/Surgical	18,823	296	93.1	318
Subtotal	24,233	370	91.7	403
Healthy Newborns	3,344	24		
<i>Grand Total</i>	27,577	393		

Source: SPARCS 2011

New York Westchester Square Medical Center (NYWSMC) is 140-bed acute care hospital located in the Southeast section of Bronx County. Approximately 99.4 percent of the hospital's discharges are allocated to the major service category of medical/surgical. In 2009, the hospital recorded 6,812 total inpatient discharges. By 2011, these discharges declined by 15.0 percent, to 5,788. In 2009, NYWSMC's patients generated an average daily census of 127 patients. By 2011, the average daily census declined by 17.3 percent to 105. The related overall occupancy rate was 90.4 percent in 2009. This declined to 84.4 percent in 2010, and 75.2 percent in 2011.

New York Westchester Square Medical Center: Inpatient Utilization by Major Service Category				
<i>Service Category</i>	<i>2009</i>	<i>2010</i>	<i>2011</i>	<i>Current Beds</i>
Discharges				
Medical/Surgical	6,757	6,450	5,767	
Pediatric	0	0	1	
Obstetric	9	5	1	
General Psychiatric	18	3	4	
Chemical Dependency	28	22	15	
<i>Total</i>	6,812	6,480	5,788	
Average Daily Census				
Medical/Surgical	126	118	105	
Pediatric	0	0	0	
Obstetric	0	0	0	
General Psychiatric	0	0	0	
Chemical Dependency	0	0	0	
<i>Total</i>	127	118	105	
Occupancy Based on Current Beds				
Medical/Surgical	89.9	84.1	74.9	140
Pediatric	0.0	0.0	0.0	0
Obstetric	0.0	0.0	0.0	0
General Psychiatric	0.0	0.0	0.0	0
Chemical Dependency	0.0	0.0	0.0	0
<i>Total</i>	90.4	84.4	75.2	140

Source: SPARCS 2009 - 2011

New York Westchester Square Medical Center Service Area

Based on the NYWSMC's SPARCS inpatient discharges for the years 2007 through 2011, zip codes 10461, 10469, 10462, 10473, 10465, 10472, 10467, 10460, 10475, and 10459 define the NYWSMC medical/surgical service area. During the period, NYWSMC was the fourth hospital of choice for inpatient medical/surgical services by residents of

the service area. NYWSMC captured 9.1 percent of the market from the service area. The majority of the residents in the service area chose Montefiore Medical Center – Weiler, Montefiore Medical Center – Moses, and Jacobi Medical Center for their inpatient medical/surgical needs. These facilities captured, respectively, 21.3 percent, 20.4 percent and 12.0 percent of NYWSMC’s medical/surgical market area. Lincoln Medical & Mental Health Center, St Barnabas Hospital, and Montefiore Medical Center - North Division were also able to capture a sizeable amount of NYWSMC’s market, ranging from 4.1 percent to 5.9 percent.

Distribution of Major Service Category Medical/Surgical Discharges: Based on New York Westchester Square Medical Center’s Service Area			
<i>Hospital</i>	<i>PFI</i>	<i>Average Discharges</i>	<i>% Market</i>
Montefiore Med Center - Jack D Weiler Hosp of A Einstein College	3058	13,648	21.3
Montefiore Medical Center - Henry & Lucy Moses Div	1169	13,041	20.4
Jacobi Medical Center	1165	7,687	12.0
New York Westchester Square Medical Center	1185	5,854	9.1
Montefiore Medical Center - North Division	1168	3,803	5.9
St Barnabas Hospital	1176	2,943	4.6
Lincoln Medical & Mental Health Center	1172	2,617	4.1
Bronx-Lebanon Hospital Center - Concourse Division	1178	1,841	2.9
North Central Bronx Hospital	1186	1,500	2.3
Mount Sinai Hospital	1456	1,149	1.8
New York Presbyterian Hospital - Columbia Presbyterian Center	1464	1,085	1.7
New York Presbyterian Hospital - New York Weill Cornell Center	1458	887	1.4
Lenox Hill Hospital	1450	745	1.2
Lawrence Hospital Center	1122	527	0.8
Calvary Hospital Inc	1175	480	0.7
Other NYS	9999	6,190	9.7
Total		63,997	100.0

Source SPARCS, Average 2007 – 2011

New York Westchester Square Medical Center Emergency Department Utilization

SPARCS Emergency Department (ED) data for 2007 through 2011 show that New York Westchester Square Medical Center recorded an average of 21,763 total ED visits a year. Of these, approximately 28 percent were admitted into the hospital, the remaining 72 percent were treated and released.

New York Westchester Square Medical Center: Emergency Department Statistics		
<i>Year</i>	<i>Total</i>	<i>% Admitted</i>
2007	21,865	30.2
2008	21,337	32.6
2009	21,737	28.9
2010	22,028	26.5
2011	21,846	23.1

Source: SPARCS, 2007 - 2011

New York Westchester Square Medical Center Ambulatory Surgery Statistics

In 2006, NYWSMC recorded 7,182 ambulatory surgery procedures. By 2007, these procedures declined by 9.4 percent to 6,509. The downward trend in ambulatory surgery procedures performed at the hospital continued from 2008, 2009, and 2010, as there were 5,924, 5,710 and 5,308 procedures, respectively, in these years.

New York Westchester Square Medical Center: Ambulatory Surgery Statistics	
<i>Year</i>	<i>Ambulatory Surgery Procedures</i>
2006	7,182
2007	6,509
2008	5,924
2009	5,710
2010	5,308

Source: Institutional Cost Reports 2006 – 2010

Discussion

The closure of NYWSMC could result in the need to absorb an average of approximately 105 medical/surgical patients from the service area on any given day. Two of Montefiore's acute care hospitals are the providers of medical/surgical care in NYWSMC's service area. Montefiore is planning to implement solutions to address the projected increase in inpatient utilization.

If medical/surgical inpatient use from the service area continues to follow the same pattern, it is likely that the medical/surgical average daily censuses of Montefiore Medical Center - Weiler and Montefiore Medical Center - Moses could increase by up to 25 patients on any given day. The 2011 medical/surgical occupancy rates for Weiler and Moses are 8 and 14 percentage points above the desired planning medical/surgical optimum of 85 percent. Montefiore is aware of the impact that the closure of NYWSMC's inpatient beds will have on its current medical/surgical beds and has begun to implement plans to address the projected increase in the service area.

Jacobi Medical Center's medical/surgical average daily census could also increase by about 14 patients per day. In 2011 Jacobi's medical/surgical ADC was 189 patients. It is possible that Jacobi's medical/surgical ADC could increase to 203 patients on any given day, for a projected occupancy rate of 83.9 percent, just under the desired planning optimum.

Conclusion

Montefiore has an established history of providing programs and services to address the health care needs of the residents in its service area. By acquiring the assets of New York Westchester Square Medical and creating an ambulatory division at the site, MMC will ensure that the residents of NYWSMC's service area will continue to receive the health care services that they need.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

Montefiore Medical Center is in the process of acquiring the assets, including the real property, of New York Westchester Square Medical Center. Upon the acquisition, Westchester Square will close. Montefiore is requesting to certify an extension site to include the State's first off-campus emergency department, ambulatory surgery facilities, imaging services, and other outpatient clinical services. It will not include any inpatient beds or services. The site will be known as Montefiore Medical Center - Westchester Square Campus.

The proposal includes some immediate construction/renovations including fire alarm upgrades, roof replacements, boiler replacements and miscellaneous minor facility upgrades. It also includes a large informational technology investment to make the location part of the Montefiore IT system, including software and the networking infrastructure. Future certificate of need proposals are anticipated upon further evaluations due to the age of the facility and on-going assessments regarding the need for primary and specialty care in the community.

Programmatic Considerations and Compliance with Applicable Codes, Rules and Regulations
Montefiore is an academic medical center and a pioneer accountable care organization and lead health home. Montefiore will fully incorporate the Westchester Square patients and the Westchester Square campus into its operations and its integrated health care delivery system. There will be one electronic medical record system, full clinical integration, integrated medical staff and integrated quality assurance. Montefiore will contingently appoint Westchester Square medical staff, not currently on the Montefiore medical staff and having requested appointment, based on satisfaction of primary source verification as outlined in their credentialing proposal and accepted by the Department. Contingent appointment will be in effect until the complete credentialing files are approved under state, federal and Montefiore requirements. The full service emergency department (ED) will operate 24 hours per day, each day of the year. Montefiore and the Department will work with the Fire Department of New York to ensure only basic life support (BLS) ambulance transports are brought to the site. Additionally, Montefiore will provide the timely transport of patients who present to the ED at this site, but are in need of admission or a higher level of care.

Because an off-site emergency department without inpatient beds is a new model of care in New York State, the Department recommends a five-year limited life approval for the proposed ED. During this period, the facility will be required to report operational and quality measures to the Department to aid in the evaluation of this model of care.

An off-campus emergency department is acceptable on the federal level as long as the facility meets the applicable conditions of participation. Montefiore has worked with the Centers for Medicare and Medicaid Services (CMS) and is aware of the requirements and provisions with which they must comply. The Department will also work with CMS to ensure the program is in compliance with such standards.

Conclusion

Based on the results of this review, a favorable recommendation can be made for the proposal.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Asset Purchase Agreement

The applicant has submitted an executed asset purchase agreement for the purchase of New York Westchester Square Medical Center, the terms of which is summarized below:

<i>Date:</i>	December 5, 2012
<i>Seller:</i>	New York Westchester Square Medical Center
<i>Purchaser:</i>	Montefiore Medical Center
<i>Assets Acquired:</i>	All rights, title and interest of the Seller in and to each Owned Property and under each purchased real property lease; all plans and surveys, including without limitation, those related to utilities, easements and roads, "as built" plans, engineer drawings and architectural renderings and similar items owned by Seller; all insurance proceeds and insurance proceeds receivable arising from any claim made under the Seller's insurance policies relating directly to the Purchased Assets and arising during the period prior to the Closing; all rights of the Seller under or pursuant to all warranties, representations and guarantees made by suppliers, manufacturers and contractors to the extent relating to services provided to the Seller after the Closing or to the extent affecting any Purchased Assets; all goodwill and other intangible assets owned by the Seller and associated with the Business, including customer and supplies lists and the goodwill associated with the Purchased Intellectual Property; any rights, claims or causes of action of the Seller against third parties relating to the Purchased Assets; prepaid deposits related to Purchased Assets of any purchased real property leases and Seller's furniture, equipment and inventory, identified to be acquired by the Purchaser.
<i>Excluded Assets:</i>	All cash, cash equivalents, bank deposits or similar cash items of the Seller regardless of whether on hand or in banks or other financial institutions, all

securities, all security entitlements, security accounts, commodity contracts and commodity accounts, all cash retainers held by any professional retained by the Bankruptcy Court and all cash rendered as part of the Purchase Price; all Pre-Closing, Accounts Receivable, as of the Closing Date of the contemplated transactions, and all bank accounts and lock boxes of the Seller into which deposits for Pre-Closing Accounts Receivable and other rights of payment for goods and services and made; all rights and claims under the Executed Contracts; any rights to refunds, settlements and retroactive adjustments, to the extent applicable in whole or in part to periods ending on or before the Closing Date arising in connection with the Seller's Medicare and Medicaid provider numbers and related participation agreements or any other third party healthcare payor program; all other Seller's deposits or prepaid charges and expenses or pre-paid deposits; the Seller's Medicare and Medicaid provider numbers and related provider agreements used in the Business and any use of the name "New York Westchester Square Medical Center" or any service marks, trademarks, trade names, identifying symbols, logos, emblems or signs.

Assumption of Liabilities:

At the Closing, Purchaser shall assume, effective as of the Closing, certain liabilities, including certain amounts accrued on behalf of the Seller's employees in an amount not to exceed \$3,000,000, which amount shall be deducted from the Base Price. The assumed liabilities shall include: Liabilities of Seller under each assigned contract and purchased real property leases arising from and after the Closing Date and the aggregate Amounts required to be paid pursuant to Section 365 of the Bankruptcy Code and the value of the accrued paid time off in hours assumed by Purchaser for each of Seller's Eligible 1199 Employees or other former employees of Seller.

Purchase Price:

The consideration for the Purchased Assets shall be in an amount of cash equal to \$15,300,000 less the aggregate amount of the Assumed Liabilities increased in an amount not to exceed \$3,000,000.

Payment of

Purchase Price: Cash at Closing.

The applicant shall submit an affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. There presently are no known liabilities.

Total Project Cost and Financing

Total project cost, which is for land acquisition, building acquisition, and equipment acquisition, is estimated at \$20,000,000, itemized as follows:

Land Acquisition	\$1,140,995
Building Acquisition	14,159,005
Renovation and Demolition	838,000
Architect/Engineering Fees	67,040
Other Fees (Consultant)	332,960
Moveable Equipment	500,613
Telecommunications	2,850,000
CON Fee	2,000
Additional Processing Fee	<u>109,387</u>
Total Project Cost	\$20,000,000

Project costs are based on an April 1, 2013 construction start date and a one month construction period.

The applicant's financing plan appears as follows:

HEAL 21 Grant \$20,000,000

Operating Budget for Montefiore Medical Center

The applicant has submitted an operating budget, in 2012 dollars, for the first year subsequent to the change in operator, which is summarized below:

Incremental Revenues	\$40,217,985
Incremental Expenses:	
Operating	\$37,965,742
Capital	<u>2,307,275</u>
Total Incremental Expenses	\$40,273,017
Excess of Revenues over Expenses	\$(55,032)

The applicant has indicated that the projected incremental net income in year 3 will be \$946,966.

The applicant has submitted an operating budget for the combined operations for the first year of operation, summarized below:

Revenues:	
Operating Revenues	\$2,836,005,708
Grants	72,656,000
Other	<u>107,198,000</u>
Total Revenues	\$3,015,859,708
Expenses:	
Operating	\$2,945,014,742
Capital	<u>2,305,277</u>
Total Expenses	\$2,947,320,019
Excess of Revenues over Expenses	\$68,539,689
Utilization:	
Inpatient: (Discharges)	84,753
Outpatient: (Visits)	1,727,162

Grants and other revenues are projected to remain constant from 2011 levels.

Utilization for the combined Montefiore operations by payor source for inpatient services is as follows:

	<u>Historical</u>	<u>Year One</u>
Medicaid Fee-for-Service	14.60%	14.53%
Medicaid Managed Care	24.63%	24.48%
Medicare Fee-for-Service	21.05%	21.18%
Medicare Managed Care	17.29%	17.42%
Commercial Fee-for-Service	11.65%	11.62%
Commercial Managed Care	8.71%	8.70%
Charity Care	1.61%	1.60%
Other	.46%	.47%

Utilization for the combined Montefiore operations by payor source for outpatient services is as follows:

	<u>Historical</u>	<u>Year One</u>
Medicaid Fee-for-Service	10.51%	10.42%
Medicaid Managed Care	32.80%	32.59%
Medicare Fee-for-Service	9.98%	10.10%
Medicare Managed Care	11.38%	11.36%
Commercial Fee-for-Service	15.16%	15.25%
Commercial Managed Care	13.18%	13.29%
Charity Care	0.00%	.08%
Private Pay	6.39%	6.28%
Other	.60%	.63%

Expense assumptions are based on the historical experience of Montefiore Medical Center. The applicant assumed that all of the historical ambulatory surgery, referred ambulatory activity, and 90% of the emergency department activity would remain on site, operated by Montefiore. Of Westchester Square's over 5,000 inpatient admissions, it was assumed that 1,000 would migrate to Montefiore when inpatient services at Westchester Square were closed.

Capability and Feasibility

The purchase price and the total project cost totals \$20,000,000 and will be met via HEAL 21 grant funds. The applicant must submit an executed HEAL 21 grant contract that is acceptable to the Department of Health.

Working capital requirements are estimated at \$6,711,836, which appears reasonable based on two months of first year incremental expenses. The applicant will meet the working capital requirement via hospital operations. Presented as BFA Attachment A are the 2010 and 2011 certified financial statements of Montefiore Medical Center, which indicates the availability of sufficient funds to meet the working capital requirement.

The submitted budget indicates an excess of revenues over expenses of \$68,539,689 during the first year for the combined operations. Revenues are based on current reimbursement methodologies.

As shown on Attachment A, the hospital had an average positive working capital position and an average positive net asset position during the period 2010 through 2011. Also, the hospital achieved an average operating excess of revenues over expenses of \$73,961,000 during the period 2010 through 2011.

Presented as BFA Attachment B are the September 30, 2012 internal financial statements of Montefiore Medical Center. As shown on Attachment B, the hospital had a positive working capital position and a positive net asset position during the period through September 30, 2012. Also, the hospital achieved an operating excess of revenues over expenses of \$74,137,000 during the period through September 30, 2012.

Presented as BFA Attachment C are the 2010 and 2011 certified financial statements of New York Westchester Square Medical Center. As shown on Attachment C, the hospital had an average negative working capital position and an average negative net asset position during the period 2010 through 2011. Also, the hospital incurred an average operating loss of \$1,900,500 during the period 2010 through 2011.

Presented as BFA Attachment D are the September 30, 2012 and the October 31, 2012 internal financial statements of New York Westchester Square Medical Center. As shown, the hospital had a negative working capital position and a negative net asset position from these periods. Also, the hospital incurred an operating loss of \$3,648,609 through October 31, 2012.

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner; approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	2010 and 2011 certified financial statements of Montefiore Medical Center
BFA Attachment B	September 30, 2012 internal financial statements of Montefiore Medical Center
BFA Attachment C	2010 and 2011 certified financial statements of New York Westchester Square Medical Center.
BFA Attachment D	September 30, 2012 and October 31, 2012 internal financial statements of New York Square Westchester Medical Center

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION
OF HEALTH CARE FACILITIES**

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals,
Abstentions/Interests

CON Applications

Ambulatory Surgery Centers – Establish/Construct

Exhibit #8

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121395 B	Havemeyer ASC, LLC d/b/a Havemeyer Ambulatory Surgery Center (Kings County)	Contingent Approval
2.	122016 B	Omnicare Multi-Specialty Center, LLC (Kings County)	Contingent Approval

Dialysis Services – Establish/Construct

Exhibit #9

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122066 E	Hauppauge Dialysis Center, LLC (Suffolk County)	Contingent Approval
2.	122067 E	Watertown Dialysis Center, LLC (Jefferson County)	Contingent Approval
3.	122175 E	Avantus Renal Therapy New York, LLC (New York County)	Contingent Approval
4.	122242 E	LSL Newburgh, LLC d/b/a Liberty Hudson Valley Dialysis (Orange County)	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #10

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 121099 E	Parkview Care and Rehabilitation Center, Inc. d/b/a Parkview Care and Rehabilitation Center (Nassau County)	Approval

Certified Home Health Agencies – Establish/Construct

Exhibit #11

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1. 122078 E	Litson Certified Care, Inc. d/b/a Willcare (Greene County)	Contingent Approval
2. 122165 E	Hudson Valley Home Care (Dutchess County)	Contingent Approval

Amended and Restated Certificate of Incorporation

Exhibit #12

<u>Applicant</u>	<u>E.P.R.C. Recommendation</u>
1. JTM Health Facilities Foundation, Inc.	Approval

HOME HEALTH AGENCY LICENSURES

Exhibit #13

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
2076-L	Ideal Care SP, LLC (Ulster, Dutchess, Orange, Sullivan and Greene Counties)	Contingent Approval
2153-L	Garden Homecare, LLC (Erie County)	Contingent Approval



Public Health and Health Planning Council

Project # 121395-B

Havemeyer ASC, LLC d/b/a Havemeyer Ambulatory Surgery Center

County: Kings (Brooklyn)

Program: Ambulatory Surgery Center

Purpose: Establishment and Construction

Submitted: May 21, 2012

Executive Summary

Description

Havemeyer ASC, LLC, a to-be-formed proprietary limited liability company, requests approval for the establishment and construction of a multi-specialty ambulatory surgery center to serve the residents of Kings County. The Center will provide general surgical services, and will lease space located at 168 Havemeyer Street, Brooklyn, and will be known as Havemeyer Ambulatory Surgery Center.

The proposed sole member of Havemeyer ASC, LLC, is Harout Nalbandian, MD (100%).

No responses were received to the Department's inquiry to local hospitals regarding the impact of the proposed ASC in the service area.

Total project costs are estimated at \$3,574,915.

DOH Recommendation

Contingent approval, with an expiration of the operating certificate five years from the date of its issuance, should the operator not comply with the conditions of approval granted this CON.

Need Summary

Havemeyer Ambulatory Surgery Center projects 7,700 visits in the first year of operation and 9,317 by year three. It will serve the Greenpoint neighborhood in Brooklyn and will have two operating rooms. The proposed location is in a Health Professional Shortage Area (HPSA) for primary care services and has a Medically Underserved Area/Population (MUA/MUP) designation.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Total project costs will be met with equity of \$357,491 and a bank loan of \$3,217,424 (15 yrs. @ 7.00%).

Budget:	<i>Revenues:</i>	\$ 3,388,758
	<i>Expenses:</i>	<u>2,851,807</u>
	<i>Gain/(Loss):</i>	\$ 536,951

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department to provide annual reports to the DOH beginning in the second year of operation. Reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who need follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided, and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission to the Department by the governing body of the ambulatory surgery center an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center. This shall include identification of underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community. This shall also include the provision that services will be provided to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed affiliation agreement between Havemeyer ASC, LLC, Wyckoff Heights Medical Center, and Brooklyn Hospital Center that is acceptable to the Department. [BFA]
6. Submission of a loan commitment that is acceptable to the Department. [BFA]
7. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

Approval conditional upon

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by July 1, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Havemeyer ASC, LLC d/b/a Havemeyer Ambulatory Surgery Center seeks to establish and construct a freestanding multi-specialty ambulatory surgery center at 168 Havemeyer Street, Brooklyn, NY 11211, in Kings County.

Analysis

The primary service area will be the Greenpoint neighborhood in Brooklyn.

There are eight (8) freestanding ambulatory surgery centers in Kings County as follows:

- 1 - Orthopedic
- 2 - Ophthalmology
- 2- Gastroenterology
- 3- Endoscopy

Kings County also has five (5) multi-specialty freestanding ambulatory surgery centers (*Source: HFIS*).

As noted, the proposed location is in a Health Professional Shortage Area (HPSA) for primary care services and has a Medically Underserved Area/Population (MUA/MUP) designation. The number of ambulatory surgery patients in Kings County increased by 9 percent from 2008 to 2009 and by 2 percent from 2009 to 2010 (*Source: SPARCS, 2008-10*). The proposed ASC will operate Monday-Friday, 7:00 a.m.-6:00 p.m., or as needed.

The applicant has provided a statement that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with consultation of the legal counsel. This statement is acceptable to the Department.

Conclusion

Based on the growth in ambulatory surgery patients in Kings County and the HPSA designations in the service area, from a need perspective, contingent approval is recommended.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Background

Establish a diagnostic and treatment center that will also be federally certified as an ambulatory surgery center.

Proposed Operator	Havemeyer ASC, LLC
Doing Business As	Havemeyer Ambulatory Surgery Center
Site Address	168 Havemeyer Street, Brooklyn
Surgical Specialties	Multi-Specialty including: General Surgery Obstetrics & Gynecology Pain Management Ophthalmology Urology Orthopedic Periodontal
Operating Rooms	2
Procedure Rooms	0

Hours of Operation	Monday through Friday from 7:00 am to 6:00 pm (Extended as necessary).
Staffing (1 st Year / 3 rd Year)	20 FTEs / 31 FTEs
Medical Director(s)	Harout Nalbandian
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Wyckoff Heights Medical Center 3.0 miles and 10 minutes away
On-call service	Access to the facility's on-call service during hours when the facility is closed.

Character and Competence

The sole member of the LLC is Harout Nalbandian, MD, a physician currently in private practice.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Integration with Community Resources

The center anticipates the transfer and affiliation agreement will include a provision for referring patients who present themselves to the center in need of primary care services. Additionally, there is a primary care private practice located in the same building. The center will participate in community health events and local religious institutions to help ensure the community is aware of their services.

The applicant intends to utilize an Electronic Medical Record System and is in the process of evaluating different programs. Additionally, the applicant has a desire to integrate in the local Regional Health information Organization or Exchange.

Compliance with Applicable Codes, Rules and Regulations

The medical staff will ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements.

Recommendation

From a programmatic perspective, contingent approval is recommended.

<h2>Financial Analysis</h2>

Lease Rental Agreement

The applicant has submitted an executed lease rental agreement for the site to be occupied. The terms of which are summarized below:

- Premises:* 3,300 square feet located at 168 Havemeyer St., Brooklyn, NY 11211
- Lessor:* Havemeyer Realty, LLC
- Lessee:* Havemeyer ASC, LLC
- Rental:* \$180,000 annually (\$54.54 per sq. ft.) (rent will increase 3% per year over the term)
- Term:* 10 years
- Provisions:* Lessor is providing necessary repairs and maintenance, heating/air conditioning, and utilities.

The applicant has provided two letters indicating the rent reasonableness. The applicant has indicated that the lease agreement will be a non-arms length lease agreement.

Total Project Cost and Financing

Total project cost, which is for construction and the acquisition of moveable equipment, is estimated at \$3,574,915 further itemized as follows:

Renovation & Demolition	\$2,275,639
Design Contingency	227,564
Construction Contingency	227,564
Planning Consultant Fees	25,000
Architect/Engineering Fees	182,051
Other Fees	125,000
Moveable Equipment	239,057
Telecommunications	37,100
Financing Cost	153,141
Interim Interest Expense	61,256
CON Fee	2,000
Additional Processing Fee	<u>19,544</u>
Total Project Cost	\$3,574,915

Project costs are based on a January 2014 construction start date and six month construction period. The applicant's financing plan appears as follows:

Equity	\$357,491
Loan to Havemeyer ASC, LLC (Term 15 years at 7.00%)*	\$3,217,424
<i>*A letter of interest has been submitted from a financial institution for a loan indicating the stated amount above.</i>	

Operating Budget

The applicant has submitted an operating budget, in 2012 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,796,254	\$3,388,758
Expenses:		
Operating	\$1,810,865	\$2,203,611
Capital	<u>638,196</u>	<u>648,196</u>
Total Expenses	\$2,449,061	\$2,851,807
Net Income	\$347,193	\$536,951
Utilization: (Procedures)	3,343	4,045
Cost Per Procedure	\$732.59	\$705.02

Utilization by payor source for the first and third years is as follows:

	<u>Years One and Three</u>
Commercial Fee-for-Service	21%
Commercial Managed Care	21%
Medicare Fee-for-Service	39%
Medicaid Fee-for-Service	5%
Medicaid Managed Care	9%
Self Pay	3%
Charity Care	2%

Expense and utilization assumptions are based on the current physician's experience and participating surgeons and their estimate of the cases they would bring to the Center. Expense assumptions are based on the experience of the participating physicians, as well as the projections and experience of other freestanding ambulatory surgery centers in New York State.

Capability and Feasibility

The total project cost of \$3,574,915 will be met via equity of \$357,491 and a bank loan of \$ 3,217,424 at an interest rate of 7% for a term of 15 years. A letter of interest from the lending institution has been submitted. Also, as presented on BFA Attachment A, is the personal net worth statement for the sole member receiving membership interest indicating sufficient equity as a result of this application.

Working capital requirements, estimated at \$475,302 appear reasonable based on two months' of third year expenses. The proposed member will provide \$237,651 in equity to meet the working capital requirement as presented in BFA Attachment A, personal net worth statement indicating sufficient funds. Also, Havemeyer ASC, LLC, will provide the residual \$237,651 via a working capital loan with a term of 15 years at 7% for which a letter of interest has been submitted from the financial institution.

Presented as BFA Attachment B, is the pro-forma balance sheet of Havemeyer ASC, LLC, which indicates a positive shareholders' equity position of \$595,142 as of the first day of operation.

The submitted budget projects a net income of \$347,193 and \$536,951 during the first and third years of operation, respectively. Revenues are based on current reimbursement methodologies for ambulatory surgery services. The budget appears reasonable.

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Personal Net Worth Statement- Havemeyer ASC, LLC
BFA Attachment B	Pro-forma Balance Sheet- Havemeyer ASC, LLC
BHFP Attachment	Map

Supplemental Information

Outreach

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant's response to DOH's request for information on the proposed facility's volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Facility: Wyckoff Heights Medical Center
374 Stockholm Street
Brooklyn, New York 11237

No response.

Facility: Brooklyn Hospital Center – Downtown Campus
121 DeKalb Avenue
Brooklyn, New York 11201

No response.

Facility: Interfaith Medical Center
1545 Atlantic Avenue
Brooklyn, New York 11213

No response.

Facility: Woodhull Medical and Mental Health Center
760 Broadway
Brooklyn, New York 11206

No response.

Supplemental Information from Applicant

- Need and Sources of Cases

The applicant states that the projected volume of cases for the proposed ASC is based on the actual experience of the physicians who have expressed an interest in performing procedures at the facility. The applicant also states that patients will use the proposed ASC because of its convenience in scheduling and the fact that it will be located in an out-of-hospital setting.

- Staff Recruitment and Retention

The applicant plans to recruit the necessary staff through a hiring program and also states that individuals have already expressed interest in applying for positions in the ASC. To the extent that additional staff is needed, the operators are committed not to actively seek to attract staff from local hospitals. The applicant expects to retain staff through salaries, benefits and continuing education opportunities that are comparable to or better than the region's standards. The ASC will also offer flexible work schedules and focused hours of operation, with periodic long weekends or extra days off for exceptional performance.

- Office-Based Cases

The applicant states that approximately 15 percent of the procedures projected for the proposed ASC are currently performed in an office-based setting.

OHSM Comment

There were no hospital comments submitted in opposition to this application. Therefore, the Department finds no reason to consider reversal or modification of the recommendation for five-year limited life approval of the proposed ASC based on public need, financial feasibility and operator character and competence.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a freestanding multi-specialty ambulatory surgery center to be located at 168 Havemeyer Street, Brooklyn, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

121395 B

FACILITY/APPLICANT:

Havemeyer ASC, LLC d/b/a Havemeyer
Ambulatory Surgery Center

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department to provide annual reports to the DOH beginning in the second year of operation. Reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who need follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided, and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission to the Department by the governing body of the ambulatory surgery center an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center. This shall include identification of underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community. This shall also include the provision that services will be provided to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed affiliation agreement between Havemeyer ASC, LLC, Wyckoff Heights Medical Center, and Brooklyn Hospital Center that is acceptable to the Department. [BFA]
6. Submission of a loan commitment that is acceptable to the Department. [BFA]
7. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

APPROVAL CONDITIONAL UPON:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]

5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by July 1, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122016-B Omnicare Multi-Specialty Center, LLC

County: Kings (Brooklyn)
Purpose: Establishment and Construction

Program: Ambulatory Surgery Center
Submitted: July 10, 2012

Executive Summary

Description

Omnicare Multi-Specialty Center, LLC, an existing limited liability company, requests approval to establish and construct a multi-specialty freestanding ambulatory surgery center (ASC) and diagnostic and treatment center (D&TC). The center will be located on two floors in leased space at 763-765 Norstrand Avenue, Brooklyn. The new surgery center will include one operating room and one endoscopy procedure room, a Pre-Op and Recovery area with seven bays total accommodating the current and future needs of the community. New York Methodist Hospital will serve as the backup hospital.

The proposed ambulatory surgery procedures to be provided are as follows: Gastroenterology, Obstetrics/Gynecology, Orthopedics, Otolaryngology and Urology. The proposed D&TC services to be provided are as follows: Health Fairs, Medical Social Services/OP, Nutritional O/P, Ophthalmology, Pediatrics, Physical Medicine and Rehabilitation/ O/P, Podiatry O/P, Prenatal, Primary Medical Care O/P, Psychology O/P, Physical Therapy O/P and Radiology Diagnostic O/P.

The proposed members of Omnicare Multi-Specialty Center, LLC consist of 2 individual physicians and one individual non-physician member. Their proposed membership interest is as shown below:

Proposed Members	Interest
Evans Crevecoeur, MD	45.00%
Jean Lionnel Vaval, MD	45.00%
Omnicare Health Care Mgmt, LLC	10.00%
-- Igor Flikshteyn (20%)	
-- Evans Crevecoeur (40%)	
-- Jean Lionnel Vaval (40%)	

The facility will enter into a consulting and administrative services agreement with Omnicare Healthcare Management, LLC to provide management services to the Omnicare Multi-Specialty Center, LLC. The members are the same as Omnicare Healthcare Management, LLC.

In response to the Department's inquiry to local hospitals regarding the impact of the proposed ASC in the service area, objections were received from Kings County Hospital Center and University Hospital of Brooklyn. The Department does not find the comments submitted sufficient to warrant reversal or modification of the recommendation for five-year limited life approval.

Total project costs are estimated at \$1,657,460.

DOH Recommendation

Contingent approval, with an expiration of the operating certificate five years from the date of its issuance should the operator not comply with the conditions of approval granted this CON.

Need Summary

Omnicare Multi-Specialty Center, LLC proposes to provide multi-specialty ambulatory surgery services for the Central Brooklyn neighborhood. The location of the proposed ASC is in a HRSA-designated Medically Underserved Area/Population (MUA/P).

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Project costs will be met with \$333,460 in cash and a \$1,324,000 bank loan.

Budget:	<i>Revenues:</i>	\$ 2,663,821
	<i>Expenses:</i>	<u>2,386,428</u>
	<i>Gain/(Loss):</i>	\$ 277,393

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - a) Data showing actual utilization including procedures;
 - b) Data showing breakdown of visits by payor source;
 - c) Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - d) Data showing number of emergency transfers to a hospital;
 - e) Data showing percentage of charity care provided; and
 - f) Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
6. Submission of an executed assignment and assumption for the building lease that is acceptable to the Department of Health. [BFA]
7. Submission of a loan commitment for project costs acceptable to the Department of Health. [BFA]
8. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
9. Submission of site control that is acceptable to the Department. [CSL]
10. Submission of a signed statement regarding anti-kickback and self-referral that is acceptable to the Department. [CSL]
11. Submission of a Services Agreement that is acceptable to the Department. [CSL]
12. Submission of a Certificate of Amendment of the Articles of Organization that is acceptable to the Department. [CSL]
13. Submission of an Operating Agreement that is acceptable to the Department. [CSL]

Approval conditional upon:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by January 1, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Omnicare Multi-Specialty Center, LLC is seeking approval for the establishment and construction of an Article 28 diagnostic and treatment center to provide multi-specialty ambulatory surgery services. The proposed freestanding multi-specialty ambulatory surgery center will be located at 765 Nostrand Avenue, Brooklyn, 11216, in Kings County.

It is projected that there will be 4,400 surgical procedures in year one and 5,324 surgical procedures in year three. The projections are based on the actual experience of the proposed surgeons who will be utilizing the proposed center.

Currently, Kings County has five multi-specialty freestanding Ambulatory Surgery Centers and eight single-specialty freestanding Ambulatory Surgery Centers.

The type of ambulatory surgery service and number of cases performed at these centers are listed below:

Existing Ambulatory Surgery Centers: Kings County			
<u>ASC Type</u>	<u>Name</u>	<u>2010</u>	<u>2011</u>
Multi Specialty	All City Family Healthcare Center, Inc.	4,181	3,593
Multi Specialty	ASC of Brooklyn	2,485	3,976
Orthopedics	Beth Israel ASC-Brooklyn Div.	253	887
Multi Specialty	Brook Plaza ASC, Inc.	8,356	8,463
Multi Specialty	Brooklyn Endoscopy and ASC, LLC	3,876	4,990
Ophthalmology	Brooklyn Eye Surgery Center	4,647	4,566
Gastroenterology	Digestive Diseases D & TC	675	1,829
Endoscopy	Endoscopic ASC of Bay Ridge, Inc.	404	214
Endoscopy	Endoscopic D & TC, LLC	4,238	4,351
Gastroenterology	Gastroenterology Care, Inc. (Opened-3/17/11)	N/A	N/A
Endoscopy	Greater NY Endoscopic Surgical Center	5,491	6,792
Multi Specialty	Millennium ASC (Opened 6/8/2011)	N/A	N/A
Ophthalmology	Sheepshead Bay Surgery Center	3,912	4,427
Total		40,528	46,099

Source: SPARCS 2010 – 2011

The applicant is committed to serving all persons in need of surgical care regardless of their ability to pay or the source of payment.

The proposed ASC would provide services in a medically underserved area and would be only the sixth multi-specialty ASC to be established in Brooklyn, a borough of over 2.5 million people.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Background

Establish a diagnostic and treatment center that will also be federally certified as an ambulatory surgery center. As required by the Centers for Medicare and Medicaid Services the ambulatory surgery portion of the Center, including reception, will be physically separate from the rest of the Center.

Proposed Operator	Omnicare Multi-Specialty Center, LLC	
Site Address	763-765 Nostrand Avenue, Brooklyn	
Services and Surgical Specialties	Primary Care Prenatal Pediatrics Health fairs Medical Social Services Nutritional Ophthalmology Physical Medicine/Rehab Podiatry Psychology Diagnostic Radiology Occupational Therapy	Ambulatory Surgery: Multi-Specialty including: Gastroenterology Obstetrics/Gynecology Orthopedics Otolaryngology Urology
Operating Rooms	1	
Procedure Rooms	1	
Hours of Operation	Monday through Friday from 8:00 am to 6:00 pm (Extended as necessary to accommodate patient needs).	
Staffing (1 st Yr / 3 rd Yr)	22.5 FTEs / 35.1 FTEs	
Medical Director(s)	Evans Crevecoeur	
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by New York Methodist Hospital 2.1 miles and 8 minutes away.	
On-call service	Access to the facility's on-call clinical staff during hours when the facility is closed.	

Character and Competence

The members of the LLC, each with one-third membership, are:

Name

Evans Crevecoeur, MD	45.00%
Jean Lionnel Vaval, MD	45.00%
Omnicare Health Care Mgmt, LLC	10.00%
Igor Flikshteyn (20%)	
Evans Crevecoeur (40%)	
Jean Lionnel Vaval (40%)	

Two of the members are practicing physicians. Mr. Flikshteyn is the president of a construction company. Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

The center intends to utilize electronic medical records and is in the process of evaluating different systems. Additionally the facility has reached out the New York Methodist Hospital to express interest in establishing a mutual network relationship.

Compliance with Applicable Codes, Rules and Regulations

The medical staff will ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements. The Center intends to review the list acceptable procedures annually and as needed to determine the appropriateness of adding new procedures consistent with individual physician expertise.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Administrative Services Agreement

Omnicare Multi-specialty Center, LLC will enter into an Administrative Services Agreement with Omnicare Healthcare Management. The consultant would provide certain professional business and administrative services to the D&TC and ambulatory surgery center relating to the operation of the facility.

The applicant has submitted an executed agreement, which is summarized below:

Facility: Omnicare Multi-Specialty Center, LLC
Contractor: Omnicare Healthcare Management
Administrative Term: 1 Year, with option to renew year to year.
Compensation: \$255,550 per annum (\$21,295.83/month) in the first year for administrative services with an increase of approximately 7.8% in second year and 10% increase in years 3-5 plus an additional \$100,220 in the first year and an approximate 10% increase from year 2-5 for Billing and collection services.

Duties of the Contractor: Omnicare Healthcare Management, as the contractor, will provide the Financial Management, administrative services, policies and procedures, contracting services, billing and collection services and strategic planning and development.

Lease Rental Agreement/ Assignment and Assumption

The applicant will lease approximately 8,000 square feet of space on the second and third floors of 763-765 Norstrand Avenue, Brooklyn, NY under the terms of the proposed assignment and assumption of an executed lease agreement summarized below:

Date: June 19, 2012
Owner: Hazel Blue Nostrand, LLC
Assignor: Omnicare Anesthesia, P.C.
Assignee: Omnicare Multispecialty Center, LLC
Term: 14 Years
Rental: \$288,000 (\$36.00 per sq. ft.) per annum and increase 4% each year after.
Provisions: Tenant responsible for maintenance, utilities, insurance and taxes.

The applicant has indicated that the lease will be an arm's length lease arrangement. Letters of opinion from licensed commercial real estate brokers have been submitted indicating rent reasonableness.

Total Project Cost and Financing

Total project costs for renovations and the acquisition of movable equipment is estimated at \$1,657,480, itemized below:

Other Fees (Consulting)	150,000
Movable Equipment	1,456,400
Financing Costs	40,005
Application Fee	2,000
Additional Processing Fee	<u>9,055</u>
Total Project Cost	<u>\$1,657,460</u>

The applicant's financing plan appears as follows:

Equity	\$ 333,460
Bank Loan @2.0% plus prime (3.25% as of 9/21/2012) over seven years	1,324,000

A letter of interest has been submitted by M&T Bank for the purchase of equipment.

Operating Budget

The applicant has submitted an operating budget in 2012 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$1,627,886	\$2,663,821
Expenses:		
Operating	\$1,462,133	\$2,259,477
Depreciation and Rent	<u>122,343</u>	<u>126,951</u>
Total Expenses	\$1,584,476	\$2,386,428
Net Income	<u>\$43,410</u>	<u>\$277,393</u>
Utilization: (visits)	8,400	14,000
Cost Per Visit	\$188.63	\$170.46

Utilization by payor source for the first and third years is as follows:

	<u>First Year</u>	<u>Third Year</u>
Commercial Insurance	36.0%	36.0%
Medicare	35.0%	35.0%
Medicaid Fee-for-Service	10.0%	5.0%
Medicaid Managed Care	9.0%	15.0%
Self Pay	8.0%	7.0%
Charity Care	2.0%	2.0%

Expense and utilization assumptions are based on the historical data of similar proposed D&TCs in the planning area.

Capability and Feasibility

Project cost will be satisfied by a loan from M&T Bank for \$1,324,000 at stated terms, with the remaining \$333,460 from proposed member's equity. BFA Attachment A shows sufficient funds.

Working capital requirements, estimated at \$397,738, appear reasonable based on two months of third year expenses, which will be satisfied through equity by the proposed members. Presented as BFA Attachment A, is a summary of net worth statement of the proposed members of Omnicare Multi-Specialty Center, LLC, which indicates the availability of sufficient funds for the stated levels of equity. Presented as BFA Attachment B, is the pro-forma balance sheet of Omnicare Multi-Specialty Center, LLC as of the first day of operation, which indicates positive member's equity position of \$883,992.

The submitted budget indicates a net income of \$43,410 and \$277,393 during the first and third years of operation, respectively. The budget appears reasonable.

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

- BFA Attachment A Summary Net Worth Statement of Proposed Members of Omnicare Multi-Specialty Center, LLC
- BFA Attachment B Pro-forma Balance Sheet
- BHFP Attachment Map

Supplemental Information

Outreach

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant’s response to DOH’s request for information on the proposed facility’s volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Facility: Kingsbrook Jewish Medical Center
 585 Schenectady Avenue
 Brooklyn, New York 11203

No response.

Facility: Interfaith Medical Center
 1545 Atlantic Avenue
 Brooklyn, New York 11213

No response.

Facility: Kings County Hospital Center
 451 Clarkson Avenue
 Brooklyn, New York 11203

Current OR Use	Surgical Cases		Cases by Applicant Physicians	Reserved OR Time for Applicant Physicians
	Ambulatory	Inpatient		
64% OR 60% GI Suites	1,051 ¹	NA	None	NA

¹ Ob/Gyn and colonoscopy, endoscopy and sigmoidoscopy procedures only.

Kings County Hospital Center opposes the application, stating that the establishment of the proposed ASC could result in the loss of all of the hospital's 1,051 Ob/Gyn and gastroenterological ambulatory surgical procedures, with associated loss of \$742,000 in revenue. The hospital does not describe any adverse impact that this loss of revenue would have on Kings County's community-oriented programs. The hospital also states that none of the physicians of the proposed ASC are currently affiliated with Kings County Hospital Center.

In 2010, Kings County Hospital Center experienced \$60.4 million in bad debt and provided \$73.3 million in charity care. In 2011, the hospital experienced \$52.2 million in bad debt and provided \$89.6 million in charity care. Kings County is part of the New York City Health and Hospitals Corporation (HHC). Because the corporation is audited as a single entity, individual financial statements for Kings County and HHC's other member hospitals are not available.

Facility: New York Methodist Hospital
506 Sixth Street
Brooklyn, New York 11215

No response.

Facility: University Hospital of Brooklyn
445 Lenox Road
Brooklyn, New York 11203

Current OR Use	Surgical Cases		Cases by Applicant Physicians	Reserved OR Time for Applicant Physicians
	Ambulatory	Inpatient		
NA	4,718	2,361	3	No

University Hospital of Brooklyn (UHB) opposes the application, claiming that the proposed ASC will adversely affect the hospital's forthcoming expansion of the hospital's ambulatory surgery program, which is an essential component of UHB's strategic plan to stabilize and enhance the hospital's fiscal position, expand access to care, and meet the demands of health care reform. UHB does not specify the number of cases and associated revenues that might be lost to the proposed ASC. The hospital also states that only one of the proposed ASC's physicians practices at UHB and that this individual performed only three cases at the hospital in 2011.

In 2010, UHB experienced an operating loss of \$49.3 million on total operating revenues of \$464.3 million. In 2010, the hospital had a loss of \$117.3 million on operating revenues of \$556.8 million. The hospital's current assets in 2010 were \$211.6 million and current liabilities were \$141.5 million, for a working capital ratio of 1.5. In 2011, current assets were \$216.4 million and current liabilities \$216.3 million, for a working capital ratio of 1.0. UHB reports that in 2010, the hospital had bed debt costs of \$16.8 million and provided charity care valued at \$1.4 million. In 2011, the hospital experienced \$38.2 million in bad debt costs and provided \$2.7 million in charity care.

Supplemental Information from Applicant

- Need and Sources of Cases

The applicant states that the projected volume of cases for the proposed ASC is based on the actual experience of the physicians who have expressed an interest in performing procedures at the facility. The applicant also states that

patients will use the proposed ASC because of its convenience in scheduling and the fact that it will be located in an out-of-hospital setting.

- Staff Recruitment and Retention

The applicant plans to recruit the necessary staff through a hiring program and also states that individuals have already expressed interest in applying for positions in the ASC. To the extent that additional staff is needed, the operators are committed not to actively seek to attract staff from local hospitals. The applicant expects to retain staff through salaries, benefits and continuing education opportunities that are comparable to or better than the region's standards. The ASC will also offer flexible work schedules and focused hours of operation, with periodic long weekends or extra days off for exceptional performance.

- Office-Based Cases

The applicant states that approximately 25 percent of the procedures projected for the proposed ASC are currently performed in an office-based setting.

OHSM Comment

Although two hospitals oppose this application, only one of the applicant physicians has operated at either facility, with a mere three cases in 2011. The Department does not find the comments of the two hospitals sufficient to warrant reversal or modification of the recommendation for five-year limited life approval of the proposed ASC based on public need, financial feasibility and operator character and competence.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a freestanding multi-specialty ambulatory surgery center to be located at 765 Nostrand Avenue, Brooklyn, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

122016 B

Omnicare Multi-Specialty Center, LLC

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - a) Data showing actual utilization including procedures;
 - b) Data showing breakdown of visits by payor source;
 - c) Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - d) Data showing number of emergency transfers to a hospital;
 - e) Data showing percentage of charity care provided; and
 - f) Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
6. Submission of an executed assignment and assumption for the building lease that is acceptable to the Department of Health. [BFA]
7. Submission of a loan commitment for project costs acceptable to the Department of Health. [BFA]
8. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
9. Submission of site control that is acceptable to the Department. [CSL]
10. Submission of a signed statement regarding anti-kickback and self-referral that is acceptable to the Department. [CSL]
11. Submission of a Services Agreement that is acceptable to the Department. [CSL]
12. Submission of a Certificate of Amendment of the Articles of Organization that is acceptable to the Department. [CSL]

13. Submission of an Operating Agreement that is acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by January 1, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122066-E Hauppauge Dialysis Center, LLC

County: Suffolk (Hauppauge)
Purpose: Establishment

Program: Dialysis Services
Submitted: August 7, 2012

Executive Summary

Description

Hauppauge Dialysis Center, LLC, a to-be-formed limited liability corporation, requests approval to become the new operator of Suffolk Kidney Center, an existing 16-station chronic dialysis center located at 30 Central Avenue, Hauppauge. The facility will continue to provide life-sustaining hemodialysis, peritoneal dialysis, peritoneal dialysis training, and support services to End Stage Renal Disease (ESRD) patients residing in the area.

The current and proposed ownership of Suffolk Kidney Center is as follows:

Current	
<i>Apollo Hauppauge, LLC</i>	
MEMBERS:	
-- Suffolk Nephrology, PLLC	50%
-- 30 Central, LLC	50%
Proposed	
<i>Hauppauge Dialysis Center, LLC</i>	
MEMBERS:	
-- New York Dialysis Services, Inc.	75%
-- Suffolk Nephrology, PLLC	25%

Suffolk Nephrology, PLLC is owned by the following individuals: Ekambaran Illamathi, MD (20%); Mitchell Kirsch, MD (20%); Brooke Moore, MD (20%); Mark Finger, MD (20%); and Nicolae Caraiani, MD (20%). Donald Landry owns 100% of 30 Central, LLC.

New York Dialysis Services, Inc. (NYDS) is a wholly-owned and dually-established subsidiary of Fresenius Medical Care Holdings, Inc. The applicant will enter into a Contribution and Redemption Agreement and an Article 28 Asset Purchase Agreement of the facility.

The current operator has entered into a Master Administrative Services Agreement with NYDS, pursuant to which NYDS continues to provide certain administrative and support services to Apollo Hauppauge, LLC (Apollo) in connection with Apollo's operation of Suffolk Kidney

Center until this application is approved. It is anticipated that at Closing, following receipt of PHHPC approval, the Master Administrative Services Agreement will be assigned by Apollo to, and assumed by, Hauppauge Dialysis Center, LLC, which NYDS will continue to provide administrative and support services for a transition period of suitable length and, if any is required by Hauppauge Dialysis Center, LLC as Operator, for a term to be agreed upon by the Operator and NYDS.

DOH Recommendation
Contingent approval.

Need Summary

This project will not result in any changes in stations or services. There is a remaining projected need for 74 stations to treat Suffolk County residents and 132 stations to serve all people receiving ESRD services in Suffolk County.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

The purchase price for the asset purchase agreement and the contribution and redemption agreement totals \$7,600,000, which will be met from operations of Fresenius Medical Care Holdings, Inc.

Budget:	<i>Revenues:</i>	\$ 3,718,000
	<i>Expenses:</i>	<u>3,416,000</u>
	<i>Gain/(Loss):</i>	\$ 302,000

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an assumed name or d/b/a, if applicable, acceptable to the Department. [HSP]
3. Submission of a revised lease agreement with a minimum term of ten years that is acceptable to the Department of Health. [BFA]
4. Submission of a photocopy of a resolution of the organizer of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. [CSL]
6. Submission of a photocopy of an Assignment and Assumption of Lease, Consent and Amendment, acceptable to the Department. [CSL]
7. Submission of a photocopy of a Master Administrative Services Agreement, acceptable to the Department. [CSL]
8. Submission of a photocopy of the Articles of Organization of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the Operating Agreement of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
10. Submission of a photocopy of the Articles of Organization of Apollo FMS Hauppauge, LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Operating Agreement of Apollo FMS Hauppauge, LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of the Articles of Organization of Suffolk Nephrology, PLLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the Operating Agreement of Suffolk Nephrology, PLLC, acceptable to the Department. [CSL]
14. Submission of revised legal documentation reflecting the change in the proposed name of the operator from FMS Hauppauge, LLC to Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
15. Submission of the Certificate of Incorporation of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
16. Submission of the Bylaws of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
17. Submission of a photocopy of the Articles of Dissolution of Apollo Hauppauge, LLC or a Certificate of Amendment to the Articles of Organization of Apollo Hauppauge, LLC, acceptable to the Department. [CSL]

Council Action Date

February 7, 2013.

Need Analysis

Background

Hauppauge Dialysis Center, LLC seeks approval to become the owner of a 16-station dialysis facility that is currently operated by Suffolk Kidney Center and is located at 30 Central Ave Hauppauge, 11788, in Suffolk County.

Analysis

The primary service area for the Suffolk Kidney Center is Suffolk County, which had a population of 1,498,816 in 2010. The percentage of the population aged 65 and over was 13.9%. The nonwhite population percentage was 29%. These are the two population groups that are most in need of end stage renal dialysis service. Comparisons between Suffolk County and New York State are listed below.

Ages 65 and Over:	13.9%	State Average:	13.7%
Nonwhite:	29.0%	State Average:	42.0%

Source: U.S. Census 2011

Although the nonwhite population of the county is below the State average, it is still sizable and warrants the continued operation of existing stations.

Capacity

The Department's methodology to estimate capacity for chronic dialysis stations is specified in Part 709.4 of Title 10 and is as follows:

One freestanding station represents 702 treatments per year. This is based on the expectation that the center will operate 2.5 patient shifts per day at 6 days per week, which can accommodate 15 patients per week (2.5 x 6 x 15 x 52 weeks). This projected 702 treatments per year is based on a potential 780 treatments x 52 weeks x 90% utilization rate = 702. The estimated average number of dialysis procedures each patient receives per year is 156.

One hospital based station is calculated at 499 treatments per year per station. This is the result of 2.0 shifts per day x 6 days per week x 52 weeks x 80% utilization rate. One hospital based station can treat 3 patients per year.

Per Department policy, hospital-based stations can treat fewer patients per year. Statewide, the majority of stations are freestanding, as are the majority of applications for new stations. As such, when calculating the need for additional stations, the Department bases the projected need on the establishment of additional freestanding stations.

There are currently 287 free standing chronic dialysis stations operating in Suffolk County. This project will not add any stations to the system.

Based upon DOH methodology, the 287 existing freestanding stations in Suffolk County could treat a total of 1292 patients annually.

Projected Need

	2011		2016	
	Total Patients Treated	Total Residents Treated	***Projected Total Patients Treated	***Projected Residents Treated
	1527	1439	1771	1669
Freestanding Stations Needed	340	320	394	371
Existing Stations	287	287	287	287
w/Approval of This CON	287	287	287	287
Unmet Need With Approval	53	33	107	84

***FS – Free Standing*

****Based upon a estimate of a three percent annual increase*

The data in the first row, "Freestanding Stations Needed," comes from the DOH methodology of each station being able to treat 4.5 patients, and each hospital station being able to treat 3 patients annually. The data in the next row, "Existing Stations," comes from the Department's Health Facilities Information System (HFIS). "Unmet Need" comes from subtracting needed stations from existing stations. "Total Patients Treated" is from IPRO data from 2011.

Conclusion

The facility currently accommodates a population in need of access to dialysis stations in the service area and this change in ownership will help support the continued operation of the facility's 16 stations. Therefore, since there is additional unmet need in the planning area and there will be no reduction in the current level of services, this application is recommended for approval.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

Establish Hauppauge Dialysis Center, LLC as the new operator of Suffolk Kidney Center.

Character and Competence

The members of Hauppauge Dialysis Center, LLC are:

<u>Name</u>		
Apollo FMS Hauppauge, LLC		100.00%
New York Dialysis Services, Inc.	75%	
Suffolk Nephrology, PLLC	25%	
Mark Finger, MD	20%	
Ekambaram Ilamathi, MD	20%	
Brooke Moore, MD	20%	
Mitchell Kirsch, MD	20%	
Nicolae Caraiani, MD	20%	

New York Dialysis Services, Inc. is an established Article 28 dialysis provider operating over 30 dialysis centers statewide and is a subsidiary of Fresenius Medical Care Holdings (FMCH). Suffolk Nephrology, PLLC is a private physician practice composed of five nephrologists.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Drs. Kirsch and Caraiani each disclosed one pending malpractice case.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Apollo Healthcare d/b/a Niagara Renal Center was fined \$2,000 in 2006 for building a dialysis center without certificate of need approval.

FMCH disclosed four lawsuits and investigations. One involves possible improper laboratory tests. A second involves a subsidiary supply company. The third is investigating the relationship between retail pharmacies and outpatient dialysis facilities and the reimbursement of medications provided to ESRD patients. The fourth involves labeling and warnings for dialysate concentrate products. Each disclosure involves multiple parties with overlapping authority. At this time there are no findings.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Asset Purchase Agreement

The change in operational ownership will be effectuated in accordance with the agreement summarized below:

<i>Dated:</i>	December 1, 2010
<i>Buyer:</i>	FMS Hauppauge, LLC
<i>Seller:</i>	Apollo Hauppauge, LLC who has the following members: 30 Central, LLC and Suffolk Nephrology, PLLC.
<i>Assets Acquired:</i>	Transferred Assets mean all of the assets, rights and properties of Apollo-Hauppauge, Seller or Contributor used or useable in connection with the Business, including without limitation copies of patient lists, patient appointment books and other medical records for the extent permitted by applicable legal requirements.
<i>Excluded Assets:</i>	The transferred assets shall not include any of the following assets: pre-first closing assets; original medical records; the rights arising under any contracts that are not assumed contracts; any inter-company balances due to or from any transferor or equity holder or any of their respective affiliates; all properties and third party software that is not assignable to the Company or that the Company chooses not to assume at Closing; all income tax refunds and tax deposits; all minute books or similar company records and tax returns of the transferor and any insurance policies.
<i>Liabilities Assumed:</i>	On the Closing Date, the Company shall assume, and shall thereafter timely pay and perform the following obligations and liabilities of Apollo-Hauppauge; obligations under the Assumed Contracts and professional malpractice claims against Apollo.
<i>Purchase Price:</i>	\$3,600,000, of which \$2,400,000 will have been paid to 30 Central, LLC for their entire interest in Apollo FMS Hauppauge and \$1,200,000 to be paid to Suffolk Nephrology, PLLC in consideration of the transfer to NYDS of one half of its ownership interest in Apollo FMS Hauppauge.

The applicant submitted an affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the Contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently there are no outstanding liabilities.

Contribution and Redemption Agreement

The applicant has submitted an executed contribution and redemption agreement, which is summarized below:

<i>Dated:</i>	December 1, 2010
<i>Company:</i>	FMS Hauppauge, LLC
<i>Contributor:</i>	Apollo Hauppauge, LLC
<i>Equity Holders:</i>	30 Central, LLC and Suffolk Nephrology, PLLC

Contribution of Assets: On the terms and subject to the conditions of this Agreement, on the Closing Date, effective as of the Effective Time, Contributor shall contribute, convey, assign, and deliver of the Contributed Assets to the Company, and the Company shall acquire and accept the Contributed Assets from the Contributor, free and clear of any liens except for Permitted Liens.

Contributed Assets: Contributed Assets shall mean all of the Contributor's rights, title, and interest in and to all of its properties used or useable in connection with the business, which includes the following: all fixed assets; all inventory to the extent permitted by legal requirements; all proprietary rights; all proprietary software and rights in third party software that are assignable to the Company; except for Excluded Files and Medical Records, all other files, records, documents, data, plans, proposals and all other recorded knowledge of the Contributor used or generated in connection with the Business and all claims and rights relating to the Contributed Assets or the Assumed Liabilities.

Excluded Assets: The Contributed Assets shall not include any of the following assets: all cash, cash equivalents and short term investments of cash; all interests in any Leased Real Property; all rights that Contributor has in any leasehold improvements associated with Leased Property; all permits, including Contributor's Medicare and Medicaid provider numbers and National Provider Identification number used in the Business; all patient lists, patient appointment books and other medical records used or generated in connection with the Business; all telephone numbers used in the connection with the Business and all directory listings of the such telephone numbers; all proprietary software and rights in third party software that is not assignable to the Company; all income tax refunds and tax deposits; any insurance policies; any Home Program Epogen; and Accounts Receivable as of the Effective Time; all rights relating to the use of the names under which the business has been conducted, including Apollo-Hauppauge and Suffolk Kidney Center, and all similar phrases and related marks as trade names and trademarks and all rebates or refunds due to Contributor relating to items or services purchased prior to the Effective Time.

Liabilities Assumed: The liabilities arising after the Effective Time under the Assumed Contracts and the obligation for up to 80 hours of accrued vacation time and up to 32 hours of sick time for each employee hired by the Company.

Purchase Price: The consideration of the transfer to the Company of the Contributed Assets is \$4,000,000.

Consulting and Administrative Services Agreement

FMS Hauppauge, LLC will enter into a consulting administrative services agreement with New York Dialysis Services, Inc., the terms of which are summarized below:

Date: April 23, 2012

Company: New York Dialysis Services, Inc.

Facility Operator: FMS Hauppauge, LLC

Term: 20 years

Services Provided: Responsibilities of the consultant are as follows: Company licenses to Owner on an exclusive basis the use of the equipment; the Company will provide all full time and part time personnel necessary to manage and operate the non physician aspects of the Business, of which the personnel will be employees or independent contractors of the Company; the Company shall prepare and submit on behalf of the Owner all bills for items and services provided by the Business; the Company shall verify patient eligibility, enrollment and termination with respect to Medicare, Medicaid and other third party payor programs, and shall respond to billing inquiries from patients, payors and physicians; the Company shall provide, or arrange for the provision of, accounting and financial services to the Owner; Company will provide to the Owner during the term of this agreement copies of its standard policy manuals for use by the Business; the Company shall negotiate, execute and maintain contracts and arrangements for and in the name of the

Owner with such individuals or entities appropriate for the Business; the Company shall perform medical record audits and conduct utilization review and quality assurance/control review and at the request of the Owner, the Company will assist in the development and maintenance of a program for home dialysis, including CAPD, CCPD and home hemodialysis.

Compensation: Monthly service fee equal to \$61,665 per month, which is \$739,980 annually. The Service Fee shall be adjusted annually as of each anniversary of the date of this agreement to reflect a fair market value rate for the 12 month period then beginning, and the parties shall use commercially reasonable efforts to complete negotiations regarding such adjustments by the date two months prior to the Anniversary Month. If the parties have not reached agreement by the anniversary date, then until agreement is reached, the Service Fee for the 12 month period then beginning shall increase by a rate equal to the same percentage as the percentage increase over the previous calendar year, if any, in the Consumer Price Index.

Although the agreement provides for the contracting of multiple services, the facility will maintain ultimate authority and responsibility for the conduct of the operation of the facility. Specifically, the operator will retain authority for maintenance of the facility's fiscal stability, level of services and quality of care; hiring and termination of key management personnel such as the administrative; controlling and maintaining books and business records; disposing of assets and incurring liabilities; adopting and enforcing policies; and employment of all professional staff.

The applicant indicates that the fee is based on current market rates for the proposed services for the dialysis entity and that the amount of compensation provided for within the Consulting and Administrative Services Agreement is in compliance with the commercially reasonable standard for such agreements.

Limited Administrative Services Agreement

The applicant has submitted an executed limited administrative services agreement, which is summarized below:

Date: December 1, 2010
Company: FMS New York Services, LLC, an affiliate of Fresenius Medical Care Holdings, Inc.
Facility Operator (Administrator): FMS Hauppauge, LLC
Term: 20 years
Services Provided: The Company will provide all full time and part time personnel necessary to manage and operate the non-physician aspects of the Business, of which such personnel will be employees or independent contractors of the Company; the Company shall prepare and submit on behalf of the Business all bills for items and services provided by the Business and shall administer controls and systems for the recording and collection of the revenues of the Business; the Company shall provide, or arrange for the provision of accounting and financial services to the Administrator for the Business; the Company will provide to the Administrator during the term of this Agreement copies of its standard policy manuals for use by the Business; the Company shall make available to the Business owner the opportunity to participate in the FMS New York Services affiliate's Ultracare Program; the Company shall negotiate, execute and maintain contracts and arrangements for in the name of the Business owner with such individuals or entities appropriate for the Business; the Company shall provide such project development assistance as the Administrator may reasonably require in connection with any expansion or modification to the business office and clinic space; the Company shall perform medical record audits and conduct utilization review and quality assurance/control review for the Business; the Company will assist in the development and maintenance of a program for home dialysis, including CAPD, CCPD and home hemodialysis and the Company will provide training (including compliance training) and education to all Company employees who render services to the Business.

Compensation: Monthly service fee equal to \$19,110 per month, which is \$229,320 annually. Also, there will be a project development fee equal to seven percent (7%) of "Total Project Costs", which includes the cost of architectural and engineering fees, the total amount payable to any general contractor or other contractors.

The fee is based on current market rates for the proposed services for the dialysis entity.

Lease Rental Agreement

The applicant has submitted an assignment of the current lease; the terms are summarized below:

Premises: 6,000 sq. ft. located at 30 Central Avenue, Hauppauge, New York
Lessor: J&S Realty Holding Co., LLC
Lessee: FMS Hauppauge, LLC
Term: The expiration of the lease is June 30, 2013 and the tenant has one renewal option under the lease for a period of five years.
Rental: \$7,994.18 per month- \$95,930.16 annually (\$15.98 per sq. ft.)
Provisions: The lessee shall be responsible for maintenance and utilities.

The applicant has indicated that they have been in discussion with the landlord relative to a new lease with a lease term of ten years. As a contingency of approval, the applicant must provide a lease agreement with a term of ten years, which is acceptable to the Department of Health.

Operating Budget

The applicant has submitted an operating budget for the first year after the change in operator. The budget, summarized below, reflects first year revenues and first year expenses in 2012 dollars.

Revenues*	\$3,718,000
Expenses:	
Operating	\$3,241,000
Capital	<u>175,000</u>
Total Expenses:	\$3,416,000
Net Income:	\$302,000

Utilization: (treatments)	11,520
Cost Per Treatment:	\$296.53

**Includes epogen and other pharmaceuticals.*

Utilization by payor source for the first year after the change in ownership is as follows:

Medicare	81.46%
Medicaid	.69%
HMO	6.74%
Commercial	11.11%

Expense and utilization assumptions are based on the historical experience of Suffolk Kidney Center.

Capability and Feasibility

The purchase price for the asset purchase agreement and the contribution and redemption agreement totals \$7,600,000, which will be met from operations of Fresenius Medical Care Holdings, Inc.

Working capital requirements are estimated at \$570,000, which appears reasonable based on two months of first year expenses. The working capital requirements will be met via equity from Fresenius Medical Care Holdings, Inc. Presented as BFA Attachment A are the 2010 and 2011 certified financial statements of Fresenius Medical Care

Holdings, Inc., which indicates the availability of sufficient funds for the equity contribution to meet the purchase price and the working capital requirement.

The submitted budget projects a net income of \$302,000 during the first year after the change in operator. Revenues are based on current reimbursement methodologies. The submitted budget appears reasonable.

Presented as BFA Attachment B are the 2010 certified financial statements and the 2011 internal financial statements of Apollo Hauppauge, LLC.

As shown on Attachment B, the facility had an average positive working capital position and an average positive net asset position from 2010 and 2011. Also, the facility achieved an average net income of \$783,138 from 2010 and 2011.

Presented as BFA Attachment C are the August 31, 2012 internal financial statements of Apollo Hauppauge, LLC. As shown on Attachment C, the facility had a positive working capital position and a positive net asset position through August 31, 2012. Also, the facility achieved a net income of \$586,670 through August 31, 2012.

Subject to the noted contingency, the applicant has demonstrated the capability to proceed in a financially feasible manner and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Financial Summary- 2010 and 2011 certified financial statements of Fresenius Medical Care Holdings, Inc.
BFA Attachment B	Financial Summary- 2010 certified financial statements and the 2011 internal financial statements of Apollo Hauppauge, LLC
BFA Attachment C	August 31, 2012 internal financial statements of Apollo Hauppauge, LLC

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Hauppauge Dialysis Center, LLC as the new operator of Suffolk Kidney Center, an existing diagnostic and treatment center, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

122066 E

Hauppauge Dialysis Center, LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an assumed name or d/b/a, if applicable, acceptable to the Department. [HSP]
3. Submission of a revised lease agreement with a minimum term of ten years that is acceptable to the Department of Health. [BFA]
4. Submission of a photocopy of a resolution of the organizer of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. [CSL]
6. Submission of a photocopy of an Assignment and Assumption of Lease, Consent and Amendment, acceptable to the Department. [CSL]
7. Submission of a photocopy of a Master Administrative Services Agreement, acceptable to the Department. [CSL]
8. Submission of a photocopy of the Articles of Organization of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the Operating Agreement of Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
10. Submission of a photocopy of the Articles of Organization of Apollo FMS Hauppauge, LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Operating Agreement of Apollo FMS Hauppauge, LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of the Articles of Organization of Suffolk Nephrology, PLLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the Operating Agreement of Suffolk Nephrology, PLLC, acceptable to the Department. [CSL]
14. Submission of revised legal documentation reflecting the change in the proposed name of the operator from FMS Hauppauge, LLC to Hauppauge Dialysis Center, LLC, acceptable to the Department. [CSL]
15. Submission of the Certificate of Incorporation of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
16. Submission of the Bylaws of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
17. Submission of a photocopy of the Articles of Dissolution of Apollo Hauppauge, LLC or a Certificate of Amendment to the Articles of Organization of Apollo Hauppauge, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122067-E Watertown Dialysis Center, LLC

County: Jefferson (Watertown)
Purpose: Establishment

Program: Dialysis Services
Submitted: August 7, 2012

Executive Summary

Description

Watertown Dialysis Center, LLC, a to-be-formed-limited liability corporation, requests approval to become the new operator of Renal Care of Northern New York, LLC (RCNNY), an existing 24-station chronic dialysis center located at 19328 Washington Street, Watertown. The facility will continue to provide, life-sustaining hemodialysis, peritoneal dialysis, peritoneal dialysis training, and support services to End Stage Renal Disease (ESRD) patients residing in the area.

will provide certain administrative and facility support services to RCNNY, in connection with their operation of the facility until this application is finally approved. It is anticipated that at closing, following receipt of PHHPC approval, the Master Administrative Services Agreement will be assigned by RCNNY to, and assumed by, Watertown Dialysis Center, LLC. NYDS will continue to provide administrative and facility support services for a transition period of suitable length, for a term to be agreed upon by the Operator and NYDS.

The current and proposed ownership of Renal Care of Northern New York, LLC is as follows:

DOH Recommendation
Contingent approval.

Current	
<i>Renal Care of Northern New York, LLC</i>	
MEMBERS:	
-- Apollo Healthcare, LLC	(50%)
-- Nephrology Associates Holding, LLC	(50%)
Proposed	
<i>Watertown Dialysis Center, LLC</i>	
MEMBERS:	
-- New York Dialysis Services, Inc.	(75%)
-- Nephrology Associates Holding, LLC	(25%)

Need Summary

This project is a change in ownership and does not result in any capacity or service changes. Jefferson County has a need for an additional two stations to treat residents or ten stations to treat all patients receiving treatments.

Apollo Health Care, LLC, is owned by Donald Landry, M.D (50%), Ph.D., and Michael Sloma (50%), and Nephrology Associates Holdings, LLC is owned 100% by Khalid P. Sindhu, M.D.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

New York Dialysis Services, Inc. is a wholly-owned and dually established subsidiary of Fresenius Medical Care Holdings, Inc. The applicant will enter into a Contribution and Redemption Agreement and an Article 28 Asset Purchase Agreement of the facility. These agreements will be discussed in a subsequent section.

Financial Summary

The purchase price for the asset purchase agreement and the contribution and redemption agreement totals \$5,400,000, which will be met from operations of Fresenius Medical Care Holdings, Inc.

Budget:	<i>Revenues:</i>	\$ 6,245,000
	<i>Expenses</i>	<u>6,055,000</u>
	<i>Gain/(Loss):</i>	\$ 190,000

The current operator has entered into a Master Administrative Services Agreement with New York Dialysis Services, Inc. (NYDS) pursuant to which NYDS

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an assumed name or d/b/a, if applicable, acceptable to the Department. [HSP]
3. Submission of a photocopy of a resolution of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
4. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. [CSL]
5. Submission of a photocopy of an Assignment and Assumption of Lease, Consent and Amendment, acceptable to the Department. [CSL]
6. Submission of a photocopy of a Master Administrative services Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the Articles of Organization of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
8. Submission of a photocopy of the Operating Agreement of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
9. Submission of information regarding Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
10. Submission of a photocopy of the Articles of Organization of Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Operating Agreement of Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of the Articles of Organization of Nephrology Associates Holdings, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the Operating Agreement of Nephrology Associates Holdings, LLC, acceptable to the Department. [CSL]
14. Submission of revised legal documentation reflecting the change in the proposed name of the operator from FMS Watertown, LLC to Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
15. Submission of the Certificate of Incorporation of New York Dialysis Services, Inc. acceptable to the Department. [CSL]
16. Submission of the Bylaws of New York Dialysis Services, Inc, acceptable to the Department. [CSL]
17. Submission of a photocopy of the Articles of Dissolution of Renal Care of Northern New York, LLC or a Certificate of Amendment to the Articles or Organization of Renal Care of Northern New York, LLC, acceptable to the Department. [CSL]

Council Action Date

February 7, 2013.

Need Analysis

Background

FMS Watertown, LLC seeks approval to be the new operator of Renal Care of Northern New York, a 24 station dialysis center located at 19328 Washington Street, Watertown, 13601, in Jefferson County.

The population Jefferson County was 117,910 in 2010. The percentage of residents age 65 and over was 11.2% and the nonwhite population was 15.7%. These are the population groups that are most in need of end stage renal dialysis services.

Ages 65 and Over:	11.2%	State Average:	13.7%
Nonwhite:	15.7%	State Average:	42.0%
<i>Source: U.S. Census 2010</i>			

Capacity

The Department's methodology to estimate capacity for chronic dialysis stations is specified in Part 709.4 of Title 10 and is as follows:

One free standing station represents 702 treatments per year. This is based on the expectation that the center will operate 2.5 patient shifts per day at 6 days per week, which can accommodate 15 patients per week (2.5 x 6 x 15 x 52 weeks). This projected 702 treatments per year is based on a potential 780 treatments x 52 weeks x 90% utilization rate = 702.

One hospital based station is calculated at 499 treatments per year per station. This is the result of 2.0 shifts per day x 6 days per week x 52 weeks x 80% utilization rate. One hospital based station can treat 3 patients per year.

Per Department policy, hospital-based stations can treat fewer patients per year. Statewide, the majority of stations are freestanding, as are the majority of applications for new stations. As such, when calculation the need for additional stations, the Department bases the projected need on establishing additional freestanding stations.

There is currently 1 facility with 24 freestanding dialysis stations operating in Jefferson County. This project will not add any net new freestanding stations to the system.

Based upon DOH methodology, existing stations could treat a total of 108 patients annually.

	2011		2016	
	<i>Total Patients Treated</i>	<i>Total Residents Treated</i>	<i>*** Projected Total Patients Treated</i>	<i>*** Projected Residents Treated</i>
	152	114	177	133
Freestanding Stations Needed	34	26	40	30
Existing Stations	24	24	24	24
w/Approval of This CON	24	24	24	24
Unmet Need With Approval	10	2	16	6

***FS – Freestanding*

****Based upon a estimate of a three percent annual increase*

The data in the first row, "Freestanding Stations Needed," comes from the DOH methodology of each station being able to treat 4.5 patients. The data in the next row, "Existing Stations," comes from the Department's Health Facilities Information System (HFIS). "Unmet Need" comes from subtracting needed stations from existing stations. "Total Patients Treated" is from IPRO data from 2011.

Conclusion

The proposed establishment of FMS Watertown, LLC as the new operator of Renal Care of Northern New York, LLC will help ensure the continued operation of the facility's 24 dialysis stations, which serve an area of current unmet need and of projected additional need by 2016.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Establish Watertown Dialysis Center, LLC as the new operator of Renal Care of Northern New York.

Character and Competence

The members of Watertown Dialysis Center, LLC are:

<u>Name</u>		
Apollo FMS Watertown, LLC		100%
New York Dialysis Services, Inc.	75%	
Nephrology Associates, LLC	25%	
Khalid Sindhu, MD	100%	

New York Dialysis Services, Inc. is an established Article 28 dialysis provider operating over 30 dialysis centers statewide and is a subsidiary of Fresenius Medical Care Holdings (FMCH). The sole member of Nephrology Associates, Khalid Sindhu, is a practicing nephrologist.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Apollo Healthcare d/b/a Niagara Renal Center was fined \$2,000 in 2006 for building a dialysis center without certificate of need approval.

FMCH disclosed four lawsuits and investigations. One involves possible improper laboratory tests. A second involves a subsidiary supply company. The third is investigating the relationship between retail pharmacies and outpatient dialysis facilities and the reimbursement of medications provided to ESRD patients. The fourth involves labeling and warnings for dialysate concentrate products. Each disclosure involves multiple parties with overlapping authority. At this time there are no findings.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Asset Purchase Agreement

The applicant will purchase the operation of Renal Care of Northern, New York, and LLC under the terms of the executed asset contribution and purchase agreement, summarized below:

<i>Date:</i>	December 1, 2010
<i>Buyer:</i>	Watertown Dialysis Center, LLC - Members are: 75% New York Dialysis Services, Inc., and 25% Nephrology Associates Holding, LLC
<i>Seller:</i>	Renal Care of Northern New York, LLC (RCNNY), (Owners Apollo Health Care, LLC (50%) and Nephrology Associates Holdings, LLC (50%).
<i>Purchased Assets:</i>	Transferred Assets mean all of the assets, rights and properties of RCNNY, Seller or Contributor used or useable in connection with the Business, including without limitation, copies of patient lists, patient appointment books and other medical records for the extent permitted by applicable legal requirements.
<i>Excluded Assets:</i>	The transferred assets shall not include any of the following assets: pre-first closing assets; original medical records; the rights arising under any contracts that are not assumed contracts; any inter-company balances due to or from any transferor or equity holder or any of their respective affiliates; all properties and third party software that is not assignable to the Company or that the Company chooses not to assume at closing; all income tax refunds and tax deposits; all minute books or similar company records and tax returns of the transferor and any insurance policies.
<i>Assumed Liabilities:</i>	On the closing date, the Company shall assume, and shall thereafter timely pay and perform the following obligations and liabilities of Apollo-Hauppauge; obligations under the Assumed Contracts and professional malpractice claims against RCNNY.
<i>Purchase Price:</i>	\$5,400,000 (3,600,000 to Apollo Health Care, LLC and 1,800,000 to Nephrology Associates Holdings, LLC and a 25% ownership interest in Watertown Dialysis Center, LLC).

The applicant submitted an affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently there are no outstanding liabilities.

Contribution and Redemption Agreement

The applicant has submitted an executed contribution and redemption agreement, which is summarized below:

<i>Dated:</i>	December 1, 2010
<i>Company:</i>	Watertown Dialysis Center, LLC
<i>Contributor:</i>	Renal Care of Northern New York, LLC
<i>Equity Holders:</i>	Apollo Healthcare, LLC and Nephrology Associates Holdings, LLC
<i>Contribution of Assets:</i>	On the terms and subject to the conditions of this Agreement, on the closing date, effective as of the Effective Time, Contributor shall contribute, convey, assign, and deliver of the Contributed Assets to the Company, and the Company shall acquire and accept the Contributed Assets from the Contributor, free and clear of any liens except for Permitted Liens.
<i>Contributed Assets:</i>	Contributed Assets shall mean all of the Contributor's rights, title, and interest in and to all of its properties used or useable in connection with the business, which includes the following: all fixed assets; all inventory to the extent permitted by legal requirements; all proprietary rights; all proprietary software and rights in third party

software that are assignable to the Company; except for Excluded Files and Medical Records, all other files, records, documents, data, plans, proposals and all other recorded knowledge of the Contributor used or generated in connection with the Business and all claims and rights relating to the Contributed Assets or the Assumed Liabilities.

Excluded Assets: The Contributed Assets shall not include any of the following assets: all cash, cash equivalents and short term investments of cash; all interests in any Leased Real Property; all rights that Contributor has in any leasehold improvements associated with Leased Property; the rights arising under any contracts that are not assumed contracts, including all rights of contributor under this agreement and any other agreements being executed in connection with the transactions including but not limited to the Article 28 Asset contribution agreement and the Master Administrative Services Agreement, all inventory to the extent not transferable under legal requirements, all permits, including Contributor's Medicare and Medicaid provider numbers and National Provider Identification number used in the Business; all patient lists, patient appointment books and other medical records used or generated in connection with the Business; all other files, records, documents, data, plans, proposals and all other recorded knowledge of the contributor related to other excluded assets, all telephone numbers used in the connection with the Business and all directory listings of the such telephone numbers; all proprietary software and rights in third party software that is not assignable to the Company; all income tax refunds and tax deposits; any insurance policies; any Home Program Epogen; and Accounts Receivable as of the Effective Time; all rights relating to the use of the names under which the business has been conducted, including Renal Care of Northern New York, and all similar phrases and related marks as trade names and trademarks and all rebates or refunds due to Contributor relating to items or services purchased prior to the Effective Time.

Liabilities Assumed: The liabilities arising after the Effective Time under the Assumed Contracts and the obligation for up to 80 hours of accrued vacation time and up to 32 hours of sick time for each employee hired by the Company.

Purchase Price: The consideration of the transfer to the Company of the Contributed Assets is Included in the overall purchase price as shown in the asset purchase agreement.

Consulting and Administrative Services Agreement

Watertown Dialysis Center, LLC will enter into a consulting administrative services agreement with New York Dialysis Services, Inc., the terms of which are summarized below:

Date: April 23, 2012
Company: New York Dialysis Services, Inc.
Facility Operator: Watertown Dialysis Center, LLC
Term: 20 years
Services Provided: Responsibilities of the consultant are as follows: Company licenses to Owner on an exclusive basis the use of the equipment; the Company will provide all full time and part time personnel necessary to manage and operate the non physician aspects of the Business, of which the personnel will be employees or independent contractors of the Company; the Company shall prepare and submit on behalf of the Owner all bills for items and services provided by the Business; the Company shall verify patient eligibility, enrollment and termination with respect to Medicare, Medicaid and other third party payor programs, and shall respond to billing inquiries from patients, payors and physicians; the Company shall provide, or arrange for the provision of, accounting and financial services to the Owner; Company will provide to the Owner during the term of this agreement copies of its standard policy manuals for use by the Business; the Company shall negotiate, execute and maintain contracts and arrangements for and in the name of the Owner with such individuals or entities appropriate for the Business; the Company shall perform medical record audits and conduct utilization review and quality assurance/control review and at the request of

Compensation: the Owner, the Company will assist in the development and maintenance of a program for home dialysis, including CAPD, CCPD and home hemodialysis. Monthly service fee equal to \$61,665 per month, which is \$739,980 annually. The Service Fee shall be adjusted annually as of each anniversary of the date of this agreement to reflect a fair market value rate for the 12 month period then beginning, and the parties shall use commercially reasonable efforts to complete negotiations regarding such adjustments by the date two months prior to the Anniversary Month. If the parties have not reached agreement by the anniversary date, then until agreement is reached, the Service Fee for the 12 month period then beginning shall increase by a rate equal to the same percentage as the percentage increase over the previous calendar year, if any, in the Consumer Price Index.

Although the agreement provides for the contracting of multiple services, the facility will maintain ultimate authority and responsibility for the operation of the facility. Specifically, the operator will retain authority for maintenance of the facility's fiscal stability, level of services and quality of care; hiring and termination of key management personnel such as the administrative; controlling and maintaining books and business records; disposing of assets and incurring liabilities; adopting and enforcing policies; and employment of all professional staff.

The applicant indicates that the fee is based on current market rates for the proposed services for the dialysis entity, and that the amount of compensation provided for within the Consulting and Administrative Services Agreement is in compliance with the commercially reasonable standard for such agreements.

Limited Administrative Services Agreement

The applicant has submitted an executed limited administrative services agreement, which is summarized below:

Date: December 1, 2010
Company: FMS New York Services, LLC, an affiliate of Fresenius Medical Care Holdings, Inc.
Facility Operator (Administrator): Watertown Dialysis Center, LLC
Term: 20 years
Services Provided: The Company will provide all full time and part time personnel necessary to manage and operate the non-physician aspects of the Business, of which such personnel will be employees or independent contractors of the Company; the Company shall prepare and submit on behalf of the Business all bills for items and services provided by the Business and shall administer controls and systems for the recording and collection of the revenues of the Business; the Company shall provide, or arrange for the provision of accounting and financial services to the Administrator for the Business; the Company will provide to the Administrator during the term of this Agreement copies of its standard policy manuals for use by the Business; the Company shall make available to the Business owner the opportunity to participate in the FMS New York Services affiliate's Ultracare Program; the Company shall negotiate, execute and maintain contracts and arrangements for in the name of the Business owner with such individuals or entities appropriate for the Business; the Company shall provide such project development assistance as the Administrator may reasonably required in connection with any expansion or modification to the business office and clinic space; the Company shall perform medical record audits and conduct utilization review and quality assurance/control review for the Business; the Company will assist in the development and maintenance of a program for home dialysis, including CAPD, CCPD and home hemodialysis and the Company will provide training (including compliance training) and education to all Company employees who render services to the Business.
Compensation: Monthly service fee equal to \$35,735 per month, which is \$428,820 annually. Also, there will be a project development fee equal to seven percent (7%) of "Total Project Costs", which includes the cost of architectural and engineering fees, the total amount payable to any general contractor or other contractors.

The fee is based on current market rates for the proposed services for the dialysis entity.

Lease Rental Agreement

The applicant has submitted an assignment of the current lease; the terms are summarized below:

Premises: 10,569 sq. ft. located at 19328 Washington Street, Watertown, NY
Lessor: DFOG, LLC
Lessee: Watertown Dialysis Center, LLC
Term: The Lease term end on December 31, 2030, or they have an early termination option of December 31, 2025.
Rental: \$20,833.33 per month - \$250,000 annually (\$23.65 per sq. ft.)
Provisions: The lessee shall be responsible for maintenance and utilities.

Operating Budget

The applicant has submitted an operating budget for the first year after the change in operator. The budget, summarized below, reflects first year revenues and first year expenses in 2012 dollars.

Revenues*	\$6,245,000
Expenses:	
Operating	\$5,445,000
Capital	<u>610,000</u>
Total Expenses:	\$6,055,000
Net Income:	\$190,000

Utilization: (treatments)	20,609
Cost Per Treatment:	\$293.80

**Includes epogen and other pharmaceuticals.*

Utilization by payor source for the first year after the change in ownership is as follows:

Medicare	80.31%
Medicaid	2.57%
HMO	9.40%
Commercial	7.72%

Expense and utilization assumptions are based on the historical experience of Renal Care of Northern New York, LLC.

Capability and Feasibility

The purchase price for the asset purchase agreement and the contribution and redemption agreement totals \$5,400,000, which will be met from operations of Fresenius Medical Care Holdings, Inc.

Working capital requirements are estimated at \$1,009,167, which appears reasonable based on two months of first year expenses. The working capital requirements will be met via equity from Fresenius Medical Care Holdings, Inc. (75%), and Nephrology Associates Holding, LLC (25%). Presented as BFA Attachments A and B are the 2010 and 2011 certified financial statements of Fresenius Medical Care Holdings, Inc. and Nephrology Associates Holdings, LLC, respectively. Attachment A indicates the availability of sufficient funds for Fresenius's share of the working capital equity contribution. Nephrology Associates does not have enough liquid assets to cover their share of the working capital equity requirement, but the sole member Khalid P. Sindhu, M.D., has agreed to fund this shortfall. Please see attachment F for his personal net worth statement, which shows adequate resources available to meet Nephrology Associates share. The purchase price will be provided by Fresenius Medical Care Holdings, Inc., and as shown on BFA Attachment A, they have sufficient resources to meet their purchase price as well as the working capital requirement.

Presented as BFA Attachment A are the 2010 and 2011 certified financial statements of Fresenius Medical Care Holdings, Inc. As shown on Attachment A, they had an average positive working capital and net asset position from 2010 to 2011. Also, they have achieved an average net income of \$1,024,835,500.

The submitted budget projects a net income of \$190,000 during the first year after the change in operator. Revenues are based on current reimbursement methodologies. The submitted budget appears reasonable.

Presented as BFA Attachment B are the 2010 and 2011 certified financial statements of Nephrology Associates Holdings, LLC. As shown on Attachment B, they had an average positive working capital position and an average positive net asset position from 2010 and 2011. Also, they achieved an average net income of \$169,780 from 2010 and 2011.

Presented as BFA Attachment C are the certified financial statements of Renal Care of Northern New York, LLC. As shown on Attachment C, RCNNY had an average positive working capital and net asset position from 2010-2011. Also, they achieved an average net loss of \$119,768 from 2010-2011. The loss was caused by higher personnel costs stemming from inefficient labor productivity and higher corporate contributions made to the American Kidney Foundation (AKF). To rectify losses, RCNNY has reduced inefficiencies and gained significant labor improvements, plus they reduced the contribution to AKF due to an alteration in the contribution methodology, which accounts for actual usage now and not volume.

As shown on BFA Attachment D, a financial summary of New York Dialysis Services, Inc. indicates that the corporation has experienced negative working capital, stockholders equity and a net loss of \$8,092,565 for 2011.

The negative working capital, stockholder's equity and net loss from operations is because of management fees, due to Fresenius Medical Care Holdings, Inc. for services rendered to New York Dialysis Services, Inc. As shown on BFA Attachment E, a financial summary of New York Dialysis Services, Inc. indicates the corporation has experienced negative working capital and stockholder's equity and maintained a net income of \$2,033,563 as of November 30, 2012. The applicant has stated that losses experienced by New York Dialysis Services, Inc. will be supported by Fresenius Medical Holdings, Inc. as needed

The applicant has demonstrated the capability to proceed in a financially feasible manner, and approval is recommended.

Recommendation

From a financial perspective, approval is recommended.

Attachments

BFA Attachment A	Financial Summary 2010-2011 Certified Financial Statements of Fresenius Medical Care Holdings, Inc.
BFA Attachment B	Financial Summary 2010 and 2011 certified Financial Statements for Nephrology Associates Holdings, LLC
BFA Attachment C	Financial Summary -2010 and 2011 Renal Care of Northern New York, LLC
BFA Attachment D	Financial Summary 2011 New York Dialysis Services, Inc.
BFA Attachment E	Internal Financial Summary 2012 New York Dialysis Services, Inc.
BFA Attachment F	Net Worth Statement for Khalid P. Sindhu, M.D

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Watertown Dialysis Center, LLC as the new operator of Renal Care of Northern New York, an existing diagnostic and treatment center, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

122067 E

Watertown Dialysis Center, LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an assumed name or d/b/a, if applicable, acceptable to the Department. [HSP]
3. Submission of a photocopy of a resolution of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
4. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. [CSL]
5. Submission of a photocopy of an Assignment and Assumption of Lease, Consent and Amendment, acceptable to the Department. [CSL]
6. Submission of a photocopy of a Master Administrative Services Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the Articles of Organization of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
8. Submission of a photocopy of the Operating Agreement of Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
9. Submission of information regarding Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
10. Submission of a photocopy of the Articles of Organization of Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Operating Agreement of Apollo FMS Watertown, LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of the Articles of Organization of Nephrology Associates Holdings, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the Operating Agreement of Nephrology Associates Holdings, LLC, acceptable to the Department. [CSL]
14. Submission of revised legal documentation reflecting the change in the proposed name of the operator from FMS Watertown, LLC to Watertown Dialysis Center, LLC, acceptable to the Department. [CSL]
15. Submission of the Certificate of Incorporation of New York Dialysis Services, Inc. acceptable to the Department. [CSL]
16. Submission of the Bylaws of New York Dialysis Services, Inc, acceptable to the Department. [CSL]
17. Submission of a photocopy of the Articles of Dissolution of Renal Care of Northern New York, LLC or a Certificate of Amendment to the Articles or Organization of Renal Care of Northern New York, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

(8)

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza

Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122175-E Avantus Renal Therapy New York, LLC

County: New York (New York)
Purpose: Establishment

Program: Dialysis Services
Submitted: October 5, 2012

Executive Summary

Description

Avantus Renal Therapy New York, LLC (Avantus), an existing limited liability company, requests approval to become the operator of the following renal dialysis clinics currently operated by Beth Israel Medical Center (BIMC) in Manhattan:

Fresenius Medical Care Holdings, Inc. is the sole member of National Medical Care, Inc. National Medical Care, Inc is the sole member of Renal Research Institute, LLC and Renal Research Institute, LLC is the sole member of Avantus Renal Therapy New York, LLC. Avantus is a wholly-owned subsidiary of Fresenius Medical Care Holdings, Inc.

<u>Current Facility Name and Address</u>	<u>Current # of Stations</u>	<u>Proposed Facility Name</u>	<u>Proposed # of Stations</u>
Beth Israel Chronic Dialysis Center 120 East 16 th Street, New York	26	Avantus Irving Place Dialysis Center	28
Upper Manhattan Dialysis Center BIMC 2465-67 Broadway, New York	25	Avantus Upper Manhattan Dialysis Center	25
*Avantus Harlem Green 488 West 128 th Street, New York	12	Avantus Harlem Green Dialysis Center	12
*Avantus Upper East Side 315 East 62 nd Street, New York	14	Avantus Upper East Side Dialysis Center	14

DOH Recommendation
Contingent approval.

Need Summary
New York County currently has an unmet need of 179 stations to treat patients who are not residents. By 2016, this unmet need will increase to 62 stations for residents and 278 for all patients.

Program Summary
Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary
The total purchase price of \$1.00 will be met with equity from Fresenius Medical Care Holdings, Inc.

Incremental Budget:	<i>Revenues:</i>	\$ 23,480,000
	<i>Expenses:</i>	<u>26,684,000</u>
	<i>Gain/(Loss):</i>	(\$ 3,204,000)

Budgeted losses will be supported by Fresenius Medical Care Holdings, Inc.

* Beth Israel Medical Center is in the process of closing its dialysis extension clinic located at 1555 Third Avenue, New York, and certifying these two locations as replacements under approved administrative review CON #121396-C.

The applicant also proposes to add two stations to the main site located at 120 East 16th Street, with the other three sites being extension clinics.

Recommendations

Health Systems Agency

There is no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed administrative services agreement that is acceptable to the Department of Health. [BFA]
3. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
4. Submission of a photocopy of the executed Certificate of Amendment of the Articles of Organization of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of the executed Amended and Restated Operating Agreement of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
6. Submission of a photocopy of the executed Articles of Organization of Renal Research Institute, LLC and any amendments thereto, acceptable to the Department. [CSL]
7. Submission of a photocopy of the executed Operating Agreement of Renal Research Institute, LLC and any amendments thereto, acceptable to the Department. [CSL]
8. Submission of a photocopy of the executed Certificate of Incorporation of National Medical Care, Inc. and any amendments thereto, acceptable to the Department. [CSL]
9. Submission of a photocopy of the adopted bylaws of National Medical Care, Inc. and any amendments thereto, acceptable to the Department. [CSL]
10. Submission of a photocopy of the executed Certificate of Incorporation of Fresenius Medical Care Holdings, Inc. and any amendments thereto, acceptable to the Department. [CSL]
11. Submission of a photocopy of the adopted bylaws of Fresenius Medical Care Holdings, Inc. and any amendments thereto, acceptable to the Department. [CSL]
12. Submission of photocopies of the executed certificates of assumed name of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the finalized and executed Consulting and Administrative Services Agreement between the applicant and Renal Research Institute, LLC, acceptable to the Department. [CSL]

Approval conditional upon:

1. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
2. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
3. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
4. The clinical space must be used exclusively for the approved purpose. [HSP]
5. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
6. The applicant shall complete construction by July 1, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Avantus Renal Therapy New York, LLC (Avantus) seeks approval to be established as the operator of four facilities currently being operated by Beth Israel Medical Center:

Beth Israel Clinic Dialysis Center located at 120 East 16th Street New York, 10003,
Upper Manhattan Dialysis Center located at 2465-67 Broadway New York, 10025,
Avantus Harlem-Green located at 1361 Amsterdam Ave New York, 10027, and
Avantus Upper East Side located at 315 East 62nd Street New York, 10128.

In addition, Avantus seeks to add two stations to the Beth Israel dialysis site on East 16th Street.

Analysis

The population of New York County was 1,601,948 in 2010. The percentage of residents age 65 and over was 13.7% and the nonwhite population was 52.1%. These are the population groups that are most in need of end stage renal dialysis services.

Age 65 and Over:	13.7%	State Average:	13.7%
Nonwhite:	52.1%	State Average:	42.0%

Source: U.S. Census 2010

Capacity

The Department's methodology to estimate capacity for chronic dialysis stations is based on Section 709.4 of Title 10 and is as follows:

One free standing station represents 702 treatments per year. This is based on the expectation that the center will operate 2.5 patient shifts per day at 6 days per week, which can accommodate 15 patients per week (2.5 x 6 x 15 x 52 weeks). This projected 702 treatments per year is based on a potential 780 treatments x 52 weeks x 90% utilization rate = 702.

One hospital based station is calculated at 499 treatments per year per station. This is the result of 2.0 shifts per day x 6 days per week x 52 weeks x 80% utilization rate. One hospital based station can treat 3 patients per year.

Per Department policy, hospital based stations can treat fewer patients per year. Statewide, the majority of stations are freestanding, as are the majority of applications for new stations. As such, when calculating the need for additional stations, the Department bases the projected need on the establishment of additional freestanding stations.

There are currently 20 facilities with 430 freestanding dialysis stations operating in New York County. This project proposes to add two net new freestanding stations to the system.

Based upon the DOH dialysis methodology, existing stations could treat a total of 1,935 patients annually.

Projected Need

New York County	2011		2016	
	Total Patients Treated	Total Residents Treated	Projected Total Patients Treated	Projected Residents Treated
		2756	1917	3195
Freestanding Stations Needed	613	426	710	494
Existing Stations	430	430	430	430
w/Approval of This CON	432	432	432	432
Unmet Need Without Approval	181	-2	280	64
Unmet Need With Approval	179	-4	278	62

The data in the first row, "Freestanding Stations Needed," comes from the DOH methodology which assumes that each station is able to treat 4.5 patients. The data in the next row, "Existing Stations," comes from the Department's Health Facilities Information System (HFIS). "Unmet Need" comes from subtracting needed stations from existing stations. "Total Patients Treated" is from IPRO data from 2011.

Conclusion

The proposed change of operator would help the four affected dialysis facilities to continue to meet the need for dialysis care in New York County, where there remains a need for additional dialysis stations.

Recommendation

From a need perspective, contingent approval is recommended.

<h2 style="margin: 0;">Programmatic Analysis</h2>

Background

Establish Avantus Renal Therapy New York, LLC as the new operator of four dialysis centers currently operated by Beth Israel Medical Center. Additionally, the applicant is requesting to add two stations to one location.

Character and Competence

The sole member of the LLC is Renal Research Institute, LLC, which is a whole-owned subsidiary of Fresenius Medical Care Holdings, Inc. The officers of Avantus are:

<u>Name</u>	
Paul Balter	Director, Vice President, Chief Medical Officer
Mark Costanzo	Director, Vice President
Paul Zabetakis, MD	Director, President
Ronald J. Kuerbitz	Executive Vice President, Chief Administrative Officer
Douglas G. Kott	Senior Vice President, Secretary
Angelo Moesslang	Chief Financial Officer
Mark Fawcett	Vice President, Treasurer
Mary Sullivan	Vice President
Liam Walsh	Vice President
Paul Colantonio	Assistant Treasurer
Carl Groves	Assistant Treasurer
Bryan Mello	Assistant Treasurer
Jessica Stewart	Assistant Secretary

Staff from the Division of Hospitals and Diagnostic & Treatment Centers reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals and all related entities were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Hospitals and Diagnostic & Treatment Centers performed internet searches on the proposed managers and all related corporate entities and found nothing of concern. Staff also checked a random sample of affiliated dialysis centers via the CMS Dialysis Facility Compare website and found no pattern of substandard care.

The following disclosures were included in the project application:

On July 17, 2007, resulting from an investigation begun in 2005, the United States Attorney filed a civil complaint against Renal Care Group, Inc., its subsidiary and FMCH in its capacity as Renal Care Group's current corporate parent related to issues the operation of a supply company. The company believes the operations of the supply company were in compliance with applicable law and that its position in the litigation will ultimately be sustained.

On February 15, 2011, a qui tam relator's complaint under the False Claims Act against FCMH was unsealed. The United States has not intervened in the case United States ex rel. Chris Drennen v. Fresenius medical Care Holdings, Inc., 2009 Civ. 10179 (D. Mass.). The relator's complaint, which was first filed under seal in February 2009, alleges that the Company seeks and received reimbursement from government payors for serum ferritin and hepatitis B laboratory test that are medically unnecessary or not properly ordered by a physician. FMCH has filed a motion to dismiss the complaint. On March 16, 2011, the United States Attorney issued a Civil Investigative Demand seeking the production of documents related to the same laboratory tests that are the subject of the relator's complaint. FMCH is cooperating fully in responding to the additional Civil Investigative Demand, and will vigorously contest the relator's complaint.

On June 29, 2011, FMCH received a subpoena from the United States Attorney. On December 6, 2011, a single Company facility in New York received a subpoena from the OIG that was substantially similar to the one issued by the U.S. Attorney. These subpoenas are part of a criminal and civil investigation into relationships between retail pharmacies and outpatient dialysis facilities in the State of New York for medications provided to patients with ESRD. Among the issues encompassed by the investigation is whether retail pharmacies may have provided or received compensation from the New York Medicaid program for pharmaceutical products that should be provided by the dialysis facilities in exchange for the New York Medicaid payment to the dialysis facilities. The company is cooperating in the investigation.

On December 7, 2012, FMCH received a subpoena from the United States Attorney requesting production of a range of documents relating to products (dialysate) manufactured by FMCH. FMCH intends to cooperate fully.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Lease Agreements and Assignments

The applicant has submitted executed lease agreements and lease assignments, the terms of which are summarized below:

Avantus Irving Place Dialysis Center

Date: May 24, 2010

Premises: Approximately 28,000 sq. ft. on the entire sixth and twelfth* floors in the building located

at 120 East 16th St, New York.
Landlord: 120 East 16th Street Co, LLC
Assignor: Beth Israel Medical Center
Assignee: Avantus Renal Therapy New York, LLC
Lease Term: Ten years with the option to renew for an additional five years
Rental: \$1,080,000/year increasing 3% yearly
Provisions: The assignee shall be responsible for utilities, maintenance, insurance and taxes.
**The applicant will use the twelfth floor premises for general office space only.*

Avantus Upper Manhattan Dialysis Center

Date: February 9, 2006
Premises: Approximately 10,000 sq. ft. on the third floor in the building located at 2465-71 Broadway, New York
Landlord: 2465 Broadway Associates, LLC
Assignor: Renal Research Institute, LLC
Assignee: Avantus Renal Therapy New York, LLC
Lease Term: Three years with the option to renew for two additional terms of five and seven years.
Rental: \$385,035/year
Provisions: The assignee shall be responsible for utilities, maintenance, insurance and taxes.

Avantus Harlem Green Dialysis Center

Date: June 29, 2012
Premises: 2nd floor and portion of the ground floor totaling approximately 23,000 sq. ft. in the building located at 488 West 128th St., New York
Landlord: Janus VII LLC
Lessee: Avantus Renal Therapy New York, LLC
Lease Term: 15 years nine months with the option to renew for an additional five years.
Rental: \$764,750 for the first year increasing 3% yearly.
Provisions: The lessee shall be responsible for utilities, maintenance, insurance and taxes.

Avantus Upper East Side Dialysis Center

Date: June 27, 2012
Premises: Portion of the ground floor and basement totaling approximately 10,695 sq. ft. in the building located at 315 East 62nd Street, New York
Landlord: 315 East 62 LLC
Lessee: Avantus Renal Therapy New York, LLC
Lease Term: Twelve years
Rental: \$476,510 for the first year increasing 3% yearly.
Provisions: The lessee shall be responsible for utilities, maintenance, insurance and taxes.

The applicant has indicated that the lease assignments and agreements are arm's length agreements and letters of opinion from Licensed Commercial Real Estate Brokers have been submitted indicating rent reasonableness.

Transfer Agreement

The applicant has submitted an executed transfer agreement, the terms of which are summarized below:

Date: January 27, 2012
Transferor: Beth Israel Medical Center
Transferee: Avantus Renal Therapy New York, LLC
Assets Transferred: All assets used or held for use solely in connection with the operation of the clinics.
Assumed Liabilities: All liabilities accruing from and after the closing date
Transfer Price: \$1.00
Payment: Paid in full at the closing.

The total purchase price of \$1.00 has been assigned because of the historical and projected losses and negative cash flow associated with Beth Israel Medical Center operation of the renal dialysis clinics. Fresenius Medical Holdings has stated that they will support the budgeted losses and negative working capital.

The applicant has provided an original affidavit, which is acceptable to the Department in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law, with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liabilities and responsibilities.

Administrative Services Agreement

The applicant has submitted a proposed administrative services agreement, the terms of which are summarized below:

Facility Operator: Avantus Renal Therapy New York, LLC
Provider: Renal Research Institute, LLC
Services Provided: Accounting; bookkeeping; billing; accounts receivable; accounts payable; purchase of equipment and supplies; negotiate, execute and maintain contracts; payroll, human resources, and benefits management to all non-physician employees.
Term: 3 years with yearly renewal.
Compensation: \$20.00/dialysis treatment

Avantus Renal Therapy New York, LLC and Renal Research Institute, LLC are related parties; therefore, the agreement is a non-arm's length agreement.

Operating Budget

The applicant has submitted incremental operating budget, in 2013 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$22,744,000	\$23,480,000
Expenses:		
Operating	\$22,662,000	\$23,395,000
Capital	<u>3,289,000</u>	<u>3,289,000</u>
Total Expenses:	\$25,951,000	\$26,684,000
 Net Income/Loss	 (\$3,166,000)	 (\$3,204,000)
 Utilization(visits)	 81,082	 83,709
Cost per visit	\$320.06	\$318.77

The applicant has stated that the projected operating losses will be subsidized by Fresenius Medical Care Holdings, Inc.

Utilization by payor source for the first year is as follows:

	<u>Years One and Three</u>
Commercial Fee-for-Service	26.06%
Medicare Fee-for-Service	64.13%
Medicaid Fee-for-Service	9.79%
Private Pay	0.02%

Expense and utilization assumptions are based on historical experience of the existing dialysis centers.

Capability and Feasibility

There are no project costs associated with this application.

The transfer price of \$1.00 will be met with equity from Fresenius Medical Care Holdings, Inc. Presented as BFA Attachment B is the financial summary of Fresenius Medical Care Holding, Inc. showing sufficient funds.

Working capital contributions are estimated at \$4,325,167, based on two months of first year expenses, and will be provided by Fresenius Medical Care Holdings, Inc. Presented as BFA Attachment D, is the pro-forma balance sheet of Avantus Renal Therapy New York as of the first day of operation, which indicates positive shareholder's equity position of \$6,597,349. Any negative working capital will be supported by Fresenius Medical Care Holdings, Inc. The Pro-forma cash represents working capital contributions plus cash reserves to be made by Fresenius Medical Care Holdings, Inc. who will contribute additional working capital necessary for the first day of operations of \$3,480,238.

The submitted budget indicates a net loss of \$3,166,000 and \$3,204,000 for the first and third year subsequent to change in ownership, respectively. Revenue is based on Beth Israel Medical Center's experience in the operation of the dialysis clinics and on current reimbursement rates. The applicant indicates that losses are largely attributable to overtime labor as well as medical supply costs. The applicant will work to reduce these expenses where possible. Budgeted losses will be supported by Fresenius Medical Care Holdings, Inc. The budget appears reasonable.

As shown on BFA Attachment B, a financial summary of Fresenius Medical Care Holdings, Inc. indicates that the corporation has maintained positive working capital and equity and generated net income of \$1,177,262,000 for 2011. As shown on BFA Attachment C, internal financial summary of Fresenius Medical Care Holdings, Inc, indicates that the corporation has maintained positive working capital and equity and generated a net income of \$1,025,639,000 as of September 30, 2012.

Based on the preceding, and subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner and approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

<h2>Attachments</h2>

BFA Attachment A	Organizational Chart
BFA Attachment B	Financial Summary 2010-2011, Fresenius Medical Care Holdings, Inc.
BFA Attachment C	Internal Financial Summary as of September 30,2012, Fresenius Medical Care Holdings, Inc.
BFA Attachment D	Pro-forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Avantus Renal Therapy New York, LLC as the new operator of 4 extension clinics currently operated by Beth Israel Medical Center and adding 2 dialysis stations, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

122175 E

Avantus Renal Therapy New York, LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed administrative services agreement that is acceptable to the Department of Health. [BFA]
3. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
4. Submission of a photocopy of the executed Certificate of Amendment of the Articles of Organization of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of the executed Amended and Restated Operating Agreement of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
6. Submission of a photocopy of the executed Articles of Organization of Renal Research Institute, LLC and any amendments thereto, acceptable to the Department. [CSL]
7. Submission of a photocopy of the executed Operating Agreement of Renal Research Institute, LLC and any amendments thereto, acceptable to the Department. [CSL]
8. Submission of a photocopy of the executed Certificate of Incorporation of National Medical Care, Inc. and any amendments thereto, acceptable to the Department. [CSL]
9. Submission of a photocopy of the adopted bylaws of National Medical Care, Inc. and any amendments thereto, acceptable to the Department. [CSL]
10. Submission of a photocopy of the executed Certificate of Incorporation of Fresenius Medical Care Holdings, Inc. and any amendments thereto, acceptable to the Department. [CSL]
11. Submission of a photocopy of the adopted bylaws of Fresenius Medical Care Holdings, Inc. and any amendments thereto, acceptable to the Department. [CSL]
12. Submission of photocopies of the executed certificates of assumed name of Avantus Renal Therapy New York, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the finalized and executed Consulting and Administrative Services Agreement between the applicant and Renal Research Institute, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
2. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
3. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
4. The clinical space must be used exclusively for the approved purpose. [HSP]
5. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
6. The applicant shall complete construction by July 1, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122242-E

LSL Newburgh, LLC
d/b/a Liberty Hudson Valley Dialysis

County: Orange (Newburgh)
Purpose: Establishment

Program: Dialysis Services
Submitted: November 20, 2012

Executive Summary

Description

LSL Newburgh, LLC d/b/a Liberty Hudson Valley Dialysis, an existing proprietary chronic renal dialysis diagnostic and treatment center (D&TC) located at 4 Corwin Court, Newburgh, requests approval to transfer 55% membership interest from current member, Liberty Newburgh Holdings, LLC, to New York Dialysis Services, Inc. The 17-stations center will continue to provide home hemodialysis training and support, home peritoneal dialysis training and support and chronic renal dialysis upon approval.

Membership of the operation before and after the requested change is as follows:

Current	
Liberty Newburgh Holdings, LLC	55%
St. Luke's Cornwall Hospital	15%
Shoib Aziz	15%
Hamid Hossain	15%
Proposed	
New York Dialysis Services, Inc	55%
St. Luke's Cornwall Hospital	15%
Shoib Aziz	15%
Hamid Hossain	15%

New York Dialysis Services, Inc. is a wholly-owned subsidiary of Fresenius Medical Care Holdings, Inc. Liberty Hudson Valley Dialysis will continue to have site control under their current lease. New York Dialysis Services, Inc. will be added to the lease upon approval.

Under the proposed assignment and assumption agreement Liberty Dialysis, LLC and Liberty Newburgh Holdings, LLC transfers to New York Dialysis Services, Inc. and LSL Newburgh LLC respectively all of their rights, title and interest in and to the Independent Vendor Agreement, which has a remaining term of seven years with the option to renew for an additional five years.

Under the amendment to the option to purchase membership interest agreement between Liberty Dialysis LLC and Liberty Newburgh Holdings LLC, Liberty Dialysis LLC assigned its option to purchase Liberty Newburgh Holdings, LLC interest to New York Dialysis Services, Inc.

DOH Recommendation
 Contingent approval.

Need Summary

This change in ownership will not result in any modifications in the total number of stations or services. There is a remaining need for 16 stations to treat Orange County residents, or 29 stations to treat all patients receiving dialysis services in Orange County.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

There are no project costs associated with this application. The total purchase price of \$1.00 will be met with equity from New York Dialysis Services, Inc.

Incremental Budget:	<i>Revenues:</i>	\$ 11,669,189
	<i>Expenses:</i>	<u>6,621,580</u>
	<i>Gain/(Loss):</i>	\$ 5,047,609

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed assignment and assumption agreement that is acceptable to the Department of Health. [BFA]
2. Submission of an executed lease assignment that is acceptable to the Department of Health. [BFA]
3. Submission of a revised CON Schedule 3B, acceptable to the Department. [CSL]
4. Submission of proof of compliance with the provisions of Public Health Law § 2801-a(4)(b)(iii) with respect to the withdrawal of Robert Santelli from LSL Newburgh, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of the Consent to Assignment and Amendment Lease, acceptable to the Department. [CSL]
6. Submission of a photocopy of the Assignment and Amendment Agreement to the Independent Vendor Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the Bylaws of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
8. Submission of an organizational chart of LSL Newburgh, LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the Membership Interest Purchase Agreement, acceptable to the Department. [CSL]
10. Submission of information regarding the Membership Interest Purchase Agreement, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Amended and Restated Operating Agreement of LSL Newburgh, LLC, acceptable to the Department. [CSL]

Council Action Date

February 7, 2013.

Need Analysis

Background

New York Dialysis Services, Inc. requests approval to purchase 55 percent of the membership interests of LSL Newburgh, LLC from Liberty Newburgh Holdings, LLC. LSL Newburgh, LLC is the operator of Liberty Hudson Valley Dialysis, a 17 station facility located at 4 Corwin Court, Newburgh, 12550, in Orange County

The population of Orange County was 374,872 in 2010. The percentage of the population over the age of 65 was 11.3%. The nonwhite population accounted for 32.3%. These are the two population groups most in need of end stage renal dialysis services.

2011:

Ages 65 and Over:	11.3%	State Average:	13.7%
Nonwhite:	32.3%	State Average:	42.0%
<i>Source: U.S. Census 2010</i>			

Although the percentage of these groups in Orange County are below those for the state as a whole, they are still sizable and warrant the need for continued operation of existing dialysis stations in the county.

Capacity

The Department's methodology to estimate capacity for chronic dialysis stations is based on Section 709.4 of Title 10 and is as follows:

One freestanding station represents 702 treatments per year. This is based on the expectation that the center will operate 2.5 patient shifts per day at 6 days per week, which can accommodate 15 patients per week (2.5 x 6 x 15 x 52 weeks). This projected 702 treatments per year is based on a potential 780 treatments x 52 weeks x 90% utilization rate = 702.

One hospital based station is calculated at 499 treatments per year per station. This is the result of 2.0 shifts per day x 6 days per week x 52 weeks x 80% utilization rate. One hospital based station can treat 3 patients per year.

Per Department policy, hospital based stations can treat fewer patients per year. Statewide, the majority of stations are freestanding, as are the majority of applications for new stations. As such, when calculating the need for additional stations, the Department bases the projected need on the establishment of additional freestanding stations.

There are currently 3 facilities with 57 free standing dialysis stations operating in Orange County. This project will not add any net new Freestanding Station to the system.

Based upon DOH methodology, existing stations could treat a total of 257 patients annually.

Projected Need

	2011		2016	
	Total Patients Treated	Total Residents Treated	***Projected Total Patients Treated	***Projected Residents Treated
	387	325	449	377
Freestanding Stations Needed	86	73	100	84
Existing Stations	57	57	57	57
w/Approval of This CON	57	57	57	57
Unmet Need With Approval	29	16	43	27

***FS – Free Standing*

****Based upon a estimate of a three percent annual increase*

The data in the first row, "Freestanding Stations Needed," comes from the DOH methodology, which assumes that each station is able to treat 4.5 patients. The data in the next row, "Existing Stations," comes from the Department's

Health Facilities Information System (HFIS). "Unmet Need" comes from subtracting needed stations from existing stations. "Total Patients Treated" is from IPRO data from 2011.

Conclusion

The services provided by this provided are needed and utilized. In addition, a need for additional stations remains in the county. The proposed ownership transfer will help ensure the continued operation of a well-utilized facility in an area with unmet need for dialysis services.

Recommendation

From a need perspective, approval is recommended.

Programmatic Analysis

Background

Establish a New York Dialysis Services, Inc. (NYDS) as the 55% member of LSL Newburgh LLC d/b/a Liberty Hudson Valley Dialysis, an existing 17-station chronic renal dialysis diagnostic and treatment center. No programmatic changes will occur as a result of this proposal.

Character and Competence

The current 55% member of center, Liberty Newburgh Holdings, LLC, is selling their membership to NYDS. The other members will remain the same, with the same membership interests. Upon approval the members of the LLC will be:

<u>Name</u>	
New York Dialysis Services, Inc	55%
St. Luke's Cornwall Hospital	15%
Shoib Aziz	15%
Hamid Hossain	15%

NYDS is an already established article 28 provider which operates over 30 dialysis centers in New York State and is a subsidiary of Fresenius Medical Care Holdings (FMCH).

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

FMCH disclosed four lawsuits and investigations. One involves possible improper laboratory tests. A second involves a subsidiary supply company. The third is investigating the relationship between retail pharmacies and outpatient dialysis facilities and the reimbursement of medications provided to ESRD patients. The fourth involves labeling and warnings for dialysate concentrate products. Each disclosure involves multiple parties with overlapping authority. At this time there are no findings.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Operating Budgets

The applicant has submitted an incremental operating budget, in 2013 dollars for the first and third years of operation, summarized below:

	<u>Years One and Three</u>
Revenues:	\$11,669,189
Expenses:	
Operating:	\$6,204,858
Capital:	<u>416,722</u>
Total Expenses:	\$6,621,580
 Net Income:	 \$5,047,609
 Utilization(treatments)	 23,831
Cost per treatment	\$277.86

Utilization by payor source for the first and third years is as follows:

	<u>Years One and Three</u>
Commercial Fee for Service	6%
Medicare Fee for Service	79%
Medicare Managed Care	2%
Medicaid Fee for Service	2%
Medicaid Managed Care	2%
Private Pay/Other	9%

Expenses and utilization are based on the historical experience of Liberty Hudson Valley Dialysis.

Capability and Feasibility

There are no project costs associated with this application.

The transfer price of \$1.00 will be met with equity from New York Dialysis Services, Inc. Presented as BFA Attachment A is the financial summary of New York Dialysis Services, Inc. showing sufficient funds.

Mark Caputo, sole member of Liberty Newburgh Holdings, LLC, granted New York Dialysis Services, Inc. the amended Option to Purchase through an executed agreement on September 28, 2012. The total purchase price was originally \$1,000 but was settled at \$1.00. At the time Liberty Newburgh Holdings LLC, acquired its interest in LNL Newburgh LLC, the article 28 operator, Mark Caputo was the CEO of Liberty Dialysis, LLC. Liberty Dialysis, LLC entered into an agreement to provide administrative/consulting services.

Consistent with the representative governance model, then in effect, Mr. Caputo also entered into an option agreement pursuant to which he agreed to sell his ownership interest for nominal consideration if it was determined that Liberty Dialysis, LLC could legally purchase such ownership interest. With the enactment of Section 2801-a(15)(a) of Public Health Law, it became permissible for corporations or limited liability companies to possess ownership interest in renal dialysis clinics, thus necessitating this CON application in order to effectuate previous contingent agreements.

The submitted budget indicates a net income of \$5,047,609 for the first and third years. Revenue is based on Liberty Hudson Valley Dialysis's experience in the operation of the dialysis center and on current reimbursement rates. The budget appears reasonable.

As shown on BFA Attachment A, a financial summary of New York Dialysis Services, Inc. indicates that the corporation has experienced negative working capital, stockholders equity and a net loss of \$9,498,702 for 2011. The negative working capital, stockholder's equity and net loss from operations is due to management fees due to Fresenius Medical Care Holdings, Inc. for services rendered to New York Dialysis Services, Inc. As shown on BFA

Attachment B, a financial summary of New York Dialysis Services, Inc. indicates the corporation has experienced negative working capital and stockholder's equity and maintained a net income of \$2,033,563 as of November 30, 2012. The applicant has stated that losses experienced by New York Dialysis Services, Inc. will be supported by Fresenius Medical Holdings, Inc. as needed.

As shown on BFA Attachment C, a financial summary of Fresenius Medical Care Holdings, Inc. indicates that the corporation has maintained positive working capital and equity and generated net income of \$1,177,262,000 for 2011. As shown on BFA Attachment D, internal financial summary of Fresenius Medical Care Holdings, Inc., indicates that the corporation has maintained positive working capital and equity and generated a net income of \$1,025,639,000 as of September 30, 2012.

As shown on BFA Attachment E, a financial summary of Liberty Hudson Valley Dialysis indicates that the facility has maintained positive working capital and member's equity and experienced income from operations of \$3,278,361 for 2011. As shown on BFA Attachment F, internal financial summary of Liberty Hudson Valley Dialysis indicates that the corporation has maintained positive working capital and equity and generated a net income of \$3,742,423 as of September, 30, 2012.

Based on the preceding, and subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner and approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Financial Summary 2011, New York Dialysis Services, Inc.
BFA Attachment B	Financial Summary as of November 30, 2012, New York Dialysis Services, Inc.
BFA Attachment C	Financial Summary 2010-2011, Fresenius Medical Care Holdings, Inc.
BFA Attachment D	Financial Summary as of September 30, 2012, Fresenius Medical Care Holdings, Inc.
BFA Attachment E	Financial Summary 2011, Liberty Hudson Valley Dialysis
BFA Attachment F	Financial Summary as of September 30, 2012, Liberty Hudson Valley Dialysis

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 55 percent membership interest of LSL Newburgh, LLC to New York Dialysis Services, Inc., and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

122242 E

FACILITY/APPLICANT:

LSL Newburgh, LLC
d/b/a Liberty Hudson Valley Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed assignment and assumption agreement that is acceptable to the Department of Health. [BFA]
2. Submission of an executed lease assignment that is acceptable to the Department of Health. [BFA]
3. Submission of a revised CON Schedule 3B, acceptable to the Department. [CSL]
4. Submission of proof of compliance with the provisions of Public Health Law § 2801-a(4)(b)(iii) with respect to the withdrawal of Robert Santelli from LSL Newburgh, LLC, acceptable to the Department. [CSL]
5. Submission of a photocopy of the Consent to Assignment and Amendment Lease, acceptable to the Department. [CSL]
6. Submission of a photocopy of the Assignment and Amendment Agreement to the Independent Vendor Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the Bylaws of New York Dialysis Services, Inc., acceptable to the Department. [CSL]
8. Submission of an organizational chart of LSL Newburgh, LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the Membership Interest Purchase Agreement, acceptable to the Department. [CSL]
10. Submission of information regarding the Membership Interest Purchase Agreement, acceptable to the Department. [CSL]
11. Submission of a photocopy of the Amended and Restated Operating Agreement of LSL Newburgh, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 121099-E
Parkview Care and Rehabilitation Center, Inc.
d/b/a Parkview Care and Rehabilitation Center

County: Nassau (Massapequa)
Purpose: Establishment

Program: Residential Health Care Facility
Submitted: February 27, 2012

Executive Summary

Description

Parkview Care and Rehabilitation Center, Inc. d/b/a Parkview Care and Rehabilitation Center, a 169-bed proprietary residential health care facility (RHCF) located at 5353 Merrick Road, Massapequa, requests approval for a change in 45% of the membership ownership of the facility. The ownership of the facility, before and after the proposed transaction, is as follows:

<u>Current</u>	<u>Pct.</u>
David Jones	50.0%
Judith Jones-Calnan	45.0%
Bent Philipson	2.5%
Ben Landa	2.5%
<u>Proposed</u>	<u>Pct.</u>
Bent Philipson	12.5%
Ben Landa	25.0%
David Jones	50.0%
Anne Gottlieb	10.0%
Jennifer Strauss	2.5%

The change in the membership percentage would diversify ownership of the facility. There will be no programmatic changes made as a result of the transfers.

Several of the proposed new members and the members gaining additional shares have ownership interest in additional RHCF facilities. Bent Philipson has ownership interest in several other New York State nursing homes, but the ownership is too recent to be able to provide full year financial statements for their operations. They are: Crown Center for Nursing and Rehabilitation-Cortland, Diamond Hill Nursing and Rehabilitation Center-Troy, Little Neck Nursing Home, Pathways Nursing and Rehabilitation Center-Hilltop, and Rosewood Rehabilitation and Nursing Center.

DOH Recommendation
Approval.

Need Summary

As this project involves only a partial change in the ownership interests, no Need recommendation is required.

Program Summary

No negative information has been received concerning the character and competence of the above applicants identified as new members.

No changes in the program or physical environment are proposed in this application. No administrative services/consulting agreement is proposed in this application.

Financial Summary

There are no project costs associated with this proposal. The purchase price for 45% ownership interest in the nursing home is \$2,122,607.74.

Budget:	<i>Revenues:</i>	\$ 14,326,437
	<i>Expenses:</i>	<u>14,093,856</u>
	<i>Gain/(Loss):</i>	\$ 232,581

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval.

Council Action Date

February 7, 2013.

Programmatic Analysis

Facility Information

	<i>Existing</i>	<i>Proposed</i>																								
<i>Facility Name</i>	Parkview Care and Rehabilitation Center	Same																								
<i>Address</i>	5353 Merrick Road Massapequa, NY 11758	Same																								
<i>RHCF Capacity</i>	169	Same																								
<i>ADHCP Capacity</i>	N/A	Same																								
<i>Type of Operator</i>	Corporation	Corporation																								
<i>Class of Operator</i>	Proprietary	Proprietary																								
<i>Operator</i>	Parkview Care and Rehabilitation Center, Inc.	Parkview Care and Rehabilitation Center, Inc.																								
	<table border="0"> <thead> <tr> <th><u>Stockholders</u></th> <th><u>Shares (%)</u></th> </tr> </thead> <tbody> <tr> <td>David Jones</td> <td>500 (50.0%)</td> </tr> <tr> <td>Judith Jones</td> <td>450 (45.0%)</td> </tr> <tr> <td>Benjamin Landa</td> <td>25 (2.5%)</td> </tr> <tr> <td>Bent Phillipson</td> <td>25 (2.5%)</td> </tr> </tbody> </table>	<u>Stockholders</u>	<u>Shares (%)</u>	David Jones	500 (50.0%)	Judith Jones	450 (45.0%)	Benjamin Landa	25 (2.5%)	Bent Phillipson	25 (2.5%)	<table border="0"> <thead> <tr> <th><u>Stockholders</u></th> <th><u>Shares (%)</u></th> </tr> </thead> <tbody> <tr> <td>David Jones</td> <td>500 (50.0%)</td> </tr> <tr> <td>Judith Jones</td> <td>0 (0.0%)</td> </tr> <tr> <td>Benjamin Landa</td> <td>250 (25.0%)</td> </tr> <tr> <td>Bent Phillipson</td> <td>125 (12.5%)</td> </tr> <tr> <td>Anne Gottlieb</td> <td>100 (10.0%)</td> </tr> <tr> <td>Jennifer Strauss</td> <td>25 (2.5%)</td> </tr> </tbody> </table>	<u>Stockholders</u>	<u>Shares (%)</u>	David Jones	500 (50.0%)	Judith Jones	0 (0.0%)	Benjamin Landa	250 (25.0%)	Bent Phillipson	125 (12.5%)	Anne Gottlieb	100 (10.0%)	Jennifer Strauss	25 (2.5%)
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Character and Competence

- FACILITIES REVIEWED:

Residential Health Care Facilities

Avalon Gardens Rehabilitation and Health Care Center	05/2003 to present
Bay Park Center for Nursing and Rehabilitation	12/2009 to present
Bayview Nursing and Rehabilitation Center	04/2003 to present
Brookhaven Rehabilitation and Health Care Center	01/2003 to present
Crown Center for Nursing and Rehabilitation	08/2010 to present
Diamond Hill Nursing and Rehabilitation Center	08/2010 to present
Little Neck Nursing Home	04/2011 to present
Eastchester Rehabilitation and Health Care Center	01/2003 to present
Forest Hills Care Center	01/2003 to present
Garden Care Center	01/2003 to present
Golden Gate Rehabilitation and Health Care Center	01/2003 to present
Grace Plaza Nursing and Rehabilitation Center	06/2012 to present
Meadow Park Rehabilitation and Health Care Center	01/2003 to present
Nassau Extended Care Facility	07/2004 to present
Nathan Miller Center for Nursing (closed)	10/2004 to 02/2011
New Surfside Nursing Home	01/2003 to present
Park Avenue Extended Care Facility	07/2004 to present
Pathways Nursing and Rehabilitative Center – Hilltop	08/2010 to present
Rockville Skilled Nursing and Rehabilitation Center	01/2003 to present
Rosewood Rehabilitation and Nursing Center	08/2010 to present
Split Rock Rehabilitation and Health Care Center	01/2003 to 02/2009
Spring Creek Rehabilitation and Nursing Center	01/2003 to present
Tarrytown Hall Care Center	01/2003 to 04/2008
The Hamptons Center for Nursing	07/2008 to present
Throgs Neck Extended Care Facility	07/2004 to present

Townhouse Extended Care Center	07/2004 to present
Wedgewood Care Center	01/2003 to 11/2005
White Plains Center for Nursing	10/2004 to present
Woodmere Rehabilitation and Health Care Center	01/2003 to present

Receiverships

Harbour Health Multicare Center for Living	07/2012 to present
Hawthorn Health Multicare Center for Living	07/2012 to present

Diagnostic and Treatment Centers

Privilege Care Diagnostic and Treatment Center	08/2005 to present
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Adult Care Facilities

Oceanview Manor Home for Adults	01/2003 to present
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Certified Home Health Agencies

Excellent Home Care Services, LLC	11/2004 to present
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• INDIVIDUAL BACKGROUND REVIEW:

Benjamin Landa lists his current employment as Assistant Administrator at New Surfside Nursing Home in Far Rockaway, Queens. Mr. Landa has extensive health care facility interests with dates of ownership, as follows.

Avalon Gardens Rehabilitation and Health Care Center	05/2003 to present
Bay Park Center for Nursing and Rehabilitation	12/2009 to present
Bayview Nursing and Rehabilitation Center	04/2003 to present
Brookhaven Rehabilitation and Health Care Center	12/2002 to present
Eastchester Rehabilitation and Health Care Center	12/2002 to present
Forest Hills Care Center	12/2002 to present
Garden Care Center	12/2002 to present
Golden Gate Rehabilitation and Health Care Center	10/2002 to present
Grace Plaza Nursing and Rehabilitation Center	06/2012 to present
Meadow Park Rehabilitation and Health Care Center	12/2002 to present
New Surfside Nursing Home	12/2002 to present
Rockville Skilled Nursing and Rehabilitation Center	12/2002 to present
Rosewood Rehabilitation and Nursing Center	08/2010 to present
Split Rock Rehabilitation and Health Care Center	12/2002 to 02/2009
Spring Creek Rehabilitation and Nursing Center (formerly Willoughby Rehabilitation and Health Care Center)	12/2002 to present
Tarrytown Hall Care Center	12/2002 to 04/2008
The Hamptons Center for Nursing	07/2008 to present
Woodmere Rehabilitation and Health Care Center	12/2002 to present
Privilege Care Diagnostic and Treatment Center (D&TC)	08/2005 to present
Oceanview Manor Home for Adults (ACF)	12/2002 to present
Excellent Home Care Services, LLC (CHHA)	11/2004 to present

Jennifer Strauss has been employed since June 2004 as a bookkeeper for Sterling Care Consultants, a billing agency located in Howell, NJ. Ms. Strauss indicates she holds no ownership interests in health care facilities.

Bent Phillipson lists his current employment as Manager at Woodmere Rehabilitation and Health Care Center in Woodmere, NY. Mr. Phillipson has extensive health care facility interests with dates of ownership, as follows.

Avalon Gardens Rehabilitation and Health Care Center	05/2003 to present
Bay Park Center for Nursing and Rehabilitation	12/2009 to present
Bayview Nursing and Rehabilitation Center	04/2003 to present
Crown Center for Nursing and Rehabilitation	08/2010 to present
Diamond Hill Nursing and Rehabilitation Center	08/2010 to present

Little Neck Nursing Home	04/2011 to present
Nassau Extended Care Facility	07/2004 to present
Park Avenue Extended Care Facility	07/2004 to present
Pathways Nursing and Rehabilitative Center – Hilltop	08/2010 to present
Rosewood Rehabilitation and Nursing Center	08/2010 to present
The Hamptons Center for Nursing	07/2008 to present
Throgs Neck Extended Care Facility	07/2004 to present
Townhouse Extended Care Center	07/2004 to present

Anne Gottlieb lists her employment since January 1, 2000 as the bookkeeper for Garden Care Center in Franklin Square, NY. Ms. Gottlieb is a licensed nursing home administrator with an active license in good standing. Ms. Gottlieb has the following health care facility interests with dates of ownership.

Meadow Park Rehabilitation and Health Care Center	12/2002 to present
Nathan Miller Center for Nursing (closed)	10/2004 to 02/2011
Wedgewood Care Center	12/2002 to 11/2005
White Plains Center for Nursing	10/2004 to present

Character and Competence – Analysis:

No negative information has been received concerning the character and competence of the above applicants identified as new members.

A review of **Avalon Gardens Rehabilitation and Health Care Center** for the period identified above reveals the following.

- The facility was fined \$2,000 pursuant to a Stipulation and Order issued April 21, 2009 for surveillance findings on May 23, 2008. Deficiencies were found under 10 NYCRR 415.12(h)(1)&(2) - Quality of Care: Accidents.
- The facility was fined \$4,000 pursuant to a Stipulation and Order issued July 16, 2012 for surveillance findings on July 29, 2011. Multiple deficiencies were found under 10 NYCRR 415.12 - Quality of Care: Practical Potential and 10 NYCRR 415.26 - Administration.

A review of **Bay Park Center for Nursing and Rehabilitation** for the period identified above reveals the following.

- The facility was fined \$4,000 pursuant to a Stipulation and Order issued March 2, 2011 for surveillance findings on December 18, 2009. Deficiencies were found under 10 NYCRR 415.12 - Quality of Care: Highest Practicable Potential and 10 NYCRR 415.12(i)(1) - Quality of Care: Nutrition Status.
- The facility was fined \$18,000 pursuant to a Stipulation and Order issued May 30, 2012 for surveillance findings on February 16, 2011. Multiple deficiencies were found under 10 NYCRR 415.4(b)(1)(i) - Free from Abuse; 10 NYCRR 415.4(b) - Development of Abuse Policies; 10 NYCRR 415.12(h)(2) - Quality of Care: Accidents; 10 NYCRR 415.12(i)(1) - Quality of Care: Nutrition; and 10 NYCRR 415.26(c)(1)(iv) - Nurse Aide Competency.

A review of **Bayview Nursing and Rehabilitation Center** for the period identified above reveals the following.

- The facility was fined \$7,000 pursuant to a Stipulation and Order issued September 29, 2005 for surveillance findings on November 16, 2004. Deficiencies were found under 10 NYCRR 415.5(h)(2) - Quality of Care: Environment; 10 NYCRR 415.12 - Quality of Care; 10 NYCRR 415.12(c)(1) - Quality of Care: Pressure Sores; and 10 NYCRR 415.12(h)(2) - Quality of Care: Accidents.
- The facility was fined \$2,000 pursuant to a Stipulation and Order issued June 13, 2007 for surveillance findings on December 2, 2005. Deficiencies were found under 10 NYCRR 415.11(c)(3) - Comprehensive Care Plans.
- The facility was fined \$10,000 pursuant to a Stipulation and Order issued December 16, 2011 for surveillance findings on December 7, 2010. Deficiencies were found under 10 NYCRR 415.12(c)(1) - Quality of Care: Pressure Sores.

A review of **Brookhaven Rehabilitation and Health Care Center** for the period identified above reveals the following.

- The facility was fined \$2,000 pursuant to a Stipulation and Order issued April 3, 2009 for surveillance findings on April 25, 2008. Deficiencies were found under 10 NYCRR 415.12 - Quality of Care.

A review of **Crown Center for Nursing and Rehabilitation** for the period identified above reveals the following.

- The facility was fined \$28,000 pursuant to a Stipulation and Order issued August 25, 2012 for surveillance findings on April 4, 2011 and February 17, 2011. Deficiencies were found under 10 NYCRR 415.12 - Quality of Care: Highest Practicable Potential; 10 NYCRR 415.12 - Quality of Care: Highest Practicable Potential; 10 NYCRR 415.12(c) - Quality of Care: Pressure Sores; 10 NYCRR 415.26(a)(1) – Administration; 10 NYCRR 415.26(b)(3)(4) - Governing Body; 10 NYCRR 415.15(a)(1)(2)(4) - Medical Director; and 10 NYCRR 415.27(a)(c)(3)(i,ii,iv,v)(4) - Quality Assurance.

A review of **Eastchester Rehabilitation and Health Care Center** for the period identified above reveals the following.

- The facility was fined \$2,000 pursuant to a Stipulation and Order issued August 9, 2008 for surveillance findings on January 15, 2008. Deficiencies were found under 10 NYCRR 415.4(b)(1)(ii) - Resident Behavior and Facility Practices: Staff Treatment of Residents.

A review of **Garden Care Center** for the period identified above reveals the following.

- The facility was fined \$2,000 pursuant to a Stipulation and Order issued December 9, 2005 for surveillance findings on June 17, 2003. Deficiencies were found under 10 NYCRR 415.12(c) – Quality of Care: Pressure Sores and 10 NYCRR 415.12(g) Quality of Care: Enteral Feeding tubes.
- The facility was fined \$4,000 pursuant to a Stipulation and Order issued November 23, 2007 for surveillance findings on May 22, 2007. Deficiencies were found under 10 NYCRR 415.12 - Quality of Care and 10 NYCRR 415.12(j) - Quality of Care: Hydration.

A review of **Golden Gate Rehabilitation and Health Care Center** for the period identified above reveals the following.

- The facility was fined \$20,000 pursuant to a Stipulation and Order issued July 9, 2009 for surveillance findings on June 27, 2009. Deficiencies were found under 10 NYCRR 415.12(h)(2) - Quality of Care: Accidents and 10 NYCRR 415.26 - Organization and Administration.
- The facility was fined \$10,000 pursuant to Stipulation and Order issued December 16, 2011 for surveillance findings on November 24, 2010. Deficiencies were found under 10 NYCRR 415.12(c)(2) - Quality of Care: Pressure Sores.

A review of **Rockville Skilled Nursing and Rehabilitation Center** for the period identified above reveals the following.

- The facility was fined \$7,500 pursuant to a Stipulation and Order issued September 17, 2007 for surveillance findings on August 28, 2006 and March 29, 2007. Deficiencies were found under 10 NYCRR 415.11(c)(3)(1) - Resident Assessment and Care Planning: Comprehensive Care Plans; 10 NYCRR 415.12 - Quality of Care: Mental and Psychosocial Functioning; 10 NYCRR 415.12(h) - Quality of Care: Accidents; 10 NYCRR 415.3(e)(2)(ii)(b) - Residents Rights: Right to Clinical Care and Treatment; 10 NYCRR 415.5(g)(1)(i-vx) - Quality of Life: Social Services; 10 NYCRR 415.11(c)(2)(i-iii) - Resident Assessment and Care Planning: Comprehensive Care Plans; and 10 NYCRR 415.(b)(1)(i-ii) Medical Services: Physician Services.

A review of **Split Rock Rehabilitation and Health Care Center** for the period identified above reveals the following.

- The facility was fined \$6,000 pursuant to Stipulation and Order issued March 19, 2007 for surveillance findings on December 5, 2005. Deficiencies were found under 10 NYCRR 415.4(b) - Resident Behavior and Facility Practices: Staff Treatment of Residents; 10 NYCRR 415.11(c) - Resident Assessment and Care Planning: Comprehensive Care Plans, and 10 NYCRR 415.12(k)(6) - Quality of Care: Special Needs.

A review of **Spring Creek Rehabilitation and Nursing Center** for the period identified above reveals the following.

- The facility was fined \$2,000 pursuant to Stipulation and Order issued August 1, 2005 for surveillance findings on November 20, 2002. Deficiencies were found under 10 NYCRR 415.12(h) - Quality of Care: Accidents.
- The facility was fined \$2,000 pursuant to Stipulation and Order issued June 16, 2006 for surveillance findings on October 8, 2003. Deficiencies were found under 10 NYCRR 415.4(b) - Resident Behavior and Facility Practices: Staff Treatment of Residents.

A review of **The Hamptons Center for Nursing** for the period identified above reveals the following.

- The facility was fined \$8,000 pursuant to a Stipulation and Order issued June 1, 2009 for surveillance findings on April 21, 2009. Deficiencies were found under 10 NYCRR 415.4(b)(1)(ii) Resident Behavior and Facility Practices: Staff Treatment of Residents, NYCRR 415.12(h)(2) Quality of Care: Accidents and 415.26 Organization and Administration.
- The facility was fined \$4,000 pursuant to a Stipulation and Order issued December 6, 2010 for surveillance findings on September 16, 2009. Deficiencies were found under 10 NYCRR 415.12(h)(1)(2) Quality of Care: Accidents & Supervision and 415.26 Administration.
- The facility was fined \$10,000 pursuant to Stipulation and Order issued May 24, 2011 for surveillance findings on July 30, 2010. Deficiencies were found under 10 NYCRR 415.12 - Provide Care/Services for Highest Well Being.

A review of **Wedgewood Care Center** for the period identified above reveals the following.

- The facility was fined \$1,000 pursuant to Stipulation and Order issued August 16, 2005 for surveillance findings on August 27, 2004. Deficiencies were found under 10 NYCRR 415.12(c)(2) - Quality of Care: Pressure Sores.

A review of operations for the **Bay Park Center for Nursing and Rehabilitation, Bayview Nursing and Rehabilitation Center, Brookhaven Rehabilitation and Health Care Center, Crown Center for Nursing and Rehabilitation, Eastchester Rehabilitation and Health Care Center, Golden Gate Rehabilitation and Health Care Center, Rockville Skilled Nursing and Rehabilitation Center, Split Rock Rehabilitation and Health Care Center, Spring Creek Rehabilitation and Nursing Center, the Hamptons Center for Rehab and Nursing, and the Wedgewood Care Center** for the period identified above, results in a conclusion of substantially consistent high level of care since there were no repeat enforcements.

A review of operations for the **Little Neck Nursing Home, Forest Hills Care Center, Grace Plaza Nursing and Rehabilitation Center, Meadow Park Rehabilitation and Health Care Center, New Surfside Nursing Home, Park Avenue Extended Care Facility, Throgs Neck Extended Care Facility, White Plains Center for Nursing, Woodmere Rehabilitation and Health Care Center, Diamond Hill Nursing and Rehabilitation Center, Nassau Extended Care Facility, Pathways Nursing and Rehabilitative Center – Hilltop, Rosewood Rehabilitation and Nursing Center, Tarrytown Hall Care Center, Townhouse Extended Care Center, and the Nathan Miller Center for Nursing** for the periods identified above, results in a conclusion of substantially consistent high level of care since there were no enforcements.

A review of operations for **Hawthorn Health Multicare Center for Living and Harbour Health Multicare Center for Living** the period identified above, results in a conclusion of substantially consistent high level of care since there were no enforcements.

A review of the operations for **Privilege Care Diagnostic and Treatment Center** for the period identified above, results in a conclusion of substantially consistent high level of care since there were no enforcements.

A review of the operations for **Oceanview Manor Home for Adults** for the period identified above reveals the following

- An enforcement action was taken in 2005 against Oceanview Manor Home for Adults based on January 2004 and April 2004 surveys citing violations under in Housekeeping and Maintenance, and February 2004 and May 2004 surveys citing violations in Medication management, Personnel and Smoke/Fire Protection. This enforcement action was resolved with a \$1,500 civil penalty. Deficiencies were found under 18 NYCRR 487.4(b)(5&15), 487.5(a)(3ix)&(b)(2), 487.7(d)(11)&(e)(9)&(f)(5)&(h)(1), 487.8(e)(1), 487.9(a)(15)&(c)(15,17-18), 487.10(d)(1-2), 487.11(f)(19)&(j)(1-3), and 487.12(a-b).
- The facility was fined \$7,000 pursuant to a Stipulation and Order for surveillance findings on May 5, 2010, December 9, 2010, and May 4, 2011. Deficiencies were found under 18 NYCRR 487.7(f)(5) – Resident Services; 18 NYCRR 487.7(f)(12)(ii) – Resident Services; 18 NYCRR 487.8(e)(1) – Food Service; 18 NYCRR 487.11(f)(19) Environmental Standards; and 18 NYCRR 487.11(f)(k)(1-3) – Environmental Standards.

Upon the detailed review of the actual violations for the enforcements listed above a determination was made that they did not constitute repeat violations nor an immediate jeopardy to the health, safety, and well-being of the residents of the adult care facility. Thus, a review of operations for the **Oceanview Manor Home for Adults** for the period identified above results in a conclusion of substantially consistent high level of care.

A review of the operations for **Excellent Home Care Services, LLC** for the period identified above reveals the following.

A Settlement Agreement was signed in December, 2009 between the New York State Office of the Attorney General and Excellent Home Care Services, LLC regarding the fraudulent submission of Medicaid claims and the receipt of payments for home health aide services. Excellent Home Care Services, LLC was cited for hiring home health aides who had presented false certifications indicating their satisfactory completion of the required home health aide training program, and for the submission of claims to Medicaid for home health aide services all or a portion of which were not rendered as claimed. The subject licensed home care services agency paid a total fine of \$3,730,000.

A review of Excellent Home Care Services, LLC reveals that a substantially consistent high level of care has been provided since there were no enforcements.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Membership Purchase Agreement

The applicant has submitted an executed membership purchase agreement for the change of 45% membership interest, the terms of which are summarized below:

<i>Purpose:</i>	The sale of 45% membership interests of Parkview Care and Rehabilitation Center.
<i>Sellers:</i>	Judith Jones-Calnan
<i>Purchasers:</i>	Ben Landa (22.50%), Bent Philipson (10%), Anne Gottlieb (10%) and Jennifer Strauss (2.5%)
<i>Purchase Price:</i>	\$2,122,607.74 (\$47,169.10 per percent)
<i>Payment of Purchase Price:</i>	The payment is comprised of 3 components: (1) the cash sum of \$404,392.26 to be

paid at \$1,000 per month for 42 months, due and payable to the sellers on the first day of each month commencing with the first month after the effective date. On the later of the first day of the 43rd month after the effective date (the payout date) or the second closing date, \$362,392.26 is due and payable to the sellers.

(2) Assumed funds priority claims in the sum of \$512,145.27, were assumed by the purchasers and paid directly to the SEIU 1199 benefit fund.

(3) the DOH assessment payment in the sum of \$1,206,070.21 shall be payable by the purchasers to the Department of Health in quarterly installments pursuant to the schedule set forth in the revised third amended plan of reorganization, after payment by Parkview Care and Rehabilitation Center, Inc., of the first \$512,145.27 of the assessment; the total DOH assessment payment is for \$1,718,215.48, which has been split up as shown above.

Capability and Feasibility

The issue of capability centers on the applicant's ability to meet the purchase price for their respective ownership percentages. Presented as BFA Attachment A is the summary net worth statements for the proposed members. Several of the current members and the proposed members have provided affidavits that state they will cover any of the other members' unmet equity requirements. Per BFA Attachment A, it appears that the applicant has sufficient resources to meet the terms for the purchase price.

The issue of feasibility is centered on the applicant's ability to offset expenses with revenue and maintain a viable operating entity. The submitted budget indicates an excess of revenues over expenses of \$232,581 during the first and third years of operation. The applicant indicates that the budgeted turnaround from the previous losses is due primarily to three factors: (1) reducing nursing hours, which saved approximately \$300,000, (2) switching to one food vendor instead of several, which allowed them to get better rates, which saved them approximately \$500,000, and, (3) the facility underwent staff changes, which saved them approximately \$100,000. The budget appears reasonable.

As shown on BFA Attachment B, Financial Summary Parkview Care and Rehabilitation Center had average negative working capital and net asset positions, and generated an average net loss of \$433,046 during the period 2009 through 2011. The reason for the loss from 2009-2011 was caused by the facility declaring bankruptcy and incurring a large amount of administrative expenses during this time. In order to correct this, the facility sold a total of 45% of their ownership to Ben Landa (22.50%), Bent Philipson (10.00%), Anne Gottlieb (10.00%), and Jennifer Strauss (2.50%). The applicant has expectations that by using Mr. Landa's and Mr. Philipson's expertise in reviving and operating nursing homes, that the facility will be able to achieve positive financial results.

As shown on BFA Attachment C Financial Summary for Avalon Gardens Rehabilitation and Health Care Center had an average negative working capital position and an average positive net asset position, and generated an average net income of \$1,307,820 during the period 2008 through 2011.

As shown on BFA Attachment D Financial Summary for Bay Park Center for Nursing and Rehab, had an average negative working capital position and an average negative net asset position, and generated an average net loss of \$1,958,712 during the period 2008 through 2011. The loss for both 2008 and 2009 was due to the fact that the operation was purchased in 2007, and was still operating at the budgeted rate.

In 2010, the facility achieved profitability due to receiving a significant retroactive adjustment and receiving the correct operating rate. The 2011 loss is due to the facility being negatively impacted by the new reimbursement methodology. They are currently working to address this issue and return back to profitability.

As shown on BFA Attachment E Financial Summary for Bayview Nursing and Rehabilitation Center, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$1,098,706 during the period 2008 through 2011.

As shown on BFA Attachment F Financial Summary for Brookhaven Rehabilitation Healthcare Center, had average positive working capital position and an average positive net asset position, and generated an average net income of \$1,735,195 during the period 2008 through 2011.

As shown on BFA Attachment G Financial Summary for Eastchester Rehabilitation and Health Care Center, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$681,323 during the period 2008 through 2011.

As shown on BFA Attachment H Financial Summary for Forest Hills Care Center, had an average positive working capital and net asset positions, and generated an average net income of \$240,964 during the period 2008 through 2011. The 2011 loss is attributed to a change in the Medicaid rate methodology and a related party management fee payment of \$360,000. The facility is working on ways to address this, and return the facility back to profitability.

As shown on BFA Attachment I Financial Summary for Garden Care Center, had an average positive working capital position and an average positive net asset position, and generated an average net loss of \$305,139 during the period 2008 through 2011. The 2011 loss was due to the DOH Medicaid retroactive adjustment. The facility has however been able to become profitable again and as of the July 31, 2012, internal financial statements they have shown a net income of \$564,782.

As shown on BFA Attachment J Financial Summary for Golden Gate Rehabilitation and Health Care Center, had average negative working capital and an average positive net asset position, and generated an average net income of \$706,921 during the period 2008 through 2011.

As shown on BFA Attachment K Financial Summary for Grace Plaza Nursing and Rehabilitation Center, had average positive working capital and net asset positions, and generated an average net income of \$1,752,066 during the period 2008 through 2011.

As shown on BFA Attachment L Financial Summary for Meadow Park Rehabilitation and Health Care Center, had average negative working capital and net asset positions, and generated an average net income of \$262,485 during the period 2008 through 2011. The 2011 loss was attributable to the elimination of the previously paid trend factor. The facility is working towards returning the operations to a positive position at this time.

As shown on BFA Attachment M Financial Summary for New Surfside Nursing Home, had an average positive working capital position and a negative net asset position, and generated an average net loss of \$1,529,443 during the period 2008 through 2011. The Loss in 2009 was due to a one time adjustment in the case mix index. The 2011 loss was due to the Medicaid retroactive adjustment and the elimination of the previously paid trend factor. The facility is working towards returning the operations to a positive position at this time.

As shown on BFA Attachment N Financial Summary for Rockville Residence Manor, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$505,832 during the period 2008 through 2011.

As shown on BFA Attachment O Financial Summary for Split Rock Rehabilitation and Health Care Center, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$1,706,778 during the year 2008. None of the current or incoming members of Parkview Care and Rehabilitation Center, Inc. held any ownership interest in the facility after February 2009.

As shown on BFA Attachment P Financial Summary for The Hamptons Center for Rehabilitation and Nursing, had an average negative working capital position and an average negative net asset position, and generated an average net loss of \$1,424,545 during the period 2008 through 2011. The loss was caused by the facility just opening in July 2006, and being under the initial budget based rate. In 2009, the facility was able to reduce their losses by almost one million dollars from 2008. This was accomplished through a reduction in costs and a favorable working capital loan refinancing, as well as the facility receiving a rebased rate based on the 2008 cost report submission. Also, the facility reduced expenses by using more staff and reducing the use of outside agencies. By doing this, the operation expects to become profitable within the next 3 to 5 years. By the end of 2010, the facility achieved its first profitable year of operations with a net income of \$3,911,918 and in 2011, achieved its second profitable year with a net income of \$866,956.

During the first few years that the facility was in operation, the losses were covered by a credit line from the bank and from member's funds, which were more than sufficient to cover historical and projected losses.

As shown on BFA Attachment Q Financial Summary for Willoughby Rehabilitation and Health Care Center, had an average negative working capital position and an average negative net asset position, and generated an average net loss of \$6,750 during the period 2008 through 2011.

The 2009 loss was due to the facility's operations being in their first year at its new facility; they had not received the correct reimbursement rate based on the new property, plus the occupancy rate was lower than 2008, due to the fact that not all of the patients had been transferred to the new facility. Since that time, the facility has received the correct reimbursement rate and the patient census has been stable. These one time occurrences have since been corrected and Willoughby is now profitable.

As shown on BFA Attachment R Financial Summary for Woodmere Rehabilitation and Health Care Center, had an average positive working capital position and an average positive net asset position, and generated an average net income of \$1,647,493 during the period 2008 through 2011.

As shown on BFA Attachment S Financial Summary for Nassau Extended Care Facility, had an average positive working capital position and an average positive net asset position, and generated an average net income of \$1,129,553 during the period 2008 through 2011.

As shown on BFA Attachment T Financial Summary for Park Avenue Extended Care Facility, had an average positive working capital position and an average positive net asset position, and generated an average net income of \$733,921 during the period 2008 through 2011. The 2011 loss was due to the Department of Health's Medicaid retroactive adjustment.

As shown on BFA Attachment U Financial Summary for Throgs Neck Extended Care Facility, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$317,198 during the period 2008 through 2011.

As shown on BFA Attachment V Financial Summary for Townhouse Extended Care Center, had an average positive working capital position and an average positive net asset position, and generated an average net loss of \$118,982 during the period 2008 through 2011. The 2008 loss was caused by a prior period liability being accrued in 2008; the accrual was for \$1,054,509 for a Medicaid overpayment. This is a one time occurrence and without the accrual, the facility would have had positive income for the year. The 2011 loss was due to an increase in employee benefits; in 2011, the union rate increased and also an accrued union audit was settled. The audit adjustment is a one time occurrence, but the union rate is not and the applicant indicates that the facility needs to address this in the future in order to keep the facility operating profitability.

As shown on BFA Attachment W Financial Summary for Nathan Miller Center for Nursing, Nathan Miller had average negative working capital and net asset positions, and generated an average net loss of \$30,485 during the period 2008 through 2010. The loss was caused by the facility not receiving their rebased rates for several years after the change in ownership took place in October 2004.

The facility started receiving the rebased rate in 2008, and in 2008, showed a positive net income due to their receiving all of the rebased rates and relevant adjustments in 2008. In 2009, the facility again had a negative net income. The operator indicates that the loss is due to the facility being too small to achieve a breakeven or profitable position. The facility had a plan to build, and add more beds in order to become financially feasible, but this expansion was stopped by a community effort. The operator has decided to sell the facility and it will be converted into an assisted living program (ALP). The closure plan called for a February 2011 closing date and the facility was closed as of February 7, 2011.

As shown on BFA Attachment X Financial Summary for White Plains Center for Nursing, had an average negative working capital position and an average positive net asset position, and generated an average net income of \$514,792 during the period 2008 through 2011. The 2008 loss was due to the fact that the facility did not begin receiving reimbursement at the rebased rate for a lengthy period of time, which had a negative impact on the facility's revenues, which resulted in the loss. As of 2009, the facility has been receiving the rebased rates and has been profitable ever since.

Based on the preceding, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner and approval is recommended

Recommendation

From a financial perspective, approval is recommended.

Attachments

BFA Attachment A	Net Worth Proposed Members
BFA Attachment B	Financial Summary- Parkview Care And Rehabilitation Center
BFA Attachment C	Financial Summary- Avalon Gardens Rehabilitation and Health Care Center
BFA Attachment D	Financial Summary- Bay Park Center For Nursing and Rehab
BFA Attachment E	Financial Summary- Bayview Nursing and Rehabilitation Center
BFA Attachment F	Financial Summary- Brookhaven Rehabilitation Healthcare Center
BFA Attachment G	Financial Summary- Eastchester Rehabilitation and Health Care Center
BFA Attachment H	Financial Summary- Forest Hills Care Center
BFA Attachment I	Financial Summary- Garden Care Center
BFA Attachment J	Financial Summary- Golden Gate Rehabilitation and Health Care Center
BFA Attachment K	Financial Summary- Grace Plaza Nursing and Rehabilitation Center
BFA Attachment L	Financial Summary- Meadow Park Rehabilitation and Health Care Center
BFA Attachment M	Financial Summary- New Surfside Nursing Home
BFA Attachment N	Financial Summary- Rockville Residence Manor
BFA Attachment O	Financial Summary- Split Rock Rehabilitation and Health Care Center
BFA Attachment P	Financial Summary- The Hamptons Center for Rehabilitation and Nursing
BFA Attachment Q	Financial Summary- Willoughby Rehabilitation and Health Care Center
BFA Attachment R	Financial Summary- Woodmere Rehabilitation and Health Care Center
BFA Attachment S	Financial Summary- Nassau Extended Care Facility
BFA Attachment T	Financial Summary- Park Avenue Extended Care Facility
BFA Attachment U	Financial Summary- Throgs Neck Extended Care Facility
BFA Attachment V	Financial Summary- Townhouse Extended Care Center
BFA Attachment W	Financial Summary- Nathan Miller Center for Nursing
BFA Attachment X	Financial Summary- White Plains Center for Nursing

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer the total 45% stock of Judith Jones as follows; 32.5% to existing members, 10% to new member Anne Gottlieb and 2.5% to new member Jennifer Strauss, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

121009 E

Parkview Care and Rehabilitation Center, Inc.
d/b/a Parkview Care and Rehabilitation Center

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122078-E
Litson Certified Care, Inc.
d/b/a Willcare

County: Greene (Catskill)
Purpose: Establishment

Program: Certified Home Health Agency
Submitted: August 10, 2012

Executive Summary

Description

Litson Certified Care, Inc. d/b/a Willcare (Willcare), an existing Article 36 proprietary corporation, requests approval to purchase certain assets of the Greene County Health Department's certified home health agency (CHHA), serving the residents of Greene County. The application seeks to add Greene County to Willcare's current operating certificate for their Orange County location. At the present time, the Greene county patients will be served from the current branch location in Lake Katrine (Ulster County).

Willcare currently operates Article 36 CHHAs in the following counties: Orange, Ulster, and Westchester, along with a long term home health care program (LTHHCP) in Ulster County, and a special needs CHHA in Sullivan, Dutchess, and Putnam Counties. Litson Certified Care, Inc. d/b/a Willcare acquired the assets of the Ulster County CHHA and LTHHCP, via an asset purchase agreement – CON #101147-E, contingently-approved Public Health and Health Planning Council (PHHPC) with contingent approval on June, 16, 2011, final approval October 21, 2011.

Litson Certified Care, Inc. is a wholly-owned subsidiary of Bracor, Inc. d/b/a Willcare. Bracor, Inc. d/b/a Willcare, as a parent corporation, owns and operates through its subsidiaries, licensed and certified home health care agencies in Western New York, the Hudson Valley, Ohio and Connecticut. Bracor, Inc. d/b/a Willcare is currently owned by:

David Brason	(13.92%)
Todd Brason	(13.92%)
Summer Street Capital II, L.P.	(48.10%)
Summer Street Capital NYS Fund II, L.P.	(24.06%)

DOH Recommendation

Contingent approval.

Program Summary

Litson Certified Care, Inc. d/b/a Willcare and its principals all possess the appropriate character and competence for approval of this application.

Financial Summary

The \$125,000 asset purchase price for Greene County's CHHA will be provided from accumulated funds of the company. There are no project costs associated with this proposal.

Budget:	<i>Revenues:</i>	\$ 385,623
	<i>Expenses:</i>	<u>309,050</u>
	<i>Gain/(Loss):</i>	\$ 76,573

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed Administrative Services Agreement that is acceptable to the Department of Health.
[BFA]

Council Action Date

February 7, 2013.

Programmatic Analysis

Background

Litson Certified Care, Inc., a business corporation, operating under the assumed name of WILLCARE, was established as the operator of an Article 36 general population certified home health agency (CHHA) serving Orange, Ulster and Westchester Counties, a special needs CHHA serving Dutchess, Putnam and Sullivan Counties and a Long Term Home Health Care Program (LTHHCP) serving Ulster County.

Litson Certified Care, Inc. is applying for approval to purchase and become the new owner/operator of the CHHA currently operating Greene County Department of Health Home Health Agency. Litson Certified Care, Inc. d/b/a WILLCARE plans to merge the Greene County Department of Health CHHA operations into its existing Litson Certified Care, Inc. d/b/a WILLCARE CHHA and close Greene County Department of Health CHHA. Litson Certified Care, Inc. d/b/a WILLCARE proposes to serve its CHHA patients in Greene County from their existing branch office located in Lake Katrine, NY, Ulster County, which is contiguous to Greene County.

The Litson Certified Care, Inc. d/b/a WILLCARE CHHA, will be approved as a general service CHHA serving Greene, Orange, Ulster and Westchester Counties and a Special Needs CHHA serving the OPWDD populations in Dutchess, Putnam and Sullivan Counties. Litson Certified Care, Inc. d/b/a WILLCARE CHHA will continue to provide the services of Home Health Aide, Medical Social Services, Medical Supplies/Equipment/Appliances, Nursing, Occupational Therapy, Physical Therapy, Respiratory Therapy, Audiology, Personal Care, Homemaker, Housekeeper and Speech Language Pathology.

Litson Certified Care, Inc. d/b/a WILLCARE is a wholly owned subsidiary of Western Region Health Corporation d/b/a WILLCARE. Western Region Health Corporation is a wholly owned subsidiary of Bracor, Inc.

Western Region Health Corporation, Inc., Litson Certified Care, Inc., and the WILLCARE LTHHCP currently operate under a management agreement with their ultimate parent corporation Bracor, Inc. Summer Street Capital II, LP; and Summer Street Capital NYS Fund II, LP, both currently operate under a management agreement with Summer Street Capital Partners, LLC.

Litson Certified Care, Inc. d/b/a WILLCARE is authorized 200 shares of stock. 181 shares have been issued to Western Region Health Corporation, Inc. 19 shares remain unissued.

The members of the Board of Directors of Litson Certified Care, Inc. will be as follows:

<p>Todd W. Brason, President President and CEO, Bracor, Inc. d/b/a WILLCARE</p> <p><u>Affiliations:</u></p> <ul style="list-style-type: none">• Western Region Health Corporation, Inc. d/b/a WILLCARE (CHHA);• Litson Certified Care, Inc. d/b/a WILLCARE (CHHA);• Litson Healthcare, Inc. d/b/a WILLCARE (LHCSA);• WILLCARE, Inc. (LHCSA);• BHC Services, Inc. (Ohio CHHA and LHCSA)• Patient's Choice Homecare, LLC d/b/a WILLCARE (Connecticut CHHA) <p>Andrew L. Fors, Director Partner, Summer Street Capital Partners, LLC</p> <p><u>Affiliations:</u></p> <ul style="list-style-type: none">• Western Region Health Corporation, Inc.	<p>Michael P. McQueeney, Director Managing Partner, Summer Street Capital Partners, LLC</p> <p><u>Affiliations:</u></p> <ul style="list-style-type: none">• Western Region Health Corporation, Inc. d/b/a WILLCARE (CHHA);• Litson Certified Care, Inc. d/b/a WILLCARE (CHHA);• Litson Healthcare, Inc. d/b/a WILLCARE (LHCSA);• WILLCARE, Inc. (LHCSA);• BHC Services, Inc. (Ohio CHHA and LHCSA)• Patient's Choice Homecare, LLC d/b/a WILLCARE (Connecticut CHHA)
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- d/b/a WILLCARE (CHHA);
- Litson Certified Care, Inc. d/b/a WILLCARE (CHHA);
- Litson Healthcare, Inc. d/b/a WILLCARE (LHCSA);
- WILLCARE, Inc. (LHCSA);
- BHC Services, Inc. (Ohio CHHA and LHCSA)
- Patient's Choice Homecare, LLC d/b/a WILLCARE (Connecticut CHHA)

Western Region Health Corporation, Inc. is authorized 200 shares of stock, all of which are issued. Bracor, Inc. d/b/a is the current stockholder of the corporation and owns all 200 shares of stock.

The members of the Board of Directors of Western Region Health Corporation, Inc. will be as follows:

Todd W. Brason, President - Director
Previously Disclosed

Michael P. McQueeney - Director
Previously Disclosed

Andrew L. Fors - Director
Previously Disclosed

Bracor, Inc., a New York corporation, has 1,500,000 shares authorized, consisting of: (a) 90,000 shares of Series A Voting Common Stock, (b) 90,000 shares of Series B Non-Voting Common Stock, and (c) 1,320,000 shares of Preferred Stock, consisting of: (i) 1,200,000 shares of Series A Preferred Stock, and (ii) 120,000 shares of undesignated Preferred Stock. As of December 6, 2010, there are currently 11,970.44 shares of Series A Voting Common Stock and 474,029.55 shares of Series A Preferred Stock issued and outstanding. The board has issued to the shareholders warrants to purchase an aggregate of 30,000 shares of Series A Voting Common Stock at a purchase price of \$0.01 per share. The warrants expire on May 21, 2024. No shares of Series B Non-Voting Common Stock have been issued, though the board has granted to certain employees, directors and consultants options to purchase 33,271 shares of Series B Non-Voting Common Stock at an exercise price of \$1.23 per share. Current shareholders and their shareholdings are as follows:

<u>Shareholder</u>	<u>Number of Shares of Series A Voting Common Stock</u>	<u>Warrants to Purchase Shares of Series A Voting Common Stock</u>	<u>Number of Shares of Series A Preferred Stock</u>
Summer Street Capital II, L.P.	5,758.07	14,666.67	228,019.70
Summer Street Capital NYS Fund II, L.P.	2,879.03	7,333.33	114,009.85
David Brason	1,666.67	3,000.00	66,000.00
Todd Brason	1,666.67	5,000.00	66,000.00
<i>Total</i>	<i>11,970.44</i>	<i>30,000.00</i>	<i>474,029.55</i>

The private equity investment funds themselves will be passive investors that will not exercise any control or decision making over Bracor, Inc. or its subsidiary corporations operating the CHHAs and LTHHCP. Instead, the investment funds' management company, Summer Street Capital Partners, LLC, will be the controlling entity of the Bracor, Inc. stock holdings that are allocated to its respective funds.

The members of the Board of Directors of Bracor, Inc. will be as follows:

Todd W. Brason – President
Previously Disclosed

David W. Brason, Secretary/Treasurer
Vice President and CFO, Bracor, Inc. d/b/a WILLCARE
Affiliations:

- Western Region Health Corporation, Inc. d/b/a WILLCARE (CHHA);
- Litson Certified Care, Inc. d/b/a WILLCARE (CHHA);
- Litson Healthcare, Inc. d/b/a WILLCARE (LHCSA);
- WILLCARE, Inc. (LHCSA);
- BHC Services, Inc. (Ohio CHHA and LHCSA)
- Patient's Choice Homecare, LLC d/b/a WILLCARE (Connecticut CHHA)

Michael P. McQueeney - Director
Previously Disclosed

Andrew L. Fors - Director
Previously Disclosed

Baris Civelek – Director
Principal, Summer Street Capital

The current partners of Summer Street Capital II, LP consist of 54 partners, whose individual partnership interests total 100%. The only two partners owning 10% or more interest in the LP are HSBC Capital (USA), Inc. with 11.7% partnership interest, and Summer Street Capital II Advisors, LLC with 17.3% partnership interest. The current partners of Summer Street Capital NYS Fund II, LP are The NYS Common Retirement Fund with 99% partnership interest, and Summer Street Capital II Advisors, LLC with 1% partnership interest. As explained above, the individual equity funds themselves will be passive investors that will not possess any voting rights in, or exercise any control or decision making over, Bracor, Inc. or its subsidiary corporations operating the CHHAs and LTHHCP. Accordingly, the individual partners within each limited partnership will also have no voting rights or control in Bracor, Inc. The investment funds' management company, Summer Street Capital Partners, LLC, will be the sole voting and controlling entity of the Bracor, Inc. stock holdings that are allocated to its respective funds.

The current members of the managing company of the two Summer Street funds, Summer Street Capital Partners, LLC, and the percentage of member ownership interest for each, are as follows:

Michael P. McQueeney – 35.8% interest
Managing Member
Previously Disclosed

Andrew L. Fors – 16.5% interest
Previously Disclosed

Jennifer C. Balbach – 5.9% interest
Partner, Summer Street Capital Partners, LLC

Brian T. D'Amico – 27.6% interest
Managing Partner, Summer Street Capital Partners, LLC

Gary P. Hull – 14.2% interest
Partner, Summer Street Capital Partners, LLC

A search of all of the above named individuals, employers, and affiliations revealed no matches on either the Medicaid Disqualified Provider List or the Office of the Inspector General's Provider Exclusion List.

The Division of Home and Community Based Care reviewed the compliance histories of the CHHAs, LHCSAs, and LTHHCP and determined that the agencies have exercised sufficient supervisory responsibility to protect the health, safety, and welfare of patients and to prevent the recurrence of code violations.

Out-of-State Compliance Request Forms were sent to Ohio and Connecticut. The licensing / regulating agencies of the State of Ohio and the State of Connecticut have reviewed the compliance history of the above noted health care provider. Ohio has determined that the health care provider has been in substantial compliance with all applicable

codes, rules, and regulations, with no enforcements or administrative actions imposed. Although Connecticut indicated that they would not “rate” any agency, the information provided did not indicate any enforcement action.

A review of all personal qualifying information indicates there is nothing in the background of the principals listed above to adversely effect their positions in the proposed organizational structure. The applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Total Project Cost and Financing

There are no project costs associated with this application. The purchase price of \$125,000 will be paid by cash from applicant resources at closing.

Asset Purchase Agreement

The change in ownership will be effectuated in accordance with an executed asset purchase agreement, the terms of which are summarized below:

- Date:* May 9, 2012
- Sellers:* County of Greene, a political subdivision of New York State
- Buyers:* Litson Certified Care, Inc. d/b/a Willcare
- Assets Purchased:* All rights, title, interest to the following: CHHA ownership and operating rights; copies of all current patient lists, the goodwill of the agency; and all sellers’ rights under assumed operating contracts.
- Assumed Liabilities:* No liabilities assumed
- Excluded Liabilities:* Buyer shall not assume or be responsible for any obligations of the Seller, further describe as: accounts payable, any amounts owed to Medicare, Medicaid, or third party payor; any liability arising from provider agreements or operating contracts; any liability for employee compensation; any liability arising from excluded assets; all contracts, understandings, and collective bargaining; and any an all claims.
- Purchase Price:* \$125,000
- Payment Terms:* Payable in full at closing

The applicant has provided an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility.

Adminstrative Services Agreement

Litson Certified Services, Inc. d/b/a Willcare, has entered into an Administrative Services Agreement with Bracor, Inc., for their other CHHA and LTHHCPs and will allow them to provide the services for this facility as well, the terms of which are summarized below. They are currently in the process of signing a renewal of the current agreement.

- Provider:* Bracor, Inc.
- Facility Operator:* Litson Certified Services, Inc. d/b/a/Willcare.
- Services Provided:* Accounting, payroll, accounts payable, Medicare Medicaid and LTHHCP cost reports preparation, analysis and submission, evaluation of accounts receivable, financial reporting and analysis, human resources, computer and MIS, general and administrative, and insurance.
- Term:* Renewal of their current 3 year term ending December 31, 2012, to be renewed for an additional 3 year ending December 31, 2015.
- Compensation:* \$135,000 a month (\$1,620,000 annually)

Although the agreement provides for the contracting of multiple services, the facility will maintain ultimate authority and responsibility for the conduct of the operation of the facility. Specifically, the operator will retain authority for maintenance of the facility's fiscal stability, level of services and quality of care; hiring and termination of key management personnel such as the administrator; controlling and maintaining books and business records; disposing of assets and incurring liabilities; adopting and enforcing policies, and employment of all professional staff.

Operating Budget

The applicant has submitted an incremental operating budget for the first and third years, in 2012 dollars, which is summarized below:

	<u>Year One</u>	<u>Year Three</u>
<u>Revenues:</u>		
Medicaid	\$97,261	\$105,042
Medicaid Managed Care	7,040	7,603
Medicare	196,591	212,319
Medicare Managed Care	13,071	14,117
Commercial	36,449	39,364
Other	<u>6,646</u>	<u>7,178</u>
Total Revenues	\$357,058	\$385,623
Expenses	<u>\$286,157</u>	<u>\$309,050</u>
Net Gain(Loss)	\$70,901	\$76,573

Utilization by payor source for combined programs in the first and third years is as follows:

<u>Payor</u>	<u>Years One and Three</u>
Commercial	11.25%
Medicare	60.69%
Medicare Managed Care	2.84%
Medicaid	18.62%
Medicaid Managed Care	1.47%
Other	2.66%
Charity Care	2.47%

Expense and utilization assumptions are based on the existing CHHA Program's historical experience. Revenues are reflective of current payment rates, as well as the recent implementation of the Medicaid Episodic Payment System, in which the lower of the incremental cost to episodic payment was projected for year one and year three for a conservative approach.

Capability and Feasibility

There are no project costs associated with this application. The \$125,000 purchase price for Clinton County's CHHA assets will be funded from accumulated funds of the company. Presented as BFA Attachment B, is the certified financial statement for the facility, which shows adequate resources to fund the purchase.

Working capital requirements are estimated at \$51,508, which appears reasonable based upon two months of third year expenses. A review of BFA Attachment B demonstrates the ability to provide the financial support for this project.

The budgets project an operating surplus of \$70,901 and \$76,573 in the first and third years, respectively. Revenues were estimated based the payors' current reimbursement methodology. The budget appears reasonable.

Presented as BFA Attachment A is the 2009 - 2010 certified financial statements for Bracor, Inc. and Subsidiaries, which shows a negative average working capital position and a positive average equity position for the period shown. The facility also has an average positive net income of \$3,591,001 for the period shown.

Presented as BFA Attachment B, is the 2011 interim financial statements for Bracor, Inc. and Subsidiaries, which shows a negative working capital position, a positive net asset position, and an overall net loss of \$421,484. The loss is due to a computer crash in July of 2011, which caused substantial AR balances at year end due to the recovery process, and delays in addition to other year end adjustments. In order to account for this, the auditors required a large reserve of almost 2 million dollars on the books to account for possible bad debt. If this situation did not happen, and the reserve was not required, Bracor would have had a positive net income of \$1,502,197 for 2011.

Presented as BFA Attachment C is the 2009 - 2011 certified financial statements for Litson Certified Care, Inc., which shows a positive average working capital position and a positive average equity position for the period shown. The facility also had an average positive net income of \$3,386,906 for the period shown.

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

<h2>Attachments</h2>

BFA Attachment A	Financial Summary for the certified 2009-2010 Bracor, Inc. and Subsidiaries financial statements
BFA Attachment B	Financial Summary for the interim 2011 Bracor, Inc. and Subsidiaries financial statements
BFA Attachment C	Financial Summary for the certified 2009-2011 Litson Certified Care, Inc.
BFA Attachment D	List of Ownership for Summer Street Capital II, LP
BFA Attachment E	List of Ownership for Summer Street Capital NYS Fund II, LP
BFA Attachment F	Organizational Chart

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to establish Litson Certified Care, Inc. d/b/a Willcare, as the new operator of Greene County's Certified Home Health Agency, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

122078 E

Litson Certified Care, Inc. d/b/a Willcare

APPROVAL CONTINGENT UPON:

1. Submission of an executed Administrative Services Agreement that is acceptable to the Department of Health. [BFA]

APPROVAL CONDITIONED UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122165-E
Hudson Valley Home Care

County: Dutchess (Poughkeepsie)
Purpose: Establishment

Program: Certified Home Health Agency
Submitted: October 1, 2012

Executive Summary

Description

Hudson Valley Home Care, Inc., an existing Article 36 CHHA serving Dutchess County proposes to purchase the assets and become the new owner/operator of the Dutchess County Department of Health Home Health Agency (CHHA). Hudson Valley Home Care, Inc. plans to merge the Dutchess County Department of Health Home Health Agency's operations into its existing CHHA operations, and close the Dutchess County Department of Health CHHA.

The applicant will continue to provide the same services as the existing operator, which are as follows: nursing care, physical therapy, speech therapy, occupational therapy, medical social services and home health aide services.

Hudson Valley Home Care (HVHC), an affiliate of Health Quest System, Inc., is a not-for-profit Certified Home Health Agency and Licensed Home Care Company. HVHC has served the residents of Dutchess County since 1987 and provides multidisciplinary services annually to over 2,000 adults, infants and children.

DOH Recommendation
Contingent approval.

Program Summary

Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Financial Summary

The purchase price for the CHHA is \$425,000 and will be met as follows: \$42,500 has been deposited with the Seller and the remaining \$382,500 will be paid at the closing.

Budget:	<i>Revenues:</i>	\$	316,694
	<i>Expenses:</i>		<u>231,814</u>
	<i>Gain/(Loss):</i>	\$	84,880

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a copy of the fully executed Bylaws of Hudson Valley Home Care, Inc., acceptable to the Department of Health. [CSL]
2. Submission of a copy of the fully executed Bylaws of Health Quest Systems, Inc., acceptable to the Department. [CSL]

Council Action Date

February 7, 2013.

Programmatic Analysis

Background

Hudson Valley Home Care, Inc., an existing Article 36 CHHA serving Dutchess County proposes to purchase the assets and become the new owner/operator of the Dutchess County Department of Health Home Health Agency (CHHA). Hudson Valley Home Care, Inc. plans to merge the Dutchess County Department of Health Home Health Agency's operations into its existing CHHA operations and to close the Dutchess County Department of Health CHHA.

Hudson Valley Home Care, Inc., an affiliate of Health Quest Systems, Inc., a not-for-profit Certified Home Health Agency and Licensed Home Care Company. Health Quests Systems, Inc. owns the following organizations:

Vassar Brothers Medical Center	Hospital
Putnam Hospital Center	Hospital
Northern Dutchess Hospital	Hospital
Northern Dutchess Residential Health Care Facility (The Thompson House)	Nursing Home
Hudson Valley Home Care, Inc. (Certified)	CHHA
Hudson Valley Home Care, Inc. (Licensed)	LHCSA

The applicant proposes to continue to operate the CHHA from its existing Dutchess County office located at 1 Pine Street Spur, Poughkeepsie, NY 12601. The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Medical Social Services
Physical Therapy	Occupational Therapy	Respiratory Therapy
Speech Language Pathology	Audiology	Nutrition
Medical Supplies, Equipment, and Appliances		

The Board of Directors of Hudson Valley Home Care, Inc., Inc. comprises the following individuals:

Anthony "Rick" Bottini, Jr. , Member Owner , Bottini Fuel	Joan A. Pagonos , Member Retired
Christopher Chestney , Member Funeral Director, Dapson-Chestney Funeral Home	Michael J. Prince , Member/Secretary Retired
Kari Redl-Daniels , Member Managing Partner, Herb Redl Properties	Herbert H. Redl , Member Founder/Partner, Herb Redl Properties
Robert Dooley , Member Owner, Mahoney's at Casperkill (restaurant)	Rose E. Rider , Member Budget Officer, Town of Red Hook
Charles A. Freni, Jr. , Member / Chairman Sr. Vice Pres, Central Hudson Gas & Electric	Thomas S. Robinson, M.D. , Member Primary Care Physician – Family Medicine
Laurence W. Johnson , Member VP of Marketing, William A. Smith & Son, Inc.	Michael T. Weber , President CEO, Health Quest Systems, Inc.
Edward L. McCormick , Member Retired	

The Board of Directors of Health Quest Systems, Inc. comprises the following individuals:

Robert R. Dyson , Chairman CEO, Patterson Planning & Services	Mary D. Madden , Second Vice Chairman CEO, Hudson Valley Federal Credit Union
Gregory W. Rakow , First Vice Chairman Owner/President, Fraleigh & Rakow Inc.	Michael T. Weber , President and CEO Disclosed above
James A. Brudvig , Member VP for Administration, Bard College	Carl E. Meyer , Member President, The Solar Energy Consortium
Thomas G. Eastwood , Member Retired	Wayne L. Nussbickel , Member President/CEO, N & S Supply
Keiren M. Farquhar , EMT, Member Medical Reserve Coordinator, Putnam County Dept. of Health	Michael J. Nesheiwat, MD , Member Primary Care Physician, Putnam Family Medicine PC
Joseph L. DiVestea , Member Financial Advisor, Merrill Lynch	Lillian S. Weigert, Esq. , Member Attorney, Gellert & Klein PC
Richard J. Friedland, MD , Member President/CEO, DRA Imaging	Michael S. Moses, MD , Member President, Cross River Anesthesiologist Sciences
Steven V. Lant , Member President/CEO, C.H. Energy Group, Inc.	

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The Office of the Professions of the State Education Department, the New York State Physician Profile and the Office of Professional Medical Conduct, where appropriate, indicate no issues with the licensure of the health professionals associated with this application.

The applicant has confirmed that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with the consultation of legal counsel, and it is concluded that proceeding with the proposal is appropriate.

A Certificate of Good Standing has been received for all attorneys.

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Vassar Brothers Medical Center	Hospital
Putnam Hospital Center	Hospital
Northern Dutchess Hospital	Hospital
Northern Dutchess Residential Health Care Facility (The Thompson House)	Nursing Home
Hudson Valley Home Care, Inc. (Certified)	CHHA
Hudson Valley Home Care, Inc. (Licensed)	LHCSA

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

The Information provided by the Bureau of Quality Assurance for Nursing Homes has indicated that the residential health care facilities reviewed have provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

The information provided by the Division of Hospitals and Diagnostic & Treatment Centers has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Background

The applicant has submitted an executed asset purchase agreement for the CHHA, which they are going to acquire, and is summarized below:

<i>Date:</i>	June 7, 2012
<i>Seller:</i>	County of Dutchess
<i>Buyer:</i>	Hudson Valley Home Care, Inc.
<i>Assets Acquired:</i>	The license or operating certificate held or owned by Seller relating to the ownership or operation of the CHHA and goodwill of the Agency.
<i>Excluded Assets:</i>	The excluded assets shall include, but not be limited to the following assets relating to the Agency; cash, prepaid expenses, accounts receivable of the Seller arising before the Closing Date and miscellaneous deposits; any records which by law Seller is required to retain in its possession; any real property; any books and records of Seller; Buyer shall not be taking over from the Seller any office space; Buyer shall not be taking over any equipment; Buyer shall not be taking over the Medicare and Medicaid provider number of the Seller; Buyer shall not be taking on Medicare/Medicaid liability except to the extent mutually agreed with the Seller; Buyer shall not be taking over staff; Buyer shall not be taking over expense (vendor) contracts and Buyer shall not be taking over revenue/affiliation contracts.
<i>Liabilities:</i>	Buyer will be responsible for the following: all liabilities relating to the Buyer's ownership or use of the Purchased Assets after the Closing Date and all liabilities for in respect to taxes (if any) in connection with the Purchased Assets that are the responsibility of the Buyer or arising after the Closing Date with respect to periods after the Closing Date.
<i>Purchase Price:</i>	\$425,000
<i>Payment of Purchase Price:</i>	Upon award of bid, Buyer shall deposit \$42,500 with Seller and the balance of \$382,500 shall be paid on the Closing Date.

The applicant submitted an affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently, there are no outstanding liabilities.

Operating Budget

The applicant has submitted an operating budget, in 2012 dollars, for the first year subsequent to the change in operator, summarized below:

Revenues:	\$316,694
Expenses:	<u>231,814</u>
Excess of Revenues over Expenses:	\$84,880

Expense and utilization assumptions are based on the applicant's historical experience. Revenues are reflective of current payment rates as well as the recent implementation of the Medicaid Episodic Payment System.

Utilization, broken down by payor source during the first year is as follows:

Medicaid Managed Care	24.04%
Medicare Managed Care	68.30%
Commercial Managed Care	7.66%

Capability and Feasibility

The purchase price for the acquisition of the CHHA is \$425,000 and will be paid via equity from Health Quest Systems, Inc.

Working capital requirements are estimated at \$38,636, which is equivalent to two months of first year expenses. The applicant will provide equity to meet the working capital requirement, which will be provided from funds of Health Quest Systems, Inc. Presented as BFA Attachment A are the 2010 and 2011 certified financial statements of Health Quest Systems, Inc. and Subsidiaries, which indicates the availability of sufficient funds for the equity contribution to meet the purchase price for the operation and the working capital requirements.

The submitted budget indicates an excess of revenues over expenses of \$84,880 during the first year subsequent to the change in operator. Revenue is based on current payment rates for certified home health agencies. The budget appears reasonable.

As shown on Attachment A, Health Quest System, Inc. and Subsidiaries had an average positive working capital position and an average positive net asset position from 2010 through 2011. Also, the entity achieved an average excess of revenues over expenses of \$15,453,500 from 2010 through 2011.

Presented as BFA Attachment B are the 2010 and 2011 certified financial statements of Hudson Valley Home Care, which is part of Health Quest Systems, Inc. As shown on Attachment B, the facility had an average negative working capital position and an average negative net asset position from 2010 through 2011. Also, the facility incurred an average excess of expenses over revenues of \$503,500 from 2010 through 2011. The applicant has indicated that the reasons for the losses are as follows: experienced clinical difficulties and experienced low volume.

The applicant has indicated that the applicant implemented the following steps to improve operations: implemented a recovery plan that included the reduction of 2 full time non-clinical operations staff and reorganized the clinical functions of supervisory staff, increased recruitment of patients in Dutchess County, hired a team of per diem clinicians, both registered nurses and physical therapists, expanded their community liaison activities to increase admission volume, while simultaneously hiring new staff, added new managed care contracts to serve more patients, and increased volume by 5% in 2012.

The applicant has provided historical operations of Dutchess County Department of Health CHHA from 2010 through 2011. The entity incurred an average excess of expenses over revenues of \$32,929 from 2010 through 2011.

The applicant has demonstrated the capability to proceed in a financially feasible manner, and approval is recommended.

Recommendation

From a financial perspective, approval is recommended.

Attachments

BFA Attachment A	Financial Summary - 2010 and 2011 certified financial statements of Health Quest Systems, Inc.
BFA Attachment B	Financial Summary - 2010 and 2011 certified financial statements of Hudson Valley Home Care

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to establish purchase assets and become the new owner/operator of the Dutchess County Department of Health Home Health Agency, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

122165 E

Hudson Valley Home Care

APPROVAL CONTINGENT UPON:

1. Submission of a copy of the fully executed Bylaws of Hudson Valley Home Care, Inc., acceptable to the Department of Health. [CSL]
2. Submission of a copy of the fully executed Bylaws of Health Quest Systems, Inc., acceptable to the Department. [CSL]

APPROVAL CONDITIONED UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



STATE OF NEW YORK - DEPARTMENT OF HEALTH

MEMORANDUM

TO: Public Health and Health Planning Council

FROM: *James E. Dering for JES*
James E. Dering, General Counsel

DATE: December 28, 2012

SUBJECT: Proposed Amended and Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc.

JTM Health Facilities Foundation, Inc. (the "Foundation") requests Public Health and Health Planning Council ("PHHPC") approval of the attached proposed Amended and Restated Certificate of Incorporation. Public Health Law § 2801-a (6) and Not-for-Profit Corporation Law § 804 (a) (i) require that amendments and restatements of an Article 28 not-for-profit corporation's Certificate of Incorporation which alter the corporate purpose be approved by PHHPC.

In 1984, the Foundation was formed pursuant to Not-for-Profit Corporation Law § 402 to foster and promotes health care education and research, coordinate and support other not-for-profit corporations promoting health care, and promote and advance relationships between health care institutions. Because the Foundation's Certificate of Incorporation did not include the solicitation of funds on behalf of an Article 28 facility as a purpose, PHHPC approval was not required for the Foundation to file its 1984 Certificate of Incorporation with the Department of State. The Foundation now seeks PHHPC approval of its Amended and Restated Certificate of Incorporation which adds to the Foundation's purposes the solicitation of funds for the benefit of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc., an Article 28 facility.

In addition to the proposed Amended and Restated Certificate of Incorporation, the following documents and information are attached in support of the Foundation's request for approval:

- 1) A copy of the Foundation's proposed Amended and Restated Certificate of Incorporation;
- 2) A copy of the Foundation's current bylaws;
- 3) A letter, dated April 11, 2012, from applicant's attorney requesting PHHPC approval of the Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc.;

- 4) A letter, dated December 7, 2012, from applicant's attorney providing: (a) a generalized description of the fundraising activities to be undertaken by the Foundation; (b) information identifying the organizational relationships between the Foundation and the Article 28 beneficiaries; and (c) a list of any entities which control or are controlled by the Foundation and the nature of such relationships;
- 5) A letter from Kenneth Roberts, President of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc., acknowledging intent to accept funds raised by the Foundation; and
- 6) A copy of a document containing information regarding the Foundation's Board of Directors.

The proposed Amended and Restated Certificate of Incorporation is in legally acceptable form.

Attachments.

RESTATED
CERTIFICATE OF INCORPORATION
OF

JTM HEALTH FACILITIES FOUNDATION, INC.

Under Section 805 of the Not-for-Profit Corporation Law

The undersigned, being the Chairman of the Board of Directors of JTM HEALTH FACILITIES FOUNDATION, INC., hereby certifies:

FIRST: The name of the corporation is JTM HEALTH FACILITIES FOUNDATION, INC. (the "Corporation").

SECOND: The Certificate of Incorporation of the Corporation was filed by the Department of State on April 25, 1984.

THIRD: The Corporation is a corporation as defined in subparagraph (a)(5) of Section 102 of the New York State Not-for-Profit Corporation Law ("NFPCL"). The Corporation is a Type B corporation as defined under Section 201 of the NFPCL and shall remain a Type B corporation after this Restated Certificate of Incorporation is effectuated.

FOURTH: The Certificate of Incorporation of the Corporation is amended to effect the following amendments authorized by the NFPCL:

1. Paragraph "SECOND", stating the Corporation is a Type B corporation under the NFPCL, is hereby updated and as amended and restated shall read in full as follows:

"SECOND: The Corporation is a corporation as defined in subparagraph (a)(5) of Section 102 of the New York State Not-for-Profit Corporation Law ("NFPCL"). The Corporation is a Type B corporation as defined under Section 201 of the NFPCL and shall remain a Type B corporation after this Restated Certificate of Incorporation is effectuated."

2. Paragraph "THIRD", stating the purposes of the Corporation, is hereby updated to reflect the current corporate purposes and as amended and restated shall read in full as follows:

"THIRD: The purposes for which the Corporation is formed are exclusively charitable, educational and scientific in nature within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Code"). Subject to Paragraph FOURTH below, the Corporation's purposes are as follows:

A. To foster and promote the programs and services of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. through philanthropic support or otherwise from such person or persons, corporations or other organizations or entities determined by the Corporation to be engaged in activities or projects whose goals and purposes are consistent with those of the Corporation.

B. To ensure philanthropic support so that health care is provided in an atmosphere of understanding and compassion; where needs and concerns are responded to quickly and with respect for patients' dignity and privacy; and that embraces advanced state-of-the-art technology to produce best possible outcomes in both quality and safety.

C. To engage in fundraising efforts including major, capital, and endowment gift programs; events and appeals; planned giving; and grant solicitation to raise the maximum funds possible to support the healing environment at John T. Mather Memorial Hospital of Port Jefferson, New York, Inc.

D. To solicit and receive money and property for the foregoing purposes and to receive and accept for charitable purposes gifts, donations, bequests, and devises of money and property.

E. To solicit and receive grants, contracts and funds from federal, state and local government agencies, foundations or any other sources, to further the corporate purposes.

F. Do anything and everything reasonably and lawfully necessary, proper, suitable or convenient for the achievement of the foregoing purposes or for the furtherance of said purposes."

3. Paragraph "FOURTH", stating the powers of the Corporation, is hereby updated and as amended and restated shall read in full as follows:

"FOURTH: In furtherance of the foregoing purposes, the Corporation shall have (a) the right to take any and all lawful acts reasonably necessary, proper, suitable or convenient to achieve or to further any and all corporate purposes; (b) any and all general powers enumerated in Section 202(a) of the NFPCL, and (c) the power to maintain a fund or funds of real or personal property for any and all corporate purposes. The Corporation shall have the right to exercise such other powers as now are, or hereafter may be, conferred by law upon a corporation organized for the purposes herein above set forth or necessary or incidental to the powers so conferred, or conducive to the furtherance thereof, subject to the

limitations and condition that, notwithstanding any other provision of this Certificate of Incorporation, the Corporation shall not have the power to carry on any activity not permitted to be carried on by (a) an organization exempt from federal income taxation under Section 501(c)(3) of the Code (or the corresponding provisions of any future United States Internal Revenue Law) or (b) by an organization contributions to which are deductible under Section 170(c)(2) of the Code (or the corresponding provisions of any future United States Internal Revenue Law)."

4. Paragraph "FIFTH", setting forth the Corporation's power to solicit funds from the public, is hereby deleted in its entirety.

5. Paragraph "SIXTH", relating to use of the Corporation's assets, is hereby renumbered as Paragraph "FIFTH" and as amended and restated shall read in full as follows:

"FIFTH: No part of the net earnings of the Corporation shall inure to the benefit of any director, officer or employee of the Corporation or any private individual. No director, officer or employee of the Corporation or any private individual shall receive or be lawfully entitled to receive any pecuniary benefit of any kind, except reasonable compensation for service in effecting one or more purposes of the Corporation. No director, officer or employee of the Corporation or any private individual shall be entitled to share in the distribution of any of the corporate assets on dissolution of the Corporation."

6. Paragraph "SEVENTH", relating to the activities of the Corporation, is hereby renumbered as Paragraph "SIXTH" and as amended and restated shall read in full as follows:

"SIXTH: Nothing in this Certificate of Incorporation shall authorize the Corporation, directly or indirectly, to engage in or include among its purposes any of the activities mentioned in the Section 404(a) - (v) of the NFPCL, except for Sections 404(o) and 404(t). Specifically, nothing herein shall be construed as authorizing the Corporation to operate an elementary school, a secondary school, an institution of higher learning, a library, a museum, a historical society, a cable television facility or an educational television station, nor shall the corporation engage in the practice of law, medicine or any of the professions designated in Title VIII of the Education Law. (Nothing in this Certificate of Incorporation shall authorize the Corporation to (1) provide hospital services or health related services, as such terms are defined in the New York State Public Health Law ("PHL"); (2) establish, operate or maintain a hospital, a home care services agency, a hospice, or a managed care organization, as provided for by Articles 28, 36, 40 and 44 respectively, of the PHL; (3) establish and operate an independent practice association; (4) establish, operate, construct, lease, or maintain an adult home, an enriched housing program, a residence for adults, or an assisted living program, as provided for by

Article 7 of the New York State Social Services Law ("SSL"); (5) establish, operate, construct, lease or maintain an assisted living residence, as provided for by Article 46-B of the PHL; or (6) solicit any funds, contributions or grants, from any source, for the support of a SSL Article 7 facility. Additionally, nothing in this Certificate of Incorporation shall authorize the Corporation to (a) hold itself out as providing or (b) provide any health care professional services that require licensure or registration pursuant to either Title 8 of the New York State Education Law, or the PHL, including, but not limited to, medicine, nursing, psychology, social work, occupational therapy, speech therapy, physical therapy, or radiation technology."

7. Paragraph "EIGHTH", relating to the Corporation's political activities, is hereby renumbered as Paragraph "SEVENTH" and as amended and restated shall read in full as follows:

"SEVENTH: No substantial part of the activities of the Corporation shall consist of carrying on propaganda, or otherwise attempting to influence legislation. The Corporation shall not participate or intervene, including the publication or distribution of statements, in any political campaign on behalf of any candidate for public office."

8. Paragraph "NINTH", relating to the Corporation's locations for doing business, is hereby renumbered as Paragraph "EIGHTH" and is otherwise hereby restated without any amendments or changes.

9. Paragraph "TENTH", setting forth the initial directors of the Corporation, is hereby deleted in its entirety.

10. Paragraph "ELEVENTH", relating to the distribution of assets upon the Corporation's dissolution, is hereby renumbered as Paragraph "NINTH" and as amended and restated shall read in full as follows:

"NINTH: In the event of dissolution, the remaining assets and property of the Corporation, after payment of necessary expenses and the satisfaction of all liabilities shall be distributed to The John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. ("Mather Hospital"), subject to an order of a Justice of the Supreme Court of the State of New York upon application by the Corporation's Board of Directors, provided that no such distribution shall be made to Mather Hospital unless Mather Hospital shall at that time qualify as an exempt organization under Section 501(c)(3) of the Code. No distribution of any property or assets of the Corporation shall be applied other than to accomplish the religious, charitable, scientific, literary and educational purposes for which the Corporation is organized."

11. Paragraph "TWELFTH", relating to service of process upon the Secretary of State of the State of New York, is hereby renumbered as Paragraph "TENTH" and as amended and restated shall read in full as follows:

"TENTH: The Secretary of State of the State of New York is designated as the agent of the Corporation upon whom process against the Corporation may be served. The address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him is in care of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc., 75 North Country Road, Port Jefferson, New York 11777, attn: President."

FIFTH: The Text of the Certification of Incorporation of the Corporation is hereby restated as amended to read in full as follows:

RESTATED

CERTIFICATE OF INCORPORATION

OF

JTM HEALTH FACILITIES FOUNDATION, INC.

FIRST: The name of the Corporation is JTM HEALTH FACILITIES FOUNDATION, INC. (the "Corporation").

SECOND: The Corporation is a corporation as defined in subparagraph (a)(5) of Section 102 of the New York State Not-for-Profit Corporation Law ("NFPCL"). The Corporation is a Type B corporation as defined under Section 201 of the NFPCL and shall remain a Type B corporation after this Restated Certificate of Incorporation is effectuated.

THIRD: The purposes for which the Corporation is formed are exclusively charitable, educational and scientific in nature within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Code"). Subject to Paragraph FOURTH below, the Corporation's purposes are as follows:

A. To foster and promote the programs and services of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. through philanthropic support or otherwise from such person or persons, corporations or other organizations or entities determined by the Corporation to be engaged in activities or projects whose goals and purposes are consistent with those of the Corporation.

B. To ensure philanthropic support so that health care is provided in an atmosphere of understanding and compassion; where needs and concerns are responded to quickly and with respect for patients' dignity and privacy; and that embraces advanced state-of-the-art technology to produce best possible outcomes in both quality and safety.

C. To engage in fundraising efforts including major, capital, and endowment gift programs; events and appeals; planned giving; and grant solicitation to raise the maximum funds possible to support the healing environment at John T. Mather Memorial Hospital of Port Jefferson, New York, Inc.

D. To solicit and receive money and property for the foregoing purposes and to receive and accept for charitable purposes gifts, donations, bequests, and devises of money and property.

E. To solicit and receive grants, contracts and funds from federal, state and local government agencies, foundations or any other sources, to further the corporate purposes.

F. Do anything and everything reasonably and lawfully necessary, proper, suitable or convenient for the achievement of the foregoing purposes or for the furtherance of said purposes.

FOURTH: In furtherance of the foregoing purposes, the Corporation shall have (a) the right to take any and all lawful acts reasonably necessary, proper, suitable or convenient to achieve or to further any and all corporate purposes; (b) any and all general powers enumerated in Section 202(a) of the NFPCL, and (c) the power to maintain a fund or funds of real or personal property for any and all corporate purposes. The Corporation shall have the right to exercise such other powers as now are, or hereafter may be, conferred by law upon a corporation organized for the purposes herein above set forth or necessary or incidental to the powers so conferred, or conducive to the furtherance thereof, subject to the limitations and condition that, notwithstanding any other provision of this Certificate of Incorporation, the Corporation shall not have the power to carry on any activity not permitted to be carried on by (a) an organization exempt from federal income taxation under Section 501(c)(3) of the Code (or the corresponding provisions of any future United States Internal Revenue Law) or (b) by an organization contributions to which are deductible under

Section 170(c)(2) of the Code (or the corresponding provisions of any future United States Internal Revenue Law).

FIFTH: No part of the net earnings of the Corporation shall inure to the benefit of any director, officer or employee of the Corporation or any private individual. No director, officer or employee of the Corporation or any private individual shall receive or be lawfully entitled to receive any pecuniary benefit of any kind, except reasonable compensation for service in effecting one or more purposes of the Corporation. No director, officer or employee of the Corporation or any private individual shall be entitled to share in the distribution of any of the corporate assets on dissolution of the Corporation.

SIXTH: Nothing in this Certificate of Incorporation shall authorize the Corporation, directly or indirectly, to engage in or include among its purposes any of the activities mentioned in the Section 404(a) - (v) of the NFPCL, except for Sections 404(o) and 404(t). Specifically, nothing herein shall be construed as authorizing the Corporation to operate an elementary school, a secondary school, an institution of higher learning, a library, a museum, a historical society, a cable television facility or an educational television station, nor shall the corporation engage in the practice of law, medicine or any of the professions designated in Title VIII of the Education Law. Nothing in this Certificate of Incorporation shall authorize the Corporation to (1) provide hospital services or health related services, as such terms are defined in the New York State Public Health Law ("PHL"); (2) establish, operate or maintain a hospital, a home care services agency, a hospice, or a managed care organization, as provided for by Articles 28, 36, 40 and 44 respectively, of the PHL; (3) establish and operate an independent practice association; (4) establish, operate, construct, lease, or maintain an adult home, an enriched housing program, a residence for adults, or an assisted living program, as provided for by Article 7 of the New York State Social Services Law ("SSL"); (5) establish, operate, construct, lease or maintain an assisted living residence, as provided for by Article 46-B of the PHL; or (6) solicit any funds, contributions or grants, from any source, for the support of a SSL Article 7 facility. Additionally, nothing in this Certificate of Incorporation shall authorize the Corporation to (a) hold itself out as providing or (b) provide any health care professional services that require licensure or registration pursuant to either Title 8 of the New York State Education Law, or the PHL, including, but

not limited to, medicine, nursing, psychology, social work, occupational therapy, speech therapy, physical therapy, or radiation technology.

SEVENTH: No substantial part of the activities of the Corporation shall consist of carrying on propaganda, or otherwise attempting to influence legislation. The Corporation shall not participate or intervene, including the publication or distribution of statements, in any political campaign on behalf of any candidate for public office.

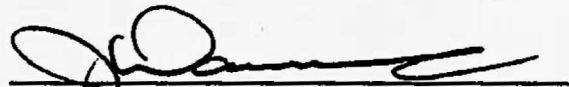
EIGHTH: The Corporation's activities will be conducted principally within the State of New York, but the activities of the Corporation shall not be limited to such territory and may be conducted, subject to all provisions of law in all jurisdictions, throughout the United States, its territories and possessions, and the rest of the world. The office of the Corporation shall be located in the Village of Port Jefferson, Town of Brookhaven, County of Suffolk, State of New York.

NINTH: In the event of dissolution, the remaining assets and property of the Corporation, after payment of necessary expenses and the satisfaction of all liabilities shall be distributed to The John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. ("Mather Hospital"), subject to an order of a Justice of the Supreme Court of the State of New York upon application by the Corporation's Board of Directors, provided that no such distribution shall be made to Mather Hospital unless Mather Hospital shall at that time qualify as an exempt organization under Section 501(c)(3) of the Code. No distribution of any property or assets of the Corporation shall be applied other than to accomplish the religious, charitable, scientific, literary and educational purposes for which the Corporation is organized."

TENTH: The Secretary of State of the State of New York is designated as the agent of the Corporation upon whom process against the Corporation may be served. The address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him is in care of John T. Mather Memorial Hospital of Port Jefferson, New York, Inc., 75 North Country Road, Port Jefferson, New York 11777, attn: President.

SIXTH: This Restated Certificate of Incorporation of JTM HEALTH FACILITIES FOUNDATION, INC. was authorized by the majority vote of the Corporation and the majority vote of Mather Health System, Inc., its sole member.

IN WITNESS WHEREOF, this Certificate has been signed and the statements made herein are affirmed as true under the penalties of perjury this 21 day of March, 2012.


James Danowski, Chairman

**BYLAWS OF
JTM HEALTH FACILITIES FOUNDATION, INC**

Adopted 08/27/1984

Amended 09/16/1987, 02/22/1988, 05/20/1988, 04/24/1999, 09/26/2005, 07/25/2011, 11/5/2012

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ARTICLE I: Purposes/Members

Section 1.1 Purpose

The principal purposes of JTM Health Facilities Foundation, Inc. (the "Foundation") shall be:

- (a) To foster and promote the programs and services of John T. Mather Memorial Hospital of Port Jefferson, NY Inc. (the "Hospital") through philanthropic support or otherwise from such person or persons, corporations or other organizations or entities determined by the Foundation to be engaged in activities or projects whose goals and purposes are consistent with those of this Foundation.
- (b) To ensure philanthropic support so that healthcare is provided in an atmosphere of understanding and compassion; where needs and concerns are responded to quickly and with respect for patients' dignity and privacy; and that embraces advanced state-of-the-art technology to produce best possible outcomes in both quality and safety.
- (c) To engage in fundraising efforts including major, capital, and endowment gift programs; events and appeals; planned giving; and grant solicitation to raise the maximum funds possible to support of the healing environment at Mather Hospital.

Section 1.2 Members

- (a) The sole member of the Foundation shall be Mather Health System, Inc. (the "Member").
- (b) The Annual Meeting, where Mather Health System is acting as sole member of the Foundation, shall be held on such date and at such place as shall be designated in the notice of such meeting. Notice of such annual meeting shall be given by first class mail to the Board of Directors of the Member not less than ten (10) nor more than fifty (50) days prior to the date of the meeting.
- (c) Special meetings of the Member may be held at any place in the Village of Port Jefferson, or at such other location as the Board of Directors of the Foundation shall determine, at any time upon the call of the Chairman of the Foundation Board of Directors, the Foundation Board of Directors, or the Executive Committee of the Foundation Board of Directors.
- (d) The Member shall at times act through the Mather Health System Board of Directors or a committee or designee thereof as determined by said Board of Directors. The Annual Meeting of the Member is distinct from any meetings which Mather Health System, Inc. may have as a corporation outside of its role as the Member of the Foundation.

- (e) The Member shall appoint the members of the Board of Directors of the Foundation in accordance with these Bylaws. The Board of Directors of the Foundation shall be comprised of a minimum of 50% plus one director who also serve on the Board of Directors of the Member.

ARTICLE II: Board of Directors

Section 2.1 Composition

The general control of the property and affairs of the Foundation shall be vested in a Board of Directors appointed by the Member as hereinafter provided. In addition, the President of the Hospital and the Chairman of the Hospital Board or his/her appointed designee shall be ex-officio voting members of the Board of Directors.

- (a) The appointed Directors shall consist of not less than seven (7) nor more than twenty-one (21) persons divided into three (3) classes of not less than two (2) persons nor more than seven (7) persons, each with a term of three (3) years. At each succeeding Annual Meeting of the Member, Directors shall be considered to fill the positions of the class whose terms have expired as well as vacancies in unexpired terms. Vacancies shall be filled by the Member.
- (b) Appointed Directors shall be selected by the Member on the basis of a demonstrated record of dedication to community service, an interest in the objectives of the Foundation as set forth in these Bylaws, as well as the ability of the candidate to participate effectively in fulfilling those objectives
- (c) **Resignation and Removal**
Any Director may resign at any time by giving written notice to the Secretary of the Corporation. Such resignation shall take effect on the date of formal acceptance. Any Director may be removed at any time by a majority vote of the Board for cause or by the Member with or without cause.

Section 2.2 Powers

The Board of Directors shall have power and authority to perform all acts and functions consistent with its responsibilities and not inconsistent with these Bylaws and to manage and control the Foundation, its property, business and concerns.

Section 2.3 Duties of the Board

In addition to its other duties, the Board of Directors shall be required to:

- (a) Define the powers and duties of the Officers of the Board of Directors who will also serve as Officers of the Foundation.
- (b) Recommend amendments of the Corporation's Bylaws.

- (c) Provide for the election of Officers of the Foundation and for the appointment of committees as necessary to effect the discharge of the Corporation's responsibilities. In addition, the Board shall adopt a schedule of meetings, attendance requirements, and methods of recording minutes of governing body proceedings.

Section 2.4 Authority of Board

The Board of Directors shall have the power and authority to perform all acts consistent with the Certificate of Incorporation of the Corporation, any amendments thereto, or with these Bylaws and any amendments thereto.

Section 2.5 Annual Meeting

The Annual Meeting of the Board of Directors shall be held in the month of May on such date and at such place as shall be designated in the Notice of such meeting.

Section 2.6 Regular Meetings

Regular Meetings of the Board of Directors shall be held bimonthly (6 times/year) after the Annual Meeting at a time and place to be fixed in the notice of each meeting.

Section 2.7 Special Meetings of the Board of Directors

Special meetings of the Board of Directors may be called at any time by the Chairman of the Board of Directors or the Executive Committee, and shall be called by the Chairman upon the request of four (4) of the members of the Board of Directors. Written notice of Special Meetings shall be mailed or emailed to each member of the Board at least five (5) days before the date of such Special Meeting. Such notice shall state in general terms the nature of the business to be transacted for which the Special Meeting has been called. No business other than that stated in the notice shall be transacted.

Section 2.8 Quorum

At all meetings of the Board of Directors, Regular and Special, a majority of the members of the Board of Directors shall constitute a quorum for the transaction of business, and a majority vote of those Directors present shall determine all questions.

Section 2.9 Attendance

Each Director shall be expected to attend at least four (4) regular bimonthly (6 times/year) meetings of the Board in each corporate year.

Section 2.10 Policy on Conflict of Interest

A conflict policy, as adopted by the Board, may be revised by the Board of Directors from time to time.

Section 2.11 Reimbursement for Out-of-Pocket Expenses

Members of the Board of Directors may be reimbursed for their actual out-of-pocket expenses incurred while acting on behalf of the Corporation, provided that such action shall have been duly and specifically authorized by the Foundation Administration or the Board of Directors and the necessary funds made available before disbursement.

Section 2.12 Indemnification

The Foundation shall indemnify any person who is, or was, a Director or Officer of the Foundation in accordance with, and to the full extent permitted by and subject to the limitations contained in, Article 7 of the Not-For-Profit Corporation Law of the State of New York ("NPCL").

ARTICLE III: Officers of the Board of Directors

Section 3.1 General

The Officers of the Board of Directors shall be a Chairman, a Vice Chairman, a Secretary, a Treasurer, and the President of the Hospital who shall serve as the President of the Foundation. These Officers shall be elected by the Board of Directors from among the Directors, to hold office for a period of one (1) year. An Officer may be removed at any time by the Board of Directors. In the case of any vacancy occurring in any said office, a successor may be elected at any Regular or Special Meeting of the Board to complete the unexpired term of the vacated office.

Section 3.2 Chairman

The Chairman shall preside at all meetings of the Board of Directors and its Executive Committee. He/she shall be an ex-officio member of all committees and shall perform such other duties as from time to time may be assigned to him/her by the Board of Directors.

Section 3.3 Vice Chairman

The Vice Chairman, in the absence or disability of the Chairman, perform the duties of the Chairman and when so acting shall have all of his/her power and authority. Should the Vice Chairman also be unable to act, a chairman pro tempore shall be chosen by the Board of Directors. The Vice Chairman shall have such additional powers and duties as may from time to time be conferred upon them by the Board.

Section 3.4 Secretary

The Secretary shall give proper notice of all meetings of the Member and the Board and shall cause an agenda for all meetings to be prepared. He/she shall oversee the records and reports of the Foundation and shall cause documents of the Foundation and of the Board of Directors to be filed. He/she shall be responsible for overseeing the records of and reporting on all transactions of the Foundation and of the Board of Directors, except those appertaining to the offices of Treasurer. He/she shall ensure that minutes of all meetings of the Member (in those instances where the Member acts as the sole Member of the Foundation) and of the Board of Directors and of their committees are maintained. He/she shall have responsibility for the seal of the Corporation, but shall cause it to be affixed to documents only upon the order of the Board of Directors. All records shall be available to the Member during regular business hours.

Section 3.5 Treasurer

The Treasurer, through employees of the Foundation or through accounting services made available to him/her, shall be responsible for overseeing the Foundation's finances, maintaining proper financial records, collecting and disposing of all corporate funds and other property of the Foundation, and the custody of all its funds, securities, deeds, mortgages and like documents of value. The Treasurer shall ensure that a report to the Directors is made at each Regular Meeting of the Board and that a detailed Annual Report and Financial Statement are presented at any Annual Meeting of the Member. The books of the Treasurer shall always be open for inspection by the members of the Board of Directors of the Foundation and available to the Member during regular business hours.

ARTICLE IV: Fidelity Bonds

The Board of Directors may, in the exercise of its discretion, require the Officers of the Foundation who have signing authority (and such other employees or agents as the Board of Directors shall designate) to be covered by fidelity bonds in amounts determined and approved by the Board. The Foundation shall pay the cost of any such fidelity bonds.

ARTICLE V: Fiscal Year

The fiscal year of this Foundation shall commence on January 1st and end as of December 31st of each year.

ARTICLE VI: Committees

Section 6.1 Committees

The Foundation may have standing committees, ad hoc (special) committees and/or Committees of the Foundation.

- (a) The standing committee shall be the Executive Committee, the Finance Committee and the Nominating Committee, and such other committees as the Board of Directors may from time to time authorize.

- (b) Every year the Chairman shall appoint the chairmen and the members of standing committees in such numbers as he/she may deem advisable, subject to confirmation of the Board.
- (c) Ad hoc (special) committees may be appointed by the Chairman upon authorization of the Board of Directors. Such committees shall have only such authority, powers, responsibilities and tenure as may be granted to them specifically by the Board of Directors.
- (d) Committees of the Foundation shall be appointed by the Chairman of the Foundation and approved by the Foundation Board of Directors in the same manner as officers of the Foundation. Committees of the Foundation may include persons who are not members of the Board of Directors.
- (e) In order for business to be conducted at any meeting of any committee, a quorum must be present. A quorum for purposes of this article shall be defined as forty (40%) percent of the total number of members of the committee then in office, and a majority vote of those members present shall determine all questions; provided, however, that a quorum for meetings of the Executive Committee shall be defined as a majority of the total number of members of the committee then in office.

Section 6.2 Executive Committee

- (a) **Composition**
The Executive Committee shall consist of a minimum of three members from the Board of the Foundation as the Chairman may select from time to time (subject to confirmation of the Board).
- (b) **Powers**
The Executive Committee shall have the power to transact all regular business of the Foundation during the interim between meetings of the Board of Directors, provided that any action shall not conflict with the policies and expressed wishes of the Board of Directors and that it shall refer all matters of major importance to the Board of Directors. Further, the Executive Committee shall report all action that it takes to the Board of Directors at the next meeting of the Board of Directors.
- (c) **Meetings**
The Executive Committee shall meet at the call of the Chairman and shall keep a full record of its proceedings which shall be entered in a Book of Minutes, with copies thereof distributed to all members of the Board of Directors.

Section 6.3 Finance Committee

- (a) **Responsibilities**

The Finance Committee shall be responsible for all matters relating to the financial condition of the Foundation. Without limiting the foregoing, the Finance Committee shall:

- (i) Ensure that all endowment, trust and capital funds be deposited with a responsible bank or properly invested and that reports of such deposits or investments are made from time to time.
 - (ii) Ensure that income from endowment and capital funds, after deduction of legitimate expense, is paid into the Foundation and ensure that both principal and income from such funds are used in accordance with the terms of the purposes for which they were established.
 - (iii) Provide for the submission of a budget to the Board of Directors. The budget shall set forth anticipated receipts and expenditures for the ensuing year.
 - (iv) Conduct an annual review of all insurance policies of the Foundation, and shall renew, negotiate, and purchase such coverage as may be necessary to protect the assets of the Foundation.
 - (v) Examine the securities of the Foundation as often as it may be considered necessary.
 - (vi) Review the annual report of the external auditor, and review all internal audit reports, if any.
- (b) **Meetings**
Meetings of the Finance Committee may be held upon the call of the Chairman of the Committee, or any two (2) members thereof. At least forty-eight (48) hours advance notice of such meetings shall be given.

Section 6.4 Nominating Committee

The Nominating Committee shall nominate from the membership of the Board of Directors candidates for the offices of Chairman, Vice Chairman, Secretary and Treasurer. Other nominations for elective office may be made from the floor.

The Nominating Committee may also accept nominations for members of the Foundation Board of Directors, determine their interest and ability to effectively contribute to the Board, and make a recommendation to the Nominating Committee of the Member.

Section 6.5 General

In the interest of expediting consideration of matters by the Board of Directors, it shall be the duty and prerogative of the Chairman of each committee to advise and consult with the

Chairman of any other committee, when the matter under examination or the action to be recommended concerns another committee. Such advice and consultation shall be made timely so as to permit a joint recommendation to the Board when that is possible.

ARTICLE VII: Rules of Procedure

Roberts' Rules of Order shall prevail at all meetings, unless otherwise provided in these Bylaws.

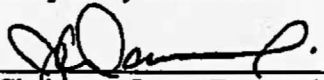
ARTICLE VIII: Execution of Instruments

All corporate documents, contracts or other instruments shall be executed by such Officers, agents or employees as may be determined by the Board of Directors of the Foundation.

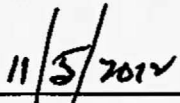
ARTICLE IX: Amendments

These Bylaws may be amended by an affirmative vote of a majority of the members of the entire Board entitled to vote at any meeting at which a quorum is present, provided that a full statement of the proposed amendment(s) is contained in the notice calling the meeting at which said amendment(s) is to be voted. Any such amendment shall be subject to approval of the Member in accordance with Section 602 of the NPCL.

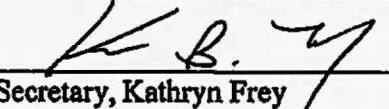
Adopted by Resolution



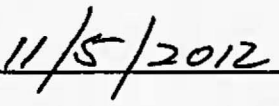
Chairman, James Danowski
JTM Health Facilities Foundation, Inc.



Date



Secretary, Kathryn Frey
JTM Health Facilities Foundation, Inc.



Date

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STEVEN D. GORELICK ••
STACEY L. GULICK ••
B. SCOTT HIGGINS •
BARBARA D. KNOTHE •••
EVE GREEN KOOPERSMITH •
JOHN P. KRALJIC •
LAUREN M. LEVINE ••
SEAN P. LEYDEN •••
JOHN G. MARTIN •
PATRICK J. MONAHAN II •
MARIANNE MONROY ••
ALAN H. PERZLEY ••
GREGG D. REISMAN •
KAREN L. RODGERS •
ROBERT E. SCHILLER •
ANDREW J. SCHULSON •
APRIL A. SHAH •
DEBRA A. SILVERMAN •
CHRISTINA VAN VOET •

JOHN BECKER •
SHANNON CARROLL ••
WENDY A. CHOW •
ZACHARY B. COHEN ••
MATTHEW COLFORD ••
WILHELMINA A. DE HARDER •
LAUREN D. GOLDBERG ••
THERESA A. HARRIS ••
JASON Y. IISI •
TRACY D. HUBBELL ••
KIMBERLY KEAPTON-SERRA •••
JAY C. KLEAR •
STACEY P. KLEIN ••
ROBERT B. KOONIN ••
STEPHANIE MATOS •
SALVATORE PUCCIO •
COURTNEY A. ROOERS •
MICHAEL D. SAILY •
MICHELLE LEWIS SALZMAN •
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COLLEEN M. TARPBY •

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OF COUNSEL
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GEORGE M. GARFUNKEL •
STUART M. HOCHRON, M.D. •

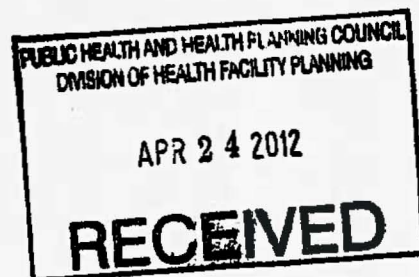
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• LICENSED IN NEW JERSEY
• LICENSED IN CONNECTICUT
• RESPONSIBLE PARTNERS FOR
NEW JERSEY OFFICE

FILE NO.: 5322.0001
REPLY TO: New York

WRITER'S EMAIL: sklein@garfunkelwild.com
WRITER'S DIRECT DIAL: (516) 393-2207

April 11, 2012

Coleen Frost, Executive Secretary
New York State Department of Health
Public Health and Health Planning Council
Corning Tower Building - 1441
Empire State Plaza
Albany, New York 12237



Re: JTM Health Facilities Foundation, Inc. ("Foundation")

Dear Ms. Frost:

Our firm is legal counsel to JTM Health Facilities Foundation, Inc. (the "Foundation"). Enclosed on behalf of the Foundation is an executed copy of the proposed Restated Certificate of Incorporation of the Foundation.

In addition, we enclose a complete copy of all documents on file with the NYS Department of State.

The Certificate of Incorporation of the Foundation is being restated to update the purposes of the corporation to reflect more clearly its purpose of supporting John T. Mather Memorial Hospital of Port Jefferson, New York, Inc.

Please review the proposed Restated Certificate of Incorporation, if acceptable, enclose the appropriate consent and return the original Restated Certificate of Incorporation to us so that we may complete the filing process.

NEW YORK

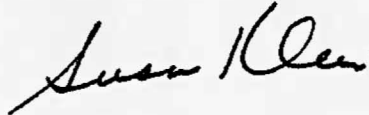
NEW JERSEY

CONNECTICUT

Coleen Frost, Executive Secretary
April 11, 2012
Page 2

In addition, please acknowledge your receipt of the enclosed by providing your stamp or signature in the space provided below on the enclosed copy of this letter and by returning same to the undersigned in the enclosed, postage-paid, self-addressed envelope.

Very truly yours,



Susan Klein
Corporate Paralegal

Enclosures

ACKNOWLEDGEMENT OF RECEIPT

I hereby acknowledge receipt of the proposed Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc.

Name:
Title:

cc: Kenneth Roberts, President, JTM Health Facilities Foundation, Inc.
James Danowski, Chairman of the Board, JTM Health Facilities Foundation, Inc.
Nancy Uzo, Vice President of Public Affairs

GARFUNKEL WILD, P.C.

GARFUNKEL WILD, P.C.
ATTORNEYS AT LAW

111 GREAT NECK ROAD • GREAT NECK, NEW YORK 11021
TEL (516) 393-2200 • FAX (516) 466-5964

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BURTON S. WESTON •
MICHAEL J. KHANE •†
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BARRY B. CEPHEWICZ, M.D. •††
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† RESPONSIBLE PARTNERS FOR
NEW JERSEY OFFICE

FILE NO.: 5322.1
REPLY TO: New York

WRITER'S EMAIL: thubbell@garfunkelwild.com
WRITER'S DIRECT DIAL: (516) 393-2530

December 7, 2012

VIA FEDERAL EXPRESS

Thomas J. King, Esq.
Assistant Attorney
Bureau of House Counsel
New York State Department of Health
Empire State Plaza
Corning Tower, 24th Floor
Albany, NY 12237-0031

RECEIVED

DEC 10 2012

NYS DEPARTMENT OF HEALTH
DIVISION OF LEGAL AFFAIRS
BUREAU OF HOUSE COUNSEL

Re: Proposed Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc.

Dear Mr. King:

I am responding to your letter dated September 4, 2012 to Susan Klein, attached hereto as Exhibit 1, regarding the proposed Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc. (the "Foundation").

Following are our responses to each of the requests in your letter:

1) *A copy of the Foundation's current bylaws;*

The Foundation's current Bylaws are attached hereto as Exhibit 2.

NEW YORK

NEW JERSEY

CONNECTICUT

- 2) *As to each of the Foundation's current directors, provide the nature and address of their present employment, their employment history, and their health care experience and community involvement, including past and present affiliations with other nonprofit organizations;*

The present employment, employment history, health care experience, and community involvement information requested for each of the Foundation's current directors is attached hereto as Exhibit 3.

- 3) *A generalized description of the fundraising activities to be undertaken by the Foundation;*

The Foundation may engage in fundraising activities through soliciting, receiving, and disbursing funds received in a variety of forms, including but not limited to, personal solicitations, fundraising events, memorial giving, mail campaigns, foundation or government grants (federal and state), gifts, and bequests, in support of its charitable purposes.

- 4) *A letter from any intended medical facility beneficiary, which states that the beneficiary is aware that the Foundation will solicit funds on its behalf and will accept those funds;*

A letter from John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. ("John T. Mather Memorial Hospital") acknowledging that the Foundation will solicit funds on its behalf and that John T. Mather Memorial Hospital will accept such funds was sent to you on October 26, 2012. See the letter attached as Exhibit 4.

- 5) *Information identifying the organizational relationships or affiliations between the Foundation and the Article 28 beneficiaries; and*

Mather Health System, Inc. is the sole member of both the Foundation and John T. Mather Memorial Hospital.

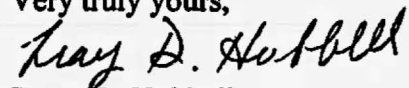
- 6) *A list of any entities which control or are controlled by the Foundation and the nature of such relationships.*

As the sole member of the Foundation, Mather Health System, Inc. appoints the Foundation's directors. The Foundation does not control any entities.

Thomas King, Esq.
December 7, 2012
Page 3

Please do not hesitate to contact us should you require any additional information. We look forward to hearing from you soon.

Very truly yours,


Tracy D. Hubbell

Encls.

cc: Kenneth Roberts, President, JTM Health Facilities Foundation, Inc.
James Danowski, Chairman of the Board, JTM Health Facilities Foundation, Inc.
Nancy Uzo, Vice President of Public Affairs

GARFUNKEL WILD, P.C.



MATHER

John T. Mather Memorial

HOSPITAL

75 NORTH COUNTRY ROAD • PORT JEFFERSON • NEW YORK 11777-2190 • 631-473-1320 • www.matherhospital.org

KENNETH A. JACOPPI
Chairman of the Board

KONRAD J. KUHN
Vice Chairman

BETSY NOYES BRITTON
Vice Chairman

HAROLD TRANCHON, JR.
Vice Chairman

WAYNE RAMPONE
Secretary

JOHN R. SINI
Treasurer

KENNETH D. ROBERTS
President

October 26, 2012

Thomas J. King, Esq.
Assistant Attorney
Bureau of House Counsel
New York State Department of Health
Empire State Plaza
Corning Tower, 24th Floor
Albany, NY 12237-0031

Dear Mr. King:

John T. Mather Memorial Hospital of Port Jefferson, New York, Inc. ("John T. Mather Memorial Hospital") acknowledges that the JTM Health Facilities Foundation will solicit funds on its behalf and that John T. Mather Memorial Hospital will accept such funds.

Sincerely,

Kenneth D. Roberts
President

JTM Health Facilities Foundation

Board Member: James Danowski, Chairman
Employment Current: Partner, Cullen & Danowski, LLP (certified public accountants)
1650 Rte 112
Port Jefferson Station, NY 11776

Employment Past:

Health Care and Community Involvement Experience:

Present:

Member, Board of Directors
John T. Mather Memorial Hospital

Member, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Member, Board of Directors
Jefferson's Ferry Life Care Community
East Setauket, NY 11720

Member, Board of Directors
Suffolk County National Bank
Riverhead, NY 11901

Past:

Member and Past President
Rocky Point Lion's Club
Rocky Point, NY 11778

Finance Committee Chairman
St. Mark's R.C. Church
Shoreham, NY 11786

Member, Board of Directors
Visiting Nurse Services of NY, Inc.
New York, NY 10013

Board Member: Alan Beck, Vice Chairman
Employment Current: Retired
Employment Past: COO, American Media Management (radio broadcast management)
Port Jefferson, NY 11777
1981-1997

Previously worked for other broadcast companies

Health Care and Community Involvement Experience:

Present:

Member, Board of Directors
John T. Mather Memorial Hospital

Member, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Past:

Member, Board of Directors
Hope House Ministries
Port Jefferson, NY 11777

Member
Patchogue Rotary Club
Patchogue, NY 11772

Member
Patchogue Chamber of Commerce
Patchogue, NY 11772

Board Member: Kathryn B. Frey, Secretary

Employment Current: President, Frey Family Foundation
40 North Country Road
Port Jefferson, NY 11777

Employment Past: Tax Adjuster
IRS
Holtsville, NY
1972-1980

Health Care and Community Involvement Experience:

Present:

Member, Board of Directors
John T. Mather Memorial Hospital

Member, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Member, Board of Directors
Hope House Ministries
Port Jefferson, NY 11777

Board Member: Thomas Kohlmann, Treasurer
Employment Current: Retired
Employment Past: CEO, Suffolk County National Bank
Riverhead, NY 11901

Health Care and Community Involvement Experience:

Present:
Member, Board of Directors
John T. Mather Memorial Hospital

Member, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Board Member: Nancy Burner, Esq.
Employment Current: Founding Manager and Partner (elder law attorney)
Nancy Burner & Associates, PC

Adjunct Professor of Law
Hofstra University Law School
Uniondale, NY 11549

Employment Past:

Health Care and Community Involvement Experience:

Present:
Legal Advisory Board, Alzheimer's Association of L.I.
Bay Shore, NY 11706

Member and Past President, Board of Directors
Suffolk County Women's Bar Association
Wading River, NY 11792

Past:
Member, Board of Directors
John T. Mather Memorial Hospital

Board Member: Kenneth D. Roberts
Employment Current: President (hospital administrator)
John T. Mather Memorial Hospital
75 North Country Rd.
Port Jefferson, NY 11777

(1986-present)

Employment Past:

Sr. Vice President
John T. Mather Memorial Hospital
(1985-1986)

Associate Director
John T. Mather Memorial Hospital
(1982-1985)

Assistant Director of Administration
South Nassau Communities Hospital
Oceanside, NY 11752
(1977-1982)

Administrative Intern
South Nassau Communities Hospital
Oceanside, NY 11752
(1976-1977)

Senior Staff Assistant
Group Health Incorporated
New York, NY
(1973-1976)

Health Care and Community Involvement Experience:

Present:
Member and President, Board of Directors
John T. Mather Memorial Hospital

Member and President, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Secretary, Board of Directors
Island Nursing Home and Rehab
Secretary, INRC Services Corp.
Holtsville, NY 11742

Member, Board of Directors
Medical Liability Mutual Insurance Company (MLMIC)
New York, NY 10016

Member and Past Chairman
Nassau-Suffolk Hospital Council
Hauppauge, NY 11788

Member, Board of Directors
Hospital Association of New York State
Rensselaer, NY 12144

Board Member: Kenneth Jacoppi, Esq.

Employment Current: Kenneth A. Jacoppi, Attorney at Law
194 Main St.
E. Setauket, NY
(Late 1960s – present)

Employment Past:

Health Care and Community Involvement Experience:

Present:

Chairman, Board of Directors
John T. Mather Memorial Hospital

Chairman, Board of Directors
Mather Health System
Port Jefferson, NY 11777

Member and Past Chairman, Board of Directors
Long Island Health Network
Melville, NY 11788

Past:

Past Chairman, Board of Directors
American Cancer Society, Long Island Div.
Hauppauge, NY 11788

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, on this 7th day of February, 2013, approves the filing of the Amended and Restated Certificate of Incorporation of JTM Health Facilities Foundation, Inc. dated March 21, 2012.

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Ideal Care SP, LLC
Address: Highland
County: Ulster
Structure: Limited Liability Company
Application Number: 2076-L

Description of Project:

Ideal Care SP, LLC, a limited liability company, requests approval for a change in ownership under Article 36 of the Public Health Law. This proposal seeks to transfer ownership of Ideal Care at Highland, LLC d/b/a Ideal Care from father, Jacob Schonberger, to Ideal Care SP, LLC, controlled by his sons, Philip and Steven Schonberger.

Ideal Care at Highland, LLC d/b/a Ideal Care was previously approved as a home care services agency by the Public Health Council at its March 14, 2008 meeting and subsequently licensed as 1432L001.

The members of Ideal Care SP, LLC comprise the following individuals:

Philip Schonberger, 50% Administrator, Evergreen Court Home for Adults	Steven Schonberger, 50% Manager of family business of adult homes and ALPs owned by father, Jacob Schonberger
--	---

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to continue to serve the residents of the following counties from an office located at 1 Grove Street, Highland, New York 12528:

Ulster Sullivan	Dutchess Greene	Orange
--------------------	--------------------	--------

The applicant proposes to continue to provide the following health care services:

Nursing	Home Health Aide	Personal Care
Physical Therapy	Occupational Therapy	Respiratory Therapy
Speech Language Pathology	Nutrition	Medical Social Services
Homemaker	Housekeeper	

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 8, 2012

Division of Home & Community Based Care
Character and Competence Staff Review

Name of Agency: Garden Homecare, LLC
Address: Kenmore
County: Erie
Structure: Limited Liability Company
Application Number: 2153-L

Description of Project:

Garden Homecare, LLC, a limited liability company, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

This application is to establish a licensed home care service agency associated with a new Assisted Living Program (ALP). This LHCSA will be associated with Kenwell Gardens Adult Care Facility Assisted Living Program.

The members of the Garden Homecare, LLC comprises the following individuals:

Brian Rosenman – 90%	Leah Rosenman – 10%
Operator, Suton Gardens, LLC	Unemployed

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant will serve the residents of the Erie County from an office located at 3456 Delaware Avenue, New York 14217.

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Medical Social Services
Physical Therapy	Occupational Therapy	Nutrition	Homemaker
Housekeeper			

A ten year review of the operations of Suton Gardens, LLC was performed as part of this review.

The Adult Care Facility Policy and Surveillance unit has indicated the following:

Suton Gardens, LLC was fined two thousand dollars (\$2,000.00) pursuant to a stipulation and order dated November 21, 2012 for surveillance findings of June 9, 2011 and August 25, 2011. Deficiencies were found under 10 NYCRR 487.8(e)(1) Food Service.

The information provided by the Adult Care Facility Policy and Surveillance unit has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 30, 2012

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following applications for licensure, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

<u>NUMBER:</u>	<u>FACILITY:</u>
2061-L	ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services-Northeast Westchester (Westchester, Putnam, Dutchess and Orange Counties)
2017-L	A-Plus Care HHC, Inc (New York, Kings, Queens, Bronx, Richmond and Westchester Counties)
1946-L	ASC of New York, LLC d/b/a Affordable Senior Care of New York (Bronx, Kings, Nassau, New York, Richmond and Queens Counties)
1878-L	Christine Home Care Services, Inc. (New York, Bronx, Queens, Kings and Nassau Counties)
2015-L	Eden Home Care Services, inc. (Bronx, Kings, New York, Queens, Richmond and Nassau Counties)

2082-L JC Beginnings, Inc. d/b/a Senior Helpers
(Nassau and Suffolk Counties)

1995-L Life Quality Homecare Agency, Inc.
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

2006-L Millennium Concepts, Inc. d/b/a Exclusive Care
(Bronx, Kings, New York, Queens, Richmond and
Nassau Counties)

2013-L Ochlor, Incorporated d/b/a Right at Home
(Kings, New York, Queens and Richmond Counties)

1979-L SonicLeibs, Inc. d/b/a Synergy HomeCare
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

1907-L SR Homecare of NY, Inc.
(New York, Kings, Queens, Bronx, Richmond, and
Westchester Counties)

1812-L St. Vincent de Paul Residence d/b/a St. Vincent de
Paul LHCSA
(Bronx County)

2153-L Garden Homecare, LLC
(Erie County)

2076-L Ideal Care SP, LLC
(Ulster, Dutchess, Orange, Sullivan and Greene
Counties)

1881-L Marian Care, Inc.
(Nassau, Suffolk, and Queens Counties)

2070-L Tri-Borough Health Careers, LLC d/b/a Metro Care
Home Services, a division of Tri-Borough Health
Careers, LLC
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

- 2069-L TriBorough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd. (Dutchess, Orange, Putnam, Sullivan Westchester, Ulster, Nassau, Suffolk, and Rockland Counties)
- 2013-L Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers, a division of Tri-Borough Home Care, Ltd. (Bronx, Kings, New York, Queens, Richmond and Westchester Counties)

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION
OF HEALTH CARE FACILITIES**

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Ambulatory Surgery Centers – Establish/Construct

Exhibit #14

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122051 B	Rockaways ASC Development, LLC (Queens County) Mr. Kraut - Interest Dr. Sullivan – Abstaining/Interest	Contingent Approval
2.	122164 B	Mason ESC, LLC d/b/a Mason Eye Surgery Center (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval

Diagnostic and Treatment Center – Establish/Construct

Exhibit #15

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121445 B	New Life Community Development Corporation d/b/a New Life Community Health Center (Queens County) Dr. Sullivan – Abstaining/Interest	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #16

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122003 E	Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare (Steuben County) Mr. Fassler – Recusal	Contingent Approval

Certified Home Health Agencies – Establish/Construct

Exhibit #17

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121325 E	Tri-Borough Certified Health Systems of New York, LLC d/b/a Tri-Borough Certified Health Systems of New York (Nassau County) Ms. Regan - Interest	Contingent Approval
2.	121328 E	Tri-Borough Certified Health Systems of the Hudson Valley, LLC d/b/a Tri-Borough Certified Health Systems of the Hudson Valley (Westchester County) Ms. Regan - Interest	Contingent Approval

Restated Certificate of Incorporation

Exhibit #18

	<u>Applicant</u>	<u>E.P.R.C. Recommendation</u>
1.	Pluta Cancer Center Foundation, Inc. Ms. Hines – Recusal Mr. Robinson - Recusal	Approval

HOME HEALTH AGENCY LICENSURES**Exhibit #19**

<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
2061-L	ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services- Northeast Westchester (Westchester, Putnam, Dutchess and Orange Counties) Ms. Regan - Interest	Contingent Approval
2017-L	A-Plus Care HHC, Inc (New York, Kings, Queens, Bronx, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
1946-L	ASC of New York, LLC d/b/a Affordable Senior Care of New York (Bronx, Kings, Nassau, New York, Richmond and Queens Counties) Ms. Regan - Interest	Contingent Approval
1878-L	Christine Home Care Services, Inc. (New York, Bronx, Queens, Kings and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2015-L	Eden Home Care Services, inc. (Bronx, Kings, New York, Queens, Richmond and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2082-L	JC Beginnings, Inc. d/b/a Senior Helpers (Nassau and Suffolk Counties) Ms. Regan - Interest	Contingent Approval

1995-L	Life Quality Homecare Agency, Inc. (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
2006-L	Millennium Concepts, Inc. d/b/a Exclusive Care (Bronx, Kings, New York, Queens, Richmond and Nassau Counties) Ms. Regan - Interest	Contingent Approval
2013-L	Ochlor, Incorporated d/b/a Right at Home (Kings, New York, Queens and Richmond Counties) Ms. Regan - Interest	Contingent Approval
1979-L	SonicLeibs, Inc. d/b/a Synergy HomeCare (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest	Contingent Approval
1907-L	SR Homecare of NY, Inc. (New York, Kings, Queens, Bronx, Richmond, and Westchester Counties) Ms. Regan - Interest	Contingent Approval
1812-L	St. Vincent de Paul Residence d/b/a St. Vincent de Paul LHCSA (Bronx County) Ms. Regan - Interest	Contingent Approval
1881-L	Marian Care, Inc. (Nassau, Suffolk, and Queens Counties) Ms. Regan - Interest	Contingent Approval

2070-L	<p>Tri-Borough Health Careers, LLC d/b/a Metro Care Home Services, a division of Tri-Borough Health Careers, LLC (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest</p>	Contingent Approval
2069-L	<p>Tri-Borough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd. (Dutchess, Orange, Putnam, Sullivan Westchester, Ulster, Nassau, Suffolk, and Rockland Counties) Ms. Regan - Interest</p>	Contingent Approval
2013-L	<p>Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers, a division of Tri-Borough Home Care, Ltd. (Bronx, Kings, New York, Queens, Richmond and Westchester Counties) Ms. Regan - Interest</p>	Contingent Approval



Public Health and Health Planning Council

Project # 122051-B Rockaways ASC Development, LLC

County: Queens (Rockaway Beach)
Purpose: Establishment and Construction

Program: Ambulatory Surgery Center
Submitted: August 1, 2012

Executive Summary

Description

Rockaways ASC Development, LLC, a proposed limited liability company, requests approval to establish and construct a multi-specialty freestanding ambulatory surgical center (ASC) to provide surgical services in the specialties of ophthalmology, urology, OB-GYN, and orthopedics. The center will be located in approximately 13,118 square feet of an existing courthouse to be renovated and to include an addition to the rear of the building located at 90-01 Beach Channel Drive, Rockaway Beach. The center will consist of three operating rooms, one procedure room, twelve pre-op/recovery beds, ancillary space and appropriate support space.

The proposed members of Rockaways ASC Development, LLC will each have 10% membership interest, and are board certified in their respective specialties and are as follows:

Proposed Member	Specialty
Mark Gelwan, M.D.	Ophthalmology
Sheldon Pike, M.D.	Urology
Anthony Pacia, M.D.	Anesthesiologist
Ira Backman, M.D.	OB/GYN
Stephen Perrone, M.D.	Ophthalmology
Anthony Horvath, M.D.	Orthopedics
Ted Du, M.D.	Ophthalmology
Michael Ahdoot, M.D.	Ophthalmology
Lawrence Blum, M.D.	Ophthalmology
Mark Friedman, M.D.	Ophthalmology

No responses were received to the Department's inquiry to local hospitals regarding the impact of the proposed ASC in the service area.

Total project costs are estimated at \$3,430,779.

DOH Recommendation

Contingent approval, with an expiration of the operating certificate five years from the date of its issuance, should the operator not comply with the conditions of approval granted this CON.

Need Summary

Rockaways ASC Development, LLC will be the only ASC located on the Rockaway Peninsula and will be comprised of ten (10) physicians who are committed to filling the void for outpatient services in the community. It is projected that there will be 3,871 surgeries in the first year of operation and 4,107 in the third year.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Total project costs will be met with \$897,827 in equity and a \$2,532,952 bank loan.

Budget:	<i>Revenues:</i>	\$ 5,729,265
	<i>Expenses:</i>	<u>4,828,610</u>
	<i>Gain/(Loss):</i>	\$ 900,655

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided; and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement from the applicant, acceptable to the Department, that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with consultation of the legal counsel, and it is concluded that proceeding with the proposal is acceptable. [RNR]
5. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission of an acceptable DBA, if applicable. [HSP]
8. Submission of an executed loan commitment that is acceptable to the Department of Health. [BFA]
9. Submission of an executed working capital loan commitment that is acceptable to the Department of Health. [BFA]
10. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01 [AER].
11. The submission of a revised site plan in SHC drawings to show additional parking spaces for drop off and pick up of patients convenient to the building entrance as required by 2010 FGI Guidelines 3.7-1.3.2.2.[AER]
12. Submission of site control that is acceptable to the Department. [CSL]
13. Submission of a signed statement regarding anti-kickback and self-referral that is acceptable to the Department. [CSL]
14. Submission of a Consulting Services Agreement that is acceptable to the Department. [CSL]
15. Submission of a Certificate of Amendment of the Articles of Organization that is acceptable to the Department. [CSL]
16. Submission of an Operating Agreement that is acceptable to the Department. [CSL]

Approval conditional upon:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities.[HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. .[HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. .[HSP]
5. The clinical space must be used exclusively for the approved purpose. .[HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction [AER].
7. The applicant shall complete construction by July 31, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Rockaways ASC Development, LLC (RASCD) seeks CON approval to establish and construct a multi-specialty ambulatory surgery center (ASC) to be located at 90-01 Beach Channel Drive, Rockaway Beach, 11693, in Queens County.

Rockaways ASC Development, LLC anticipates that 45 – 55 percent of the ASC's cases will be comprised of Medicaid and Medicare patients.

RASCD proposes to offer the following specialty services:

- Ophthalmology;
- Urology;
- OB-GYN; and
- Orthopedics.

The facility intends to provide a portion of its services to medically indigent patients and anticipates that at least 2 percent of its care will be charity care.

Currently, there are six Ambulatory Surgery Centers in Queens County; but none of these are located in the proposed service area of RASCD. The type of ambulatory surgery service and the number of cases performed at these centers are listed below.

Distribution of Ambulatory Surgery Procedures at Existing Queens County Facilities		
<u>ASC Type</u>	<u>Name</u>	<u>2010</u>
Multi-Specialty	New York Surgery Center Queens, LLC	1,505
Single - Ophthalmology	The Mackool Eye Institute LLC	7,024
Multi-Specialty	Queens Surgi-Center	6,169
Multi-Specialty	Hillside Diagnostic and Treatment Center, LLC	2,863
Multi-Specialty	Choices Women's Medical Center Inc	9,231
Multi-Specialty	Physicians Choice Surgicenter	962
	Total	27,754

Source: SPARCS 2010

The members of the proposed center are committed to serving all persons in need services without regard to race, sex, age, religion, creed, sexual orientation, source of payment, ability to pay, or other personal characteristics. The applicant understands that it must provide charity care and proposes to do so.

Because the proposed facility would serve an area where there are currently no ambulatory surgery centers, and because the projected volume of surgeries appears to be reasonable for the number of physicians participating, the facility should be approved.

Recommendation

From a need perspective, approval is recommended for a limited life of five years from the date of the issuance of an operating certificate.

Programmatic Analysis

Background

Establish a diagnostic and treatment center that will also be federally certified as a multi-specialty ambulatory surgery center.

Proposed Operator	Rockaways ASC Development, LLC
Site Address	90-01 Beach Channel drive, Rockaway Beach
Surgical Specialties	Multi-specialty including: Ophthalmology Urology OB-GYN Orthopedics
Operating Rooms	3
Procedure Rooms	1
Hours of Operation	Monday through Friday from 7:00 am to 5:00 pm
Staffing (1 st Year / 3 rd Year)	29 FTEs / 34 FTEs
Medical Director(s)	Mark Gelwan
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by St. John's Episcopal Hospital. 3.7 miles and 10 minutes away
On-call service	Each patient will be provided with an after hours contact number for their surgeon and an alternative contact number if their surgeon is unavailable.

Character and Competence

The members of the LLC, each with 10% membership, are:

Name

Mark Gelwan, Md
Sheldon Pike, MD
Anthony Pacia, MD
Ira Bachman, MD
Stephen Perrone, MD
Anthony Horvath, MD
Ted Du, MD
Michael Ahdoot, MD
Lawrence Blum, MD
Mark Friedman, MD

All the members of the LLC are practicing physicians. Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Dr. Gelwan disclosed one settled malpractice case within the last ten years. Dr. Horvath disclosed a 1997 Office of Professional Medical Conduct disciplinary action which resulted in the physician's license being permanently limited precluding the performance of independent medical evaluations of patients in connection with benefit determinations; including but not limited to workers compensation benefit determinations.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of associated facilities, if applicable. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

According to the applicant the proposed center is located in the heart of an underserved community. It will be located within an historic courthouse being renovated to accommodate a variety of health care services including primary care

and women's health services and will work with these providers to meet the needs of the surrounding community. One of the center's core missions is to serve this underserved community as evidenced by plans to serve 45-55% Medicare and Medicaid patients. Additionally, the facility intends to provide at least two percent charity care for the medically indigent.

The facility intends to become part of a local Accountable Care Organization, utilize Electronic Medical Records, and integrate into a state-based RHIO/HIE.

Compliance with Applicable Codes, Rules and Regulations

The medical staff will ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements. The Center intends to review the list acceptable procedures annually and as needed to determine the appropriateness of adding new procedures consistent with individual physician expertise.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Lease Rental Agreement

The applicant will lease approximately 2,940 square feet of new construction to the rear side of the first floor, and approximately 10,178 square feet of renovated space within the existing building located at 90-01 Beach Channel Drive, Rockaway Beach, under the terms of the executed lease agreement summarized below:

Date: June 13, 2012
Landlord: Harmony Rockaway, LLC
Lessee: Rockaways ASC Development, LLC
Term: 10 years
Rental: \$542,720/ year (\$41.37 per sq. ft.)
Provisions: The lessee will be responsible for utilities, maintenance, insurance and taxes.

The applicant has indicated that the lease will be an arm's length agreement and letters of opinion from Licensed Commercial Real Estate Brokers have been submitted indicating rent reasonableness.

Consulting Services and Billing And Collections Agreement

Rockaways ASC Development, LLC will enter into a Consulting Services and Billing and Collections Agreement with Long Island Vision Management, LLC. The consultant will provide certain non-professional business and administrative services to the ambulatory surgery center relating to the operation of the facility.

The applicant has submitted an executed agreement, which is summarized below:

Date: March 21, 2012
Facility: Rockaways ASC Development, LLC
Contractor: Long Island Vision Management, LLC
Term: 1 year term renewable yearly
Compensation: \$10,000 for billing and collection services. Hourly rate depending on years of experience. \$325/hr. for executive level, \$255/hr. for managerial level, \$175 for associate level and \$80/hr. for paraprofessional and administrative support staff.
Duties of the Consultant: Insurance verification, claims processing, collection efforts with patients and 3rd party

insurance companies, patient satisfaction evaluations, operational productivity assessments, financial and cost reviews and strategic growth and special projects.

Long Island Vision Management, LLC is a non-related party. Therefore, the consulting services and billing and collections agreement is an arm's length agreement.

Total Project Cost And Financing

Total project costs are estimated at \$3,430,779, itemized as follows:

Design Contingency	\$34,300
Planning Consultant Fees	275,000
Architect/Engineering Fees	343,000
Consultant Fees	333,582
Movable Equipment	2,418,392
Interest Expense	5,750
Application Fees	2,000
Additional Fee	<u>18,755</u>
Total Project Cost	\$3,430,779

Project cost is based on a July 1, 2013 construction start date and a twelve month construction period. The financing plan appears as follows:

Bank Loan (4.6%, 5yrs)	\$2,532,952
Member's Equity	\$897,827

A letter of interest from US Bank has been submitted by the applicant.

Operating Budget

The applicant has submitted an operating budget in 2012 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$5,241,015	\$5,729,265
Expenses:		
Operating	3,531,498	3,908,027
Capital	<u>903,237</u>	<u>920,583</u>
Total Expenses:	\$4,434,735	\$4,828,610
Net Income:	\$806,280	\$900,655
Utilization (visits)	3,991	4,415
Cost per visit	\$1,111.18	\$1,093.68

Utilization by payor source for the first and third years is as follows:

	<u>Year One</u>	<u>Year Three</u>
Commercial Fee-for-Service	32.1%	29.5%
Medicare Fee-for-Service	36.5%	39.0%
Medicaid Fee-for-Service	13.5%	14.6%
Private Pay	14.9%	13.5%
Charity Care	3.0%	3.4%

Expenses and utilization assumptions are based on the historical experience of the physician's private practices. Upon CON approval the proposed members will continue to operate their private practices. Each proposed member has provided a referral letter in support of utilization projections.

Capability And Feasibility

Total project costs of \$3,430,779 will be met through a loan from US Bank for \$2,532,952 at stated terms, with the remaining \$897,827 from proposed member's equity. Presented as BFA Attachment A is the net worth statements of proposed members, which indicates the availability of sufficient funds. The applicant has submitted an affidavit from each of the proposed members, stating that they are each willing to contribute resources disproportionate to ownership percentages.

Working capital needs are estimated at \$804,768 based on two months of third year expenses. The applicant will finance \$400,000 of working capital at an interest rate of 4.6% over 5 years for which a letter of interest has been provided by US Bank. The remaining \$404,768 will be provided as equity by the proposed members. Presented as BFA Attachment B, is the pro-forma balance sheet of Rockaways ASC Development, LLC as of the first day of operation, which indicates positive member's equity of \$1,307,363.

The submitted budget indicates a net income of \$806,280 and \$900,655 during the first and third years of operation, respectively. Revenues are based on current reimbursement methodologies for ambulatory surgery centers. The budget appears reasonable.

Based on the preceding, and subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

- BFA Attachment A Net Worth Statements of Proposed Members
- BFA Attachment B Pro-forma Balance Sheet

Supplemental Information

Outreach

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant's response to DOH's request for information on the proposed facility's volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Facility: St. John's Episcopal Hospital
 South Shore
 327 19th Street
 Far Rockaway, New York 11691

No response.

Facility: Long Beach Medical Center
455 East Bay Drive
Long Beach, New York 11561

No response.

Facility: Jamaica Hospital Medical Center
89th Avenue & Van Wyck Expressway
Jamaica, New York 11418

No response.

Facility: Beth Israel Medical Center
3201 Kings Highway
Brooklyn, New York 11234

No response.

Supplemental Information from Applicant

- Need and Sources of Cases

The applicant states that cases will be drawn from the Rockaway Peninsula area, where there are no other ambulatory surgery centers and only one remaining hospital. The applicant also cites significant recent and projected population growth in the Rockaway Peninsula as a source of initial and future cases. The applicant also states that the relative isolation of the Peninsula and associated difficulties in transportation for Peninsula residents in reaching other providers will help result in high utilization of the proposed ASC.

- Staff Recruitment and Retention

The applicant proposes to hire locally, drawing on the pool of skilled and experienced healthcare personnel formerly employed by the now-closed Peninsula Hospital. The facility will therefore not need to recruit from the existing local hospital or other providers. To help retain staff, the applicant plans to offer highly competitive salary and benefit packages and regular staff training and education.

- Office-Based Cases

The applicant states that none of the procedures projected for the proposed facility are currently performed in an office-based setting.

OHSM Comment

There were no hospital comments submitted in opposition to this application. Therefore, the Department finds no reason to consider reversal or modification of the recommendation for five-year limited life approval of the proposed ASC based on public need, financial feasibility and operator character and competence.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a multi-specialty freestanding ambulatory surgery center to provide surgical services in the specialties of ophthalmology, urology, OB-GYN, and orthopedics, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

122051 B

Rockaways ASC Development, LLC

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided; and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement from the applicant, acceptable to the Department, that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with consultation of the legal counsel, and it is concluded that proceeding with the proposal is acceptable. [RNR]
5. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission of an acceptable DBA, if applicable. [HSP]
8. Submission of an executed loan commitment that is acceptable to the Department of Health. [BFA]
9. Submission of an executed working capital loan commitment that is acceptable to the Department of Health. [BFA]
10. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01 [AER].

11. The submission of a revised site plan in SHC drawings to show additional parking spaces for drop off and pick up of patients convenient to the building entrance as required by 2010 FGI Guidelines 3.7-1.3.2.2.[AER]
12. Submission of site control that is acceptable to the Department. [CSL]
13. Submission of a signed statement regarding anti-kickback and self-referral that is acceptable to the Department. [CSL]
14. Submission of a Consulting Services Agreement that is acceptable to the Department. [CSL]
15. Submission of a Certificate of Amendment of the Articles of Organization that is acceptable to the Department. [CSL]
16. Submission of an Operating Agreement that is acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities.[HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. .[HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. .[HSP]
5. The clinical space must be used exclusively for the approved purpose. .[HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction [AER].
7. The applicant shall complete construction by July 31, 2014 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122164-B

Mason ESC, LLC
d/b/a Mason Eye Surgery Center

County: Queens (Ozone Park)

Program: Ambulatory Surgery Center

Purpose: Establishment and Construction

Submitted: October 1, 2012

Executive Summary

Description

Mason ESC, LLC, a single-member limited liability company, requests approval for the establishment and construction of a single-specialty ophthalmology ambulatory surgery center (ASC). The ASC, which will be named Mason Eye Surgery Center, will be located in leased space at 105-12 101st Avenue, Ozone Park, and consist of two procedure rooms. The sole member of Mason ESC, LLC will be Benjamin F. Mason, MD. The applicant will enter into a transfer affiliation agreement with Jamaica Hospital Medical Center.

No responses were received to the Department's inquiry to local hospitals regarding the impact of the proposed ASC in the service area.

Total project costs are estimated at \$2,323,033.

DOH Recommendation

Contingent approval, with an expiration of the operating certificate five years from the date of its issuance, should the operator not comply with the conditions of approval granted this CON.

Need Summary

Mason Eye Surgery Center will serve the patients of Dr. Mason, who currently provides services at the Mackool Eye Institute in Queens and the Ambulatory Surgery Center of Greater New York in the Bronx. It is projected that there will be 1,613 visits in the first year of operation. Based on Dr. Mason's current caseload, approximately 50 percent of those served will be Medicaid patients.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Total project costs will be met via equity of \$423,033 and a bank loan of \$1,900,000 (15 yrs. @ 5.24%).

Budget:	<i>Revenues:</i>	\$ 1,382,720
	<i>Expenses:</i>	<u>912,160</u>
	<i>Gain/(Loss):</i>	\$ 470,560

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided; and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
5. Submission of appropriate information on the operating hours of the proposed D & TCs. [RNR]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission of a bank loan commitment that is acceptable to the Department of Health. [BFA]
8. Submission of a working capital loan commitment that is acceptable to the Department of Health. [BFA]
9. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

Approval conditional upon:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by December 31, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

Mason ESC, LLC d/b/a Mason Eye Surgery Center requests approval to establish and construct a single-specialty ambulatory surgery center providing ophthalmology services, to be located at 105-12 101st Avenue, Ozone Park, 11416, in Queens County. The proposed freestanding ambulatory surgery center will include two procedure rooms.

Analysis

The primary service area for the Mason Eye Surgery Center will be consistent with Dr. Mason's current practice located at 41-41 51st Street, Woodside, in Queens County and will include the following zip codes: Woodside 11377, Jackson Heights 11372, Sunny Side 11104, and Corona 11368.

The number of projected visits is as follows:

First Year: 1,613
Third Year: 1,711

Queens County has one freestanding single specialty ambulatory surgery center for ophthalmology and five multi specialty ASCs.

Between 2009 and 2010, the number of patients requiring ophthalmology surgery procedures including cataract, glaucoma, and other eye disorders increased by 5.8% from 14,292 to 15,122 in Queens County. The proposed ASC will serve all patients in need regardless of their ability to pay.

The applicant has provided a statement that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws with consultation of the legal counsel. This statement is acceptable to the Department.

Conclusion

Mason Eye Surgery Center, LLC (MESC) will bring the existing practice of Dr. Benjamin Mason under a regulated Article 28 entity and will consolidate services in one location. Based on Dr. Mason's current caseload, approximately 50% of the patients will be Medicaid.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Background

Establish a diagnostic and treatment center that will also be federally certified as an ambulatory surgery center.

Proposed Operator	Mason ESC, LLC
Doing Business As	Mason Eye Surgery Center
Site Address	105-12 101 st Avenue, Ozone Park
Surgical Specialties	Ophthalmology
Operating Rooms	0
Procedure Rooms	2
Hours of Operation	7:00am to 3:00pm, one or two days per week initially, expanding as utilization increases.
Staffing (1 st Year / 3 rd Year)	2.6 FTEs / 2.6 FTEs
Medical Director(s)	Benjamin Mason (sole member)
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Jamaica Hospital Medical Center 2 miles and 7 minutes distance

On-call service	Access to the facility's on-call physician during hours when the facility is closed.
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Character and Competence

The sole member of the LLC is Benjamin Mason, MD, a practicing physician.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

The Center will consider becoming part of an Accountable Care Organization or Medical Home after approval and as they develop. The Center will be utilizing electronic medical records and will consider joining a Regional Health Information Organization or Health Information Exchange.

Compliance with Applicable Codes, Rules and Regulations

The medical staff will ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements. The Center intends to review the list acceptable procedures annually and as needed to determine the appropriateness of adding new procedures consistent with individual physician expertise.

Recommendation

From a programmatic perspective, contingent approval is recommended.

<h2>Financial Analysis</h2>

Lease Rental Agreement

The applicant has submitted an executed lease rental agreement for the site that they will occupy, which is summarized below:

- Premises:* 6,150 sq. ft. located at 105-12 101st Avenue, Ozone Park, New York
- Lessor:* Queens NY Realty, LLC
- Lessee:* Mason ESC, LLC
- Term:* 10 years with two additional five year terms.
- Rental:* Initial Term: \$153,750 annually (\$25.00 per sq.ft.)
 First Renewal Term: \$184,500 annually (\$30.00 per sq. ft.)
 Second Renewal Term: \$202,950 annually (\$33.00 per sq. ft.)
- Provisions:* The lease shall be responsible for utilities, taxes and maintenance.

The applicant has indicated that the lease arrangement will be a non-arms length arrangement, since the sole member of the applicant is also the sole member of the landlord entity.

Total Project Cost and Financing

Total project cost, which is for new construction and the acquisition of moveable equipment, is estimated at \$2,323,033, further itemized as follows:

New Construction	\$1,422,945
Design Contingency	142,295
Construction Contingency	89,798
Architect/Engineering Fees	118,000
Other Fees (Consultant Fees)	68,000
Moveable Equipment	407,000
Telecommunications	15,300
Interim Interest Expense	45,000
CON Fee	2,000
Additional Processing Fee	<u>12,695</u>
Total Project Cost	<u>\$ 2,323,033</u>

Project costs are based on an April 1, 2013 construction start date and a nine month construction period.

The applicant's financing plan appears as follows:

Equity	\$ 423,033
Bank Loan (5 year Treasury Constant Maturity Rate + 3.50%; approximately 5.24% as of 11/21/2012) for a fifteen year term.	\$1,900,000

Operating Budget

The applicant has submitted an operating budget, in 2013 dollars, for the first and third years, summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$1,355,465	\$1,382,720
Expenses:		
Operating	\$ 502,312	\$ 532,292
Capital	<u>396,951</u>	<u>379,868</u>
Total Expenses:	\$ 899,263	912,160
Net Income:	\$ 456,202	\$ 470,560
Utilization: (Procedures)	1,613	1,711
Cost Per Procedure:	\$557.51	\$533.12

Expense and utilization assumptions are based on the sole member's historical experience operating at two facilities. The applicant submitted a letter attesting to the utilization projections.

Utilization, itemized by payor source, during the first and third years is as follows:

	<u>Year One</u>	<u>Year Three</u>
Medicaid Managed Care	49.96%	49.91%
Medicare Fee-for-Service	23.00%	23.03%
Commercial Managed Care	25.04%	25.06%
Charity Care	2.00%	2.00%

Capability and Feasibility

Total project cost of \$2,323,033 will be met as follows: Equity of \$423,033 to be derived from the sole member's personal assets, and a bank loan of \$1,900,000 at an interest rate based on the 5 year Treasury Constant Maturity Rate +3.50% (approximately 5.24% as of 11/21/2012) for a fifteen year term. A letter of interest has been submitted in regard to the financing.

Working capital requirements are estimated at \$152,026, which is equivalent to two months of third year expenses. The applicant will finance \$76,013 at an interest rate of the 5 year Treasury Constant Maturity Rate +3.50% (approximately 5.24% as of 11/21/2012) for a five year term. The remainder, \$76,013, will be provided by the sole member's personal assets.

Presented as BFA Attachment A is the personal net worth statement of the sole member of Mason ESC, LLC, which indicates the availability of sufficient funds for the equity contributions to meet the total project cost and the working capital. Presented as BFA Attachment B, is the pro-forma balance sheet of Mason ESC, LLC, which indicates a positive net asset position of \$499,046 as of the first day of operation.

The submitted budget indicates a net income of \$456,202 and \$470,560 during the first and third years, respectively. Revenues are based on current reimbursement rates for ambulatory surgery services. The budget appears reasonable.

Subject to the noted contingencies, it appears that the applicant has been demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

- BFA Attachment A Personal Net Worth Statement- Sole member of Mason ESC, LLC
- BFA Attachment B Pro-forma Balance Sheet of Mason ESC, LLC

Supplemental Information

Outreach

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant's response to DOH's request for information on the proposed facility's volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Facility: Jamaica Hospital Medical Center
 8900 Van Wyck Expressway
 Jamaica, New York 11418

No response.

Facility: Queens Hospital Center
82-68 164th Street
Jamaica, New York 11432

No response.

Facility: Forest Hills Hospital
102-01 66th Road
Forest Hills, New York 11375

No response.

Supplemental Information from Applicant

- Need and Sources of Cases

The applicant states that the projected caseload for the proposed ASC will be exclusively patients of the applicant physician, representing a migration of his current outpatient caseload from two established freestanding ASCs to the proposed facility. This caseload includes significant minority populations, including Latino and Asian (Indian and Bangladeshi) residing within the Woodside, Jackson Heights, Sunnyside and Corona areas of Queens. Approximately 50 percent of the proposed ASC's patients will be Medicaid patients.

- Staff Recruitment and Retention

The applicant states that the staffing requirements for the facility are projected to be 2.6 FTE, most of whom will be part-time. The ASC may hire some of its nursing staff from the applicant physician's medical practice. Other staff will be recruited from accredited schools and training programs, as well as through advertisements in local newspapers and professional publications. The ASC will also offer competitive salaries and benefits and will maintain good resource and communications systems. In addition, the facility will provide a positive work environment and flexible working hours.

- Office-Based Cases

All of the projected cases for the proposed facility are currently performed in freestanding ASC's, and none in office-based settings or in hospitals.

OHSM Comment

There were no hospital comments submitted in opposition to this application. Therefore, the Department finds no reason to consider reversal or modification of the recommendation for five-year limited life approval of the proposed ASC based on public need, financial feasibility and operator character and competence.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a freestanding single-specialty ambulatory surgery center providing ophthalmology services to be located at 105-12 101st Avenue, Queens, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

122164 B

FACILITY/APPLICANT:

Mason ESC, LLC
d/b/a Mason Eye Surgery Center

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided; and
 - Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
4. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
5. Submission of appropriate information on the operating hours of the proposed D & TCs. [RNR]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission of a bank loan commitment that is acceptable to the Department of Health. [BFA]
8. Submission of a working capital loan commitment that is acceptable to the Department of Health. [BFA]
9. The submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

APPROVAL CONDITIONAL UPON:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, signed and sealed by the project architect, as described in BAEFP Drawing Submission Guidelines DSG-01, prior to the applicant's start of construction. [AER]
7. The applicant shall complete construction by December 31, 2013 in accordance with 10 NYCRR Part 710.2(b)(5) and 710.10(a), if construction is not completed on or before that date, this may constitute abandonment of the approval and this approval shall be deemed cancelled, withdrawn and annulled without further action by the Commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 121445-B
**New Life Community Development Corporation
d/b/a New Life Community Health Center**

County: Queens (Elmhurst)
Purpose: Establishment and Construction

Program: Diagnostic and Treatment Center
Submitted: June 20, 2012

Executive Summary

Description

New Life Community Development Corporation, an existing not-for-profit corporation, requests establishment and construction approval for an Article 28 primary care diagnostic and treatment center (D&TC), to be located at 82-10 Queens Boulevard, Elmhurst. The proposed corporation will do business as New Life Community Health Center.

The applicant states they have been operating a free clinic, serving uninsured immigrants, since 2005. They state they have been providing baseline services such as health education, blood pressure reading, glucose testing, and eye exams, in addition to numerous health fairs in the community. The corporation now seeks Article 28 status as the needs of the community require more resources than can be provide via volunteer staff.

DOH Recommendation
Contingent approval.

Need Summary

New Life Community Health Center has been operated by volunteers as a free clinic since 2005. In 2005, the clinic had 226 visits and in 2011 there were 1,208 visits.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

There is no project costs associated with this application. The projected budget for this facility is as follows.

Budget:	<i>Revenues:</i>	\$ 484,773
	<i>Expenses:</i>	<u>455,816</u>
	<i>Gain/(Loss):</i>	\$ 28,957

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a statement from the applicant, acceptable to the Department, documenting commitment to serve patients regardless of their ability to pay or the source of payment and the amount of charity care. [RNR]
2. Submission of information from the applicant, acceptable to the Department, describing the hours of operation of the proposed extension clinic. [RNR]
3. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
4. Submission of a Certificate of Assumed Name. [CSL]
5. Submission of a photocopy of an executed amended Certificate of Incorporation, acceptable to the Department. [CSL]

Approval conditional upon:

1. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
2. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
3. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
4. The clinical space must be used exclusively for the approved purpose. [HSP]
5. The submission of record drawings of the proposed Article 28 facility certified compliant with NYCRR Title 10. [AER]

Council Action Date

February 7, 2013.

Need Analysis

Background

New Life Community Health Center seeks approval to establish and construct an Article 28 diagnostic and treatment center at 82-10 Queens Boulevard, Elmhurst, 11373, in Queens County.

Analysis

The proposed clinic is located in zip code 11373 and serves the surrounding area in Elmhurst. The proposed services of the D & T Center are:

Dental O/P	Family Planning O/P	Medical Social Services O/P
Nutritional O/P	Ophthalmology O/P	Pediatric O/P
Pharmaceutical O/P	Prenatal O/P	Primary Medical Care O/P
Psychology O/P	Well Child	

The number of projected visits is as follows:

First Year:	4,479
Third Year:	8,117

The proposed location is in a HRSA health professional shortage area for primary care services (Medicaid Eligible-Elmhurst).

The Table below provides information on the Prevention Quality Indicator (PQI) rates for major condition categories for zip code 11368, a major portion of the service area. These rates are significantly higher than those for New York State as a whole for all PQI conditions except for the 'All Respiratory' category.

<i>PQI Rates-Hospital Admissions per 100,000 Adult</i>		
<i>PQI Rates</i>	<i>Zip code 11368</i>	<i>NYS</i>
All Acute	629	526
All Circulatory	497	456
All Diabetes	353	224
All Respiratory	310	357
All Above	1,803	1,563

Source: NYSDOH-PQI

Conclusion

NLCHC provides services in an underserved area with poor health indicators. However, the facility currently must rely on volunteers to provide services. Certification as an Article 28 D & TC will allow NLCHC to increase its revenues, which will enable it to hire salaried staff to supplement the efforts of its volunteers and to expand its volume of services in an area of high need.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Background

Establish a diagnostic and treatment center. The applicant states they have been operating a free clinic, serving uninsured immigrants, since 2005, providing baseline services such as health education, blood pressure reading,

glucose testing, and eye exams, in addition to numerous health fairs in the community. The corporation now seeks Article 28 status as the needs of the community require more resources than can be provide via volunteer staff.

Proposed Operator	New Life Community Development Corp.
Doing Business As	New Life Community Health Center
Site Address	82-10 Queens Blvd, Queens
Staffing (1 st Year / 3 rd Year)	4.8 FTEs / 8.1 FTEs
Medical Director(s)	Agustin Francisco Sanchez
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Elmhurst Hospital 1 mile and 3 minutes away

Character and Competence

The board members are:

<u>Name</u>	
Silvett Garcia-Tsuang	Secretary
Peter Glus	Vice President
Seung Chung Glus	Treasurer
Peter Scazzero	President

The proposed board members have all been involved with the center under its current format. Peter Scazzero is a minister with 25 years of experience leading community-based not-for-profit organizations serving the poor. He is one of the original founders of the corporation in 1993 and has served as the Board President for the last 12 years. The corporation, besides operating a free clinic runs a multitude of other community programs such as English classes, after-school youth programs, and food and clothing pantries. Peter Glus is a professional engineer and is the vice president of an environmental engineering company. He has overseen securing the facility and renovation of the property that the center now leases as well as helping manage the financial resources of the corporation to allow it to expand its community programs. Seung Glus is a teacher who has also served as a volunteer for many community organizations serving immigrants and impoverished. She served as the interim Executive Director for two years and helped standardize the corporations fund raising efforts. Silvett Garcia-Tsuang has degrees in urban planning and public health and has worked for a variety of not-for-profit social service organizations in the areas of urban planning and immigration services.

As none of the board members have documented medical experience or experience operating a health care facility, in keeping with past practice, disclosure information was submitted and reviewed for the medical director.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant’s ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Lease Rental Agreement

The applicant has submitted an executed lease rental agreement for the site to be occupied. The terms of which are summarized below:

Premises: 2,379 square feet located at 82-10 Queens Boulevard, Elmhurst, New York
Lessor: New Life Fellowship
Lessee: New Life Community Development Corp.
Rental: \$12,000 annually (\$5.04 per sq. ft.)
Term: Four Year lease renewable for an extended (5) years.
Provisions: Utilities are not included in the base rent. Maintenance service, security services and hot and cold water is included in the base rent. A provision in the lease to hold the renewal for the current lease for consideration of \$1,200 per year is currently being exercised by the tenant.

The applicant has provided two letters indicating the rent reasonableness. The applicant has submitted an affidavit indicating that the lease agreement will be an arms length lease agreement. The "Free Clinic" currently operating is located at the same location as the proposed new clinic.

Operating Budget

The applicant has submitted a total operating budget, in 2012 dollars, for the first and third years of operation as summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$277,529	\$484,773
Expenses:		
Operating	\$215,450	\$419,816
Capital	<u>12,000</u>	<u>18,000</u>
Total Expenses	\$227,450	\$455,816
Excess Revenues over Expenses:	\$50,079	\$28,957
Utilization: Visits	4,480	8,117
Cost Per Visit:	\$50.77	\$56.15

Utilization by payor source for the first and third year:

	<u>Year One</u>	<u>Year Three</u>
Medicaid Fee-for-Service	10%	10%
Medicaid Managed Care	30%	38%
Medicare Fee-for-Service	6%	5%
Commercial Managed Care	8%	8%
*Private Pay/Charity Care	46%	39%

**Private pay and charity care are directly related as the fee for a visit is either \$0 up to \$15 per visit if the patient can afford it based on an application completed at the time services are provided. As a free clinic, fees not collected for services rendered are not considered an uncollected receivable or "bad debt" as in a traditional clinic.*

Expense and utilization assumptions are based on the historical experience of New Life Community Health Center operating as a "Free Clinic" which has been operating for approximately seven years. The current Medical Director of New Life Community Health Center, Agustin Francisco Sanchez, MD., will stay on as the Medical Director of the newly formed article 28 clinic.

Capability and Feasibility

There are no project costs associated with this application.

Working capital requirements are estimated at \$75,970, which appears reasonable based on two months' of third year expense.

The proposed working capital requirement will be met through equity from New Life Development Corporation as presented in BFA Attachment indicating sufficient working capital equity.

The submitted budget for the facility indicates a net income of \$50,079 and \$28,957 during the first and third year of operation.

New Life Development Corp. has experienced an average positive net asset position during 2010 and 2011, and an excess of revenue over expenses of (\$30,689) and \$64,276, respectively. The reason for the loss in 2010 was due to decreased fundraising efforts. New Life Community Corporation hired new leadership to focus on fundraising and its financial efforts which have had a positive impact in 2011.

Presented as BFA Attachment B, is the pro-forma balance sheet of New Life Development Corporation, which indicates a positive equity position of \$185,130 as of the first day of operation.

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, approval is recommended.

Attachments

BFA Attachment A	Financial Summary for New Life Community Development Corp.
BFA Attachment B	Pro-forma Balance Sheet for New Life Community Health Center

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a diagnostic and treatment center to be located at 82-10 Queens Boulevard, Elmhurst, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

121445 B

FACILITY/APPLICANT:

New Life Community Development Corporation
d/b/a New Life Community Health Center

APPROVAL CONTINGENT UPON:

1. Submission of a statement from the applicant, acceptable to the Department, documenting commitment to serve patients regardless of their ability to pay or the source of payment and the amount of charity care. [RNR]
2. Submission of information from the applicant, acceptable to the Department, describing the hours of operation of the proposed extension clinic. [RNR]
3. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
4. Submission of a Certificate of Assumed Name. [CSL]
5. Submission of a photocopy of an executed amended Certificate of Incorporation, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
2. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
3. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
4. The clinical space must be used exclusively for the approved purpose. [HSP]
5. The submission of record drawings of the proposed Article 28 facility certified compliant with NYCRR Title 10. [AER]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122003-E
Pavilion Operations, LLC
d/b/a Corning Center for Rehabilitation and Healthcare

County: Steuben (Corning)
Purpose: Establishment

Program: Residential Health Care Facility
Submitted: July 2, 2012

Executive Summary

Description

Pavilion Operations, LLC, d/b/a Corning Center for Rehabilitation and Healthcare, which was formed to pursue this CON, requests approval to be established as the new operator of Founders Pavilion, Inc. (formerly named GF Corning, Inc.), an existing 120-bed not-for-profit residential health care facility (RHCF) located at 205 East First Street, Corning. A separate realty entity, Pavilion Realty, LLC, will acquire the facility's real property.

The current sole member and passive parent of Founders Pavilion, Inc., is the Guardian Foundation, a Pennsylvania based not-for-profit corporation, with headquarters in Atlanta, Georgia.

Ownership of the operating interests after the requested change is as follows:

Proposed Operator	
<i>Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare</i>	
MEMBERS:	
-- Kenneth Rozenberg	50%
-- Jeremy Strauss	25%
-- Amir Abramchik	5%
-- Abraham Bronner	5%
-- Jeffrey Sicklick	5%
-- Gedalia Klein	5%
-- David Greenberg	5%

DOH Recommendation
Contingent approval.

Need Summary

The 2016 projected need of 691 beds has been met in Steuben County. Founders Pavilion's utilization was 95.7% in 2011, which was slightly higher than that of

Steuben County at 94.3%. The proposed purchase of Founders Pavilion by Pavilion Operations, LLC will result in no change in the facility's beds and will help ensure its continued operation as a well-utilized source of RHCF care within the county.

Program Summary

No negative information has been received concerning the character and competence of the above applicants identified as new members. No changes in the program or physical environment are proposed in this application.

Financial Summary

Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation will acquire the RHCF operating assets for \$2,000,000 plus \$3,000 in fees, which will be funded as follows: \$503,000 from member's equity, and a \$1,500,000 mortgage with 20-year self-amortizing terms at a 5.5% interest rate. The real property will be purchased for \$1,000,000 by Pavilion Realty, LLC, and will be funded as follows: \$250,000 in members' equity, and \$750,000 mortgage with 20-year self-amortizing terms at a 5.5% interest rate. There are no project costs associated with this proposal.

Budget:	<i>Revenues:</i>	\$ 9,726,000
	<i>Expenses:</i>	<u>9,403,000</u>
	<i>Gain/(Loss):</i>	\$ 323,000

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

The Finger Lakes Health Systems Agency recommends conditional approval of this application.

Office of Health Systems Management

Approval contingent upon:

1. The submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
2. Submission of a plan to enhance access to Medicaid residents. At a minimum, the plan should include, but not necessarily limited to, ways in which the facility will:
 - a) Reach out to hospital discharge planners to make them aware of the facility's Medicaid Access Program;
 - b) Communicate with local hospital discharge planners on a regular basis regarding bed availability at the nursing facility;
 - c) Identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility, and inform them about the facility's Medicaid Access policy; and
 - d) Submit an annual report for two years to the DOH, which demonstrates substantial progress with the implement of the plan. The plan should include but not be limited to:
 - Information on activities relating to a-c above; and
 - Documentation pertaining to the number of referrals and the number of Medicaid admissions; and
 - Other factors as determined by the applicant to be pertinent.

The DOH reserves the right to require continued reporting beyond the two year period. [RNR]

3. Submission of a photocopy of the executed Lease Agreement between Pavilion Operations, LLC and Pavilion Realty, LLC, acceptable to the Department of Health. [BFA, CSL]
4. Submission of a mortgage commitment to purchase nursing home operations that is acceptable to the Department. [BFA]
5. Submission of a working capital commitment that is acceptable to the Department. [BFA]
6. Submission of a photocopy of the fully executed proposed Certificate of Amendment to the Certificate of Incorporation of Founders Pavilion, Inc., or the fully executed proposed Certificate of Dissolution of Founders Pavilion, Inc., acceptable to the Department. [CSL]

Approval conditional upon:

1. Submission, within 2 years, of a facility development plan which addresses the code and functional deficiencies previously addressed in CON #062442-C. [HSA]
2. Submission, within 2 years, of an application to convert at least 10 RHCF beds to a needed specialty bed service, such as ventilator-dependent, traumatic brain injury, or another type of specialty bed. [HSA]

Council Action Date

February 7, 2013.

Need Analysis

Background

Pavilion Operations, LLC seeks approval to enter into an asset purchase agreement with Founders Pavilion, Inc to purchase Founders Pavilion, a 120 bed voluntary not for profit, residential health care facility located at 205 East First Street, Corning, in Steuben County, 14830.

Founders Pavilion's bed occupancy rate was higher than the RHCF bed occupancy rate for Steuben County as a whole in 2009, 2010, and 2011, as shown in the table below:

<u>RHCF Utilization</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>
Founders Pavilion	95.2%	97.2%	95.7%
Steuben County	90.9%	91.0%	94.3%

As indicated below in the table below, the projected 2016 bed need for Steuben County is 0, as the need has been fully met in the jurisdiction.

<u>RHCF Bed Need</u>	<u>Steuben County</u>
2016 Projected Need	691
Current Beds	691
Beds Under Construction	0
Unmet Need	0

Access

Regulations indicate that the Medicaid patient admissions standard shall be 75% of the annual percentage of all Medicaid admissions for the long term care planning area in which the applicant facility is located. Such planning area percentage shall not include residential health care facilities that have an average length of stay 30 days or fewer. If there are four or fewer residential health care facilities in the planning area, the applicable standard for a planning area shall be 75% of the planning area percentage of Medicaid admissions or 75% of the Health Systems Agency area percentage of Medicaid admissions, whichever is less. In calculating such percentages, the Department will use the most current data which have been received and analyzed by the Department.

Founders Pavilion Medicaid Admissions 2009	- 6.5%
Founders Pavilion Medicaid Admissions 2010	- 15.4%
Steuben County's 75% of Total Medicaid Admissions 2009	- 9.1%
Steuben County's 75% of Total Medicaid Admissions 2010	- 17.4%

Founders Pavilion did not meet the Medicaid contingency for either 2009 or 2010.

CONCLUSION

The proposed purchase of Founders Pavilion by Pavilion Operations, LLC will result in no change in the facility's beds and will help ensure its continued operation as a well-utilized source of RHCF care within the county.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Facility Information

	<i>Existing</i>	<i>Proposed</i>
<i>Facility Name</i>	Founders Pavilion	Corning Center for Rehabilitation and Healthcare
<i>Address</i>	205 East First Street Corning, NY. 14830	Same
<i>RHCF Capacity</i>	120	Same
<i>ADHCP Capacity</i>	N/A	N/A
<i>Type of Operator</i>	Corporation	LLC
<i>Class of Operator</i>	Not-for-profit	Proprietary
<i>Operator</i>	Founders Pavilion, Inc. <u>Chairman of the Board</u> Tony Tripeny	Pavilion Operations, LLC <u>New Members</u> Kenneth Rozenberg 50% -- Managing Member Jeremy Strauss 25% Amir Abramchik 5% Abraham Bronner 5% Jeffrey Sicklick 5% Gedalia Klein 5% David Greenberg 5%

Character and Competence

- FACILITIES REVIEWED:

Residential Health Care Facilities (RHCF)

Boro Park Center for Rehabilitation and Health Care	05/2011 to present
Bronx Center for Rehabilitation and Health Care	01/2003 to present
Brooklyn Center for Rehabilitation and Residential Health	03/2007 to present
Bushwick Center for Rehabilitation and Health Care	05/2011 to present
Chittenango Center for Rehabilitation and Health Care	05/2011 to present
Dutchess Center for Rehabilitation	01/2004 to present
Fulton Center for Rehabilitation and Health Care	04/2012 to present
Holliswood Care Center	11/2010 to present
Queens Center for Rehabilitation and Residential Healthcare	01/2004 to present
Richmond Center for Rehabilitation and Specialty Healthcare	04/2012 to present
Rome Center for Rehabilitation and Health Care	05/2011 to present
Stonehedge Health and Rehabilitation Center- Chittenango	07/2008 to 04/2011
Stonehedge Health and Rehabilitation Center- Rome	07/2008 to 04/2011
Suffolk Center for Rehabilitation and Nursing	05/2007 to 07/2011
University Nursing Home	01/2003 to present
Wartburg Lutheran Home for the Aging	06/2008 to 05/2011
Waterfront Health Care Center	08/2011 to present
Williamsbridge Manor Nursing Home	01/2003 to present

Certified Home Health Agency (CHHA)

Alpine Home Health Care	07/2008 to present
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Licensed Home Care Services Agency (LHCSA)
Amazing Home Care

05/2006 to present

Emergency Medical Services (EMS)
Senior Care Emergency Ambulance Services, Inc.

05/2005 to present

• **INDIVIDUAL BACKGROUND REVIEW:**

Kenneth Rozenberg is a licensed nursing home administrator in good standing, and also a licensed New York State paramedic in good standing. Mr. Rozenberg has been employed as CEO of Bronx Center for Rehabilitation & Health Care since January, 1998. Mr. Rozenberg discloses the following health facility interests:

Williamsbridge Manor Nursing Home	11/1996 to present
Bronx Center for Rehabilitation and Health Care	10/1997 to present
University Nursing Home	08/2001 to present
Dutchess Center for Rehabilitation and Healthcare	08/2004 to present
Queens Center for Rehabilitation and Residential Health Care	06/2004 to present
Brooklyn Center for Rehabilitation and Residential Health Care	03/2007 to present
Stonehedge Health & Rehabilitation Center - Rome (receiver)	07/2008 to 04/2011
Stonehedge Health & Rehabilitation Center - Chittenango (receiver)	07/2008 to 04/2011
Rome Center for Rehabilitation and Health Care	05/2011 to present
Chittenango Center for Rehabilitation and Health Care	05/2011 to present
Bushwick Center for Rehabilitation and Health Care	05/2011 to present
Wartburg Lutheran Home for the Aging (receiver)	06/2008 to 05/2011
Boro Park Center for Rehabilitation and Healthcare	05/2011 to present
Fulton Center for Rehabilitation and Healthcare	04/2012 to present
Richmond Center for Rehabilitation and Specialty Healthcare	04/2012 to present
Holliswood Center for Rehabilitation and Healthcare (receiver)	11/2010 to present
Waterfront Health Care Center, Inc. (receiver)	08/2011 to present
Alpine Home Health Care (CHHA)	07/2008 to present
Amazing Home Care (LHCSA)	05/2006 to present
Senior Care Emergency Ambulance Services, Inc. (EMS)	06/2005 to present

Jeremy B. Strauss has been employed as Executive Director of Dutchess Center for Rehabilitation since April, 2003. Mr. Strauss discloses the following health facility interests:

Dutchess Center for Rehabilitation and Healthcare	08/2004 to present
Queens Center for Rehabilitation and Residential Health Care	06/2004 to present
Brooklyn Center for Rehabilitation and Residential Health Care	03/2007 to present
Suffolk Center for Rehabilitation and Nursing	05/2007 to 07/2011
Rome Center for Rehabilitation and Health Care	05/2011 to present
Chittenango Center for Rehabilitation and Health Care	05/2011 to present
Bushwick Center for Rehabilitation and Health Care	05/2011 to present
Boro Park Center for Rehabilitation and Healthcare	05/2011 to present
Fulton Center for Rehabilitation and Healthcare	04/2012 to present
Richmond Center for Rehabilitation and Specialty Healthcare	04/2012 to present
Senior Care Emergency Ambulance Services, Inc. (EMS)	04/2011 to present

Amir Abramchik is a nursing home administrator in good standing in the states of New York and New Jersey. Mr. Abramchik has been employed as the Director of Special Projects at Centers for Specialty Care, a nursing home billing company in Bronx, NY since January 2007. Prior to his employment at the Centers for Specialty Care, Mr. Abramchik was the Administrator of Record at the Queens Center for Rehabilitation and Health Care from August 2005 through January 2007 and the Administrator of Record at the Dutchess Center for Rehabilitation and Health Care from September 2003 through August 2005. Mr. Abramchik discloses the following health facility interests:

Chittenango Center for Rehabilitation and Health Care	05/2011 to present
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Rome Center for Rehabilitation and Health Care	05/2011 to present
Fulton Center for Rehabilitation and Healthcare	04/2012 to present
Richmond Center for Rehabilitation and Specialty Healthcare	04/2012 to present

Abraham Bronner has been employed as a controller by the Centers for Specialty Care, a nursing home billing company in Bronx, NY since March 2008. Prior to his employment at the Centers for Specialty Care, Mr. Bronner was the controller at the Stonehedge Health and Rehabilitation Center in Rome, NY from June 2007 through March 2008, the controller at the Forest Hills Care Center from October 2004 through May 2007, and the controller at Hollis Park Manor Nursing Home from 1997 through October 2004. He discloses no ownership interest in health facilities.

Jeffrey N. Sicklick is a nursing home administrator in good standing in the states of New York and New Jersey. Mr. Sicklick has been employed as the Administrator of Record at the Bronx Center for Rehabilitation & Health Care since October, 1997. Mr. Sicklick previously served as Administrator of Record at Queens Center for Rehabilitation from June 2004 to August 2004 and Dutchess Center for Rehabilitation from May 2003 to September 2003. Mr. Sicklick discloses the following health facility interests:

Dutchess Center for Rehabilitation and Healthcare	08/2004 to present
Queens Center for Rehabilitation and Residential Health Care	07/2007 to present
Boro Park Center for Rehabilitation and Healthcare	05/2011 to present
Bushwick Center for Rehabilitation and Health Care	05/2011 to present
Rome Center for Rehabilitation and Health Care	05/2011 to present
Chittenango Center for Rehabilitation and Health Care	05/2011 to present
Fulton Center for Rehabilitation and Healthcare	04/2012 to present
Richmond Center for Rehabilitation and Specialty Healthcare	04/2012 to present

Gedalia Klein is a New York licensed nursing home administrator, for which he is registered and is considered to be in good standing. He is currently employed at the Northern Services Group, a medical and social adult day health care program serving as Chief Operating Officer since May 2007. He discloses no ownership interest in health facilities.

David Greenberg is a nursing home administrator in good standing in the states of New York and New Jersey. Mr. Greenberg has been employed as the Administrator of Record at the Boro Park Center for Rehabilitation and Healthcare since July 2010. Mr. Greenberg previously served as the Administrator of Record at the Liberty House Nursing Home from May 2002 through November 2007. He discloses no ownership interest in health facilities.

Character and Competence – Analysis:

No negative information has been received concerning the character and competence of the above applicants identified as new members.

A review of **Williamsbridge Manor Nursing Home** for the period identified above reveals the following:

- Williamsbridge Manor Nursing Home was fined \$1,000 pursuant to a Stipulation and Order issued July 8, 2008 for surveillance findings of December 19, 2007. A deficiency was found under 10 NYCRR 415.12 Quality of Care.

A review of operations of **Bronx Center for Rehabilitation and Health Care** for the period identified above reveals the following:

- The facility was fined \$2,000 pursuant to a Stipulation and Order issued October 23, 2007 for surveillance findings on April 27, 2007. Deficiencies were found under 10 NYCRR 415.12 Quality of Care and 415.12(i)(1), Quality of Care: Nutrition.
- The facility was fined \$4,000 pursuant to a Stipulation and Order issued August 25, 2011 for surveillance findings on April 16, 2010. Deficiencies were found under 10 NYCRR 415.12 (h)(2) Quality of Care: Accidents and Supervision and 415.26 Administration.

A review of operations of **Stonehedge Health and Rehabilitation Center – Chittenango** (receivership), for the period identified above reveals the following:

- The facility was fined \$4,000 pursuant to a Stipulation and Order issued November 15, 2010 for surveillance findings on October 22, 2009. Deficiencies were found under 10 NYCRR 415.12(h)(1,2) Quality of Care: Accidents and Supervision and 415.26(b)(3)(4) Governing Body.

A review of the operations of **Chittenango Center for Rehabilitation and Health Care** for the period identified above reveals the following:

- The facility was fined \$20,000 pursuant to a Stipulation and Order issued February 17, 2012 for surveillance findings on January 20, 2011. Deficiencies were found under 10 NYCRR 415.12(c)(1)(2) Quality of Care: Pressure Sores and NYCRR 415.12(d)(1) and Quality of Care: Catheters

The review of operations for Williamsbridge Manor Nursing Home, Bronx Center for Rehabilitation and Health Care, and Chittenango Center for Rehabilitation and Health Care (formerly Stonehedge Health and Rehabilitation Center at Chittenango) for the time periods indicated above results in a conclusion of substantially consistent high level of care since there were no repeat enforcements.

The review of operations of University Nursing Home, Dutchess Center for Rehabilitation and Healthcare, Queens Center for Rehabilitation and Residential Health Care, Brooklyn Center for Rehabilitation and Residential Health Care, Bushwick Center for Rehabilitation and Health Care (formerly Wartburg Lutheran Home for the Aging), Boro Park Center for Rehabilitation and Healthcare, Rome Center for Rehabilitation and Health Care (formerly Stonehedge Health and Rehabilitation Center at Rome), Suffolk Center for Rehabilitation and Nursing, Holliswood Center for Rehabilitation and Healthcare, Fulton Center for Rehabilitation and Healthcare, Richmond Center for Rehabilitation and Specialty Healthcare, and Waterfront Health Care Center, Inc. for the time periods indicated above reveals that a substantially consistent high level of care has been provided since there were no enforcements.

A review of Alpine Home Health Care, LLC and Amazing Home Care reveals that a substantially consistent high level of care has been provided since there were no enforcements.

The review of Senior Care Emergency Ambulance Services, Inc. reveals that a substantially consistent high level of care has been provided since there were no enforcements.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Background

BFA Attachment A presents the proposed members' net worth statements. Several proposed members have recently acquired an ownership interest in four RHCF facilities. They include the following: Boro Park Operating Co., LLC d/b/a Boro Park Center for Rehabilitation and Healthcare (CON 092075 & 121079), Waterfront Operations Associates, LLC d/b/a Waterfront Center for Rehabilitation and Health Care (CON 112218), Fulton Operations Associates, LLC d/b/a Fulton Center for Rehabilitation and Healthcare (CON 111540), and SV Operating Three, LLC d/b/a Richmond Center for Rehabilitation and Specialty Healthcare (CON 112014). The real property for the above four transactions are owned by various entities controlled primarily by Daryl Hagler

Asset Purchase/Sale Agreement

The applicant has submitted an executed agreement to purchase the RHCF operating interest, the terms are summarized below:

<i>Date:</i>	June 1, 2012
<i>Seller:</i>	Founders Pavilion, Inc.
<i>Purchaser:</i>	Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare
<i>Assets Transferred</i>	
<i>Operations:</i>	Rights, title and interest in: business and operations; equipment, tangible

personal property; all transferable business related contracts; inventory; business and trade names, security deposits, procedure manuals and computer software, phone numbers, financial records patient records, goodwill, licenses and permits; provider agreements and provider numbers.

Excluded Assets: Cash, marketable securities, accounts receivable, third party claims, refunds, and retroactive rate increases.

Assumed Liabilities: Those accruing on or after closing date.

Purchase Price: \$2,000,000

Payment of Purchase Price:

\$200,000 1st escrow deposit –paid 1/9/2012	
\$800,000 2 nd escrow deposit- at closing	(the \$1 million in the escrow account will be held there until one year after the closing date)
\$1,000,000 balance to be paid to seller at closing	

The purchase price is proposed to be satisfied as follows:

Equity – Pavilion Operations, LLC members will contribute	\$500,000
Mortgage – 5.5%, 20-year term that’s self-amortizing	<u>1,500,000</u>
Total	\$2,000,000

The applicant has submitted an original affidavit, acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently there are no Medicaid liabilities.

Pavilion Realty, LLC will be the new owners of the real property and there members are as follows:

<u>Proposed Realty Owner</u>	
Pavilion Realty, LLC	
	<u>Membership</u>
Daryl Hagler	99%
Jonathan Hagler	1%

The applicant has noted that its members have other business relationships with Daryl Hagler, including real property transactions.

Lease Agreement and Medicaid Capital Reimbursement

The applicant has submitted an executed lease agreement, the terms of which are summarized below:

<i>Date:</i>	June 26, 2012
<i>Premises:</i>	120 Bed RHC located at 205 East First Street, Corning, NY 14830
<i>Owner/Landlord:</i>	Pavilion Realty, LLC
<i>Lessee:</i>	Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare
<i>Term:</i>	Thirty years
<i>Rent:</i>	Aggregate debt service payment plus \$250,000 which equals \$311,910 per year (\$25,992.50 per month)
<i>Lease:</i>	Triple net lease

The lease arrangement is an arm’s length agreement. Currently, Medicaid capital cost is reimbursed based on the interest and depreciation reimbursement methodology. After the change in the ownership, capital reimbursement will be based on the return of and return on equity methodology. Based on depreciable asset value, the estimated real property’s life is approximately four years.

Operating Budget

The applicant has provided an operating budget, in 2012 dollars, for the first year subsequent to the change in ownership.

The budget is summarized below:

<u>Revenues:</u>	<u>Per Diem</u>	<u>Total</u>
Medicaid*	\$187.24	\$5,695,000
Medicare	407.76	2,195,000
Private Pay*	271.53	<u>1,836,000</u>
Total Revenues:		\$9,726,000
Expenses:		
Operating		\$8,868,000
Capital		<u>535,000</u>
Total Expenses:		\$9,403,000
Net Income:		<u>\$323,000</u>
Utilization (resident days)		42,561
Occupancy		97.17%

**includes assessment revenue of \$428,662*

The following is noted with respect to the submitted operating budget:

- Medicaid rates reflect a change in property reimbursement going from a voluntary to a proprietary entity:
- Medicaid revenues are based on the projected 2012 rates.
- Medicare and private revenues are based on the actual current rates.
- Overall utilization is projected at 97.17%. Utilization for the years from 2009 through 2011 averaged 96%.
- Utilization by payor source is anticipated as follows:

Medicaid Fee-for-Service	71.47%
Medicare Fee-for-Service	12.65%
Private/Other	15.88%

- Costs are covered at approximately 94% of utilization.

Capability and Feasibility

Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare proposed to acquire the operating interest of Founders Pavilion, Inc., a 120-bed RHC for \$2,000,000 plus \$3,000 in fees.

The members will contribute \$503,000 in equity and enter into a proposed mortgage with Capital One Bank for \$1,500,000 at the above stated terms. Review of BFA Attachment A indicates the proposed members' net worth is sufficient to provide equity for the acquisition.

Working capital is estimated at \$1,567,167 and is based on two months of the first year expenses and half, or \$783,584, will be satisfied from members equity. The remaining \$783,583 will be satisfied through a five year loan at 5.5% from Capital One Bank.

Review of BFA Attachment A, summary of net worth, reveals sufficient resources for working capital equity. It is also noted that liquid resources may not be available in proportion to ownership interest. Therefore, Kenneth Rozenberg has provided an affidavit stating he is willing to contribute resources disproportionate to his membership interest.

Presented as BFA Attachments C is the pro forma balance sheets for Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare which shows the entity will start off with equity in the amount of \$1,353,500. It should be noted that Pavilion Operations, Inc. equity will be more than required. Also, the pro-forma balance sheet for Pavilion Operations, LLC shows total assets, includes \$1,850,008 in goodwill, which is not a liquid resource, nor is it recognized for Medicaid reimbursement. If goodwill was eliminated from the equation, then total net asset would become a negative \$496,508.

The submitted budget indicates \$323,000 in net income would be generated in the first year after the change in ownership. Following, is a comparison of 2010 historical and projected revenues and expenses:

Projected Income	\$ 9,726,000
Projected Expense	<u>9,403,000</u>
Projected Net Income	\$323,000
Annual 2010 Income *	\$9,638,000
Annual 2010 Expense **	<u>10,233,965</u>
Annual 2010 Net Income (Loss)	\$(595,965)
Incremental Net Income (Loss)	<u>\$918,965</u>

**excludes one-time non-reoccurring revenues of \$4,175,949 which is comprised of \$3,901,167 from a Loan forgiveness, \$273,666 in contributions from other funds, and \$1,116 from interest income.*

***excludes one time non-reoccurring expenses of \$526,459 for the impairment of property and equipment.*

It is estimate that incremental net revenue will increase approximately \$88,000, all coming from private payers. The applicant projects expenses to decline by \$830,965 coming from employee benefits, fees, and staffing. Staffing is expected to decline by 6.74 full time equivalents (FTE) in the first year, going from 139.54 FTE to 132.80 FTE. The budget was created taking into consideration comparable nursing homes in the region along with the proposed new owners experience in operating similar facilities. The budget appears reasonable.

Staff notes that with the expected 2014 implementation of managed care for nursing home residents, Medicaid reimbursement is expected to change from a state-wide price with cost-based capital component payment methodology, to a negotiated reimbursement methodology. Facility payments will be the result of negotiations between the managed long term care plans and the facility. At this point in time, it cannot be determined what financial impact this change in reimbursement methodology will have on this project.

As shown on BFA Attachment C, Founders Pavilion, Inc., had an average loss of \$509,288 before non-recurring items, and generated an average positive excess revenues over expenses of \$1,551,904 when you include the non-recurring items. According to the applicant, the operating losses were caused primarily by the following expenses: outsourcing fees for collecting account receivables, contracting with Rehab Resources for physical therapy services, and contracting with Health Services to provide dietary services. Both average net assets and average working capital were positive during the years 2009 through 2011.

As shown on BFA Attachment D, Holliswood Care Center, Inc., experienced an average negative working capital position, an average positive net asset position, and had an average net loss of \$513,020 for the years 2010-2011. The 2011 loss is attributable to non recurring expenses that the facility paid in contemplation of the transfer of ownership. They paid 1.2 million dollars in prior period workers compensation fees in order to settle a long standing liability for the facility. They also wrote off bad debt from prior periods of \$902,887. Both of these were one time occurrences and if they were not paid, the facility would have had an operating profit for 2011.

As shown on BFA Attachment E, Dutchess Center for Rehabilitation had an average negative working capital position and average positive net asset position, and generated an average net income of \$580,523 during the period 2008 through 2011.

As shown on BFA Attachment F, University Nursing Home had an average positive working capital position and average positive net asset position, and generated an average net income of \$454,980 during the period 2008 through 2011.

As shown on BFA Attachment G, Queens Center for Rehabilitation had an average negative working capital position and an average positive net asset position, and generated an average net income of \$543,940 during the period 2008 through 2011.

As shown on BFA Attachment H, Brooklyn Center for Rehabilitation had an average positive working capital position and average positive net asset position, and generated an average net Income of \$1,087,227 during the period 2008 through 2011. The facility incurred a net loss of \$907,483 for 2008. This facility was acquired in March 2007. The applicant indicates that the facility has a rate appeal with the Department for Medicaid rebasing, which would offset the losses. This was not promulgated until 2009, and was subsequently approved, creating positive net income in both 2009, 2010, and 2011, of \$465,887, \$1,254,006 and \$3,536,499, respectively.

As shown on BFA Attachment I, Suffolk Center for Rehabilitation had an average negative working capital position, an average negative net asset position, and generated an average net income of \$122,845 during the period 2008 through 2010. In 2011, Mr. Strauss, the member with ownership interest in the facility, sold his interest in the facility. Therefore, no 2011 financial data is necessary.

As shown on BFA Attachment J, Rome Center for Rehabilitation had an average negative working capital position, an average positive net asset position, and generated an average net income of \$611,315 during the period 2009 through 2011.

As shown on BFA Attachment K, Chittenango Center for Rehabilitation had an average negative working capital position, an average positive net asset position, and generated an average net income of \$404,452 during the period 2009 through 2011.

As shown on BFA Attachment L, Williamsbridge Manor had an average negative working capital position, an average positive net asset position, and generated an average net income of \$234,436 during the period 2008 through 2011.

As shown on BFA Attachment M, Bronx Center for Rehabilitation and Health had an average negative working capital position, an average positive net asset position, and generated an average net income of \$ 1,209,260 during the period 2008 through 2011.

No financial summary for Wartburg Lutheran Home for the Aging and Bushwick Center for Rehabilitation are available at this time. In June 2008, a receiver was appointed to the Wartburg Lutheran Home for the Aging, and during the period from 2008 through 2010, no cost reports were filed. In May 2010, the facility changed its name to Bushwick Center for Rehab, and combined the operations of both Wartburg Lutheran Home for the Aging and Wartburg Nursing Home, Inc., into one.

As noted above, some of the applicants have recently purchased ownership interest in the following facilities: Boro Park Center for Rehabilitation and Healthcare, Waterfront Center for Rehabilitation and Health Care, Fulton Center for Rehabilitation and Healthcare, and Richmond Center for Rehabilitation and Specialty Healthcare. No financial summaries are presented for these facilities because the acquisitions were too recent to have completed a year of financial data.

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A Net Worth of Proposed Members, Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare

BFA Attachment B	Pro-forma Balance Sheet, Pavilion Operations, LLC d/b/a Corning Center for Rehabilitation and Healthcare
BFA-Attachment C	Financial Summary, Founders Pavilion, Inc.
BFA-Attachment D	Financial Summary, Holliswood Care Center
BFA-Attachment E	Financial Summary, Dutchess Center for Rehabilitation
BFA-Attachment F	Financial Summary, University Nursing Home
BFA Attachment G	Financial Summary, Queens Center for Rehabilitation
BFA Attachment H	Financial Summary, Brooklyn Center for Rehabilitation
BFA Attachment I	Financial Summary, Suffolk Center for Rehabilitation
BFA Attachment J	Financial Summary, Rome Center for Rehabilitation
BFA Attachment K	Financial Summary, Chittenango Center for Rehabilitation
BFA Attachment L	Financial Summary, Williamsbridge Manor Nursing Home
BFA Attachment M	Financial Summary, Bronx Center for Rehabilitation and Health

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Pavilion Operations, LLC as the new operator of the Founders Pavilion, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

122003 E

FACILITY/APPLICANT:

Pavilion Operations, LLC d/b/a Corning Center
for Rehabilitation and Healthcare

APPROVAL CONTINGENT UPON:

1. The submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
2. Submission of a plan to enhance access to Medicaid residents. At a minimum, the plan should include, but not necessarily limited to, ways in which the facility will:
 - a) Reach out to hospital discharge planners to make them aware of the facility's Medicaid Access Program;
 - b) Communicate with local hospital discharge planners on a regular basis regarding bed availability at the nursing facility;
 - c) Identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility, and inform them about the facility's Medicaid Access policy; and
 - d) Submit an annual report for two years to the DOH, which demonstrates substantial progress with the implement of the plan. The plan should include but not be limited to:
 - Information on activities relating to a-c above; and
 - Documentation pertaining to the number of referrals and the number of Medicaid admissions; and
 - Other factors as determined by the applicant to be pertinent.

The DOH reserves the right to require continued reporting beyond the two year period. [RNR]

3. Submission of a photocopy of the executed Lease Agreement between Pavilion Operations, LLC and Pavilion Realty, LLC, acceptable to the Department of Health. [BFA, CSL]
4. Submission of a mortgage commitment to purchase nursing home operations that is acceptable to the Department. [BFA]
5. Submission of a working capital commitment that is acceptable to the Department. [BFA]
6. Submission of a photocopy of the fully executed proposed Certificate of Amendment to the Certificate of Incorporation of Founders Pavilion, Inc., or the fully executed proposed Certificate of Dissolution of Founders Pavilion, Inc., acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. Submission, within 2 years, of a facility development plan which addresses the code and functional deficiencies previously addressed in CON #062442-C. [HSA]
2. Submission, within 2 years, of an application to convert at least 10 RHCF beds to a needed specialty bed service, such as ventilator-dependent, traumatic brain injury, or another type of specialty bed. [HSA]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 121325-E
Tri-Borough Certified Health Systems of New York, LLC
d/b/a Tri-Borough Certified Health Systems of New York

County: Nassau (Hicksville)
Purpose: Establishment

Program: Certified Home Health Agency
Submitted: April 20, 2012

Executive Summary

Description

Tri-Borough Certified Health Systems of New York, LLC, seeks approval to purchase and become successor operator of an existing certified home health agency (CHHA) and long-term home care program, (LTHHCP). The to-be- acquired entity, Family Aides Certified Services of Nassau, Suffolk, Inc. d/b/a Family Aides Certified Services of Nassau, located at 120 W. John Street, Hicksville, currently operates a CHHA serving Nassau County and a LTHHCP with 50 slots in Nassau, 100 slots in Queens, and 50 slots in Bronx County.

As background, effective January, 31, 2012, the applicant and seller entered into a Management Agreement pursuant to which the applicant would assume responsibility for the day-to-day management of the CHHA and LTHHCP until the application is approved by the Department of Health. The Department approved this agreement on August 12, 2012. Upon approval of this application, Tri-Borough Certified Health Systems of New York, LLC plans to maintain all existing CHHA and LTHHCP services.

The sole member of Tri-Borough Certified Health Care Systems of New York, LLC is Kenrick Cort. Mr. Cort is the sole stockholder, director and officer of Tri-Borough Home Care, Ltd., a proprietary corporation operating a licensed home care services agency (LHCSA) in Nassau, Bronx, Kings and New York, Queens and Richmond Counties.

Also on this agenda for PHHPC action is a concurrent filing by Mr. Cort (CON #121328-E), which seeks to establish Tri-Borough Certified Health Systems of the Hudson Valley, LLC as the operator of Datahr Home Health Care, Inc., a CHHA servicing Dutchess, Putnam, and Westchester counties.

Effective May 1, 2012, a new Episodic Payment System (EPS) reimbursement methodology to reimburse CHHA providers for services provided to Medicaid patients receiving home care services took effect. The EPS is based on a price for 60 day episodes of care, which will be adjusted by patient acuity and regional wage differences. The EPS was recommended by the Medicaid Redesign Team (MAT proposal #5) and authorized in the 2011-2012 enacted budget. The EPS is designed to address the issue of rapid growth in Medicaid costs per patient, by better aligning payments with needed service, and is part of a broad effort to promote the development of care management for Medicaid recipients.

DOH Recommendation
Contingent approval.

Program Summary
Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Financial Summary
The total purchase price of \$1,475,000 shall be paid via equity \$1,000,000 at which \$150,000 is held in escrow and \$850,000 will be paid at closing by Kenrick Cort. The residual \$475,000 will be paid via a two-year promissory note from Kenrick Cort at 3.25% interest. There are no project costs associated with this application.

Budget:	<i>Revenues:</i>	\$ 15,571,381
	<i>Expenses:</i>	<u>11,915,772</u>
	<i>Gain/(Loss):</i>	\$ 3,665,609

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of an executed promissory note that is acceptable to the Department of Health. [BFA]
2. Submission of a corrected executed asset purchase agreement with the proper named entity listed that is acceptable to the Department of Health. [BFA]
3. Submission of an executed building lease that is acceptable to the Department of Health. [BFA]
4. Submission of a working capital loan that is acceptable to the Department of Health. [BFA]

Council Action Date

February 7, 2013.

Programmatic Analysis

Background

Tri-Borough Certified Health Systems of New York, LLC d/b/a Tri-Borough Certified Health Systems of New York is a limited liability company. Tri-Borough Certified Health Systems of New York seeks approval to purchase and become the new operator of the Family Aides Certified Services of Nassau/Suffolk, Inc. CHHA, which is approved to serve patients in Nassau County, and LTHHCP which is approved to serve patients in Nassau, Queens and Bronx counties.

The Family Aides Certified Services of Nassau/Suffolk, Inc. currently operates under a Management and Administrative Services Agreement with Tri-Borough Home Care, Ltd., which was approved by the Department on August 27, 2012.

The applicant proposes to operate the CHHA from an office located at 120 West John Street, Hicksville, New York 11801, and to serve Nassau County.

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Medical Supplies, Equipment, and Appliances
Physical Therapy	Occupational Therapy	Speech Language Pathology
Personal Care	Respiratory Therapy	Medical Social Services
Nutrition	Homemaker	Housekeeper

The applicant proposes to operate the LTHHCP from an office located at 120 West John Street, Hicksville, New York 11801 and serve the following counties:

Nassau	Queens	Bronx
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The applicant proposes to offer all thirteen of the required LTHHCP health care services:

Nursing	Home Health Aide	Personal Care
Physical Therapy	Occupational Therapy	Respiratory Therapy
Speech Language Pathology	Audiology	Medical Social Services
Nutrition	Homemaker	Housekeeper
Medical Supplies, Equipment, and Appliances		

The sole Member and sole Manager of Tri-Borough Certified Health Systems of New York, LLC is:

Kenrick L. Cort – President/CEO

Affiliations:

- President/CEO, Tri-borough Home Care, Ltd.
- President/CEO, ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
- President/CEO, ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Tri-borough Home Care, Ltd.
ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

ISIS Home Health Care, Inc., Fort Myers, FL was fined eleven thousand dollars (\$11,000.00) resulting from two survey deficiencies; one thousand dollars (\$1,000.00) for not following the Plan of Treatment and ten thousand dollars (\$10,000.00) for not following the Plan of Care, 10 patients total. ISIS Home Health Care, Inc. resolved the fine September 6, 2012.

ISIS Home Health Care, Inc., Fort Myers, FL was fined ten thousand dollars (\$10,000.00) resulting from not completing their quarterly reports for the 3rd and 4th quarter in 2008. ISIS Home Health Care, Inc. resolved the fine October 6, 2009.

The information provided by the State of Florida regulatory agency has indicated that facilities affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Asset Purchase Agreement:

The applicant has submitted an executed asset purchase agreement, the terms of which are summarized below:

<i>Date:</i>	January 31, 2012
<i>Seller:</i>	Family Aides Certified Services of Nassau, Suffolk, Inc. d/b/a Family Aides Certified Services of Nassau, Nassau County
<i>Buyer:</i>	Tri-Borough Certified Health Systems of New York, LLC.
<i>Assets Transferred:</i>	The CHHA and LTHC business consisting of furniture; fixtures and assets and records; any contracts; patient lists subject to consent; software rights; telephone numbers; and cash associated with recruitment; goodwill; patient medical records; contracts, leases or licenses. Cash; cash equivalents; marketable securities; equipment leased by seller; all contracts not specifically listed within contract; non-transferable permits and licenses; trademarks, names and the trade name "Family Care Certified Services", Family Care Certified Home Health Care Program", causes of actions.
<i>Excluded Assets:</i>	
<i>Assumed Liabilities:</i>	None
<i>Purchase Price:</i>	\$1,475,000
<i>Payment of</i>	\$150,000 paid to the applicant and \$850,000 will be paid at the time of closing. The residual of \$475,000 payable in equal installments via a promissory note for a two year period using the prime rate of interest. (The current prime rate is 3.25%).
<i>Purchase Price:</i>	

The applicant submitted an affidavit in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently, there are no outstanding Medicaid overpayment liabilities.

Assignment and Assumption Agreement

The applicant submitted a draft assignment and assumption agreement, the terms of which are summarized below:

Assignor: Tri-Borough Certified Health Systems, LLC n/k/a Tri-Borough Certified Health Systems of New York, LLC.
Assignee: Tri-Borough Certified Health Systems of New York, LLC
Obligations Assigned: Assignor's right, title and interest in, to an under the Purchase Agreement and agrees/assumes to keep, perform and fulfill all the terms, covenants, conditions and obligations of the Purchase Agreement.

Lease Rental Agreement

The applicant has submitted a letter of interest to enter into an Assignment of Lease at the proposed site, the terms of which are summarized below:

Premises: Suite G, 4,300 square feet located at 120 West John St. Hicksville, New York
Lessor: Family Aides, Inc.
Lessee: Family Care Certified Services
Sub-lessee: Tri-Borough Certified Health Systems of New York, LLC
Rental: \$42,033.60 annually (\$9.77 per sq. ft.), with an annual increase in rent of 3.5%/year.
Term: 10 years with (2) five year renewal options
Provisions: Triple net lease whereby the Lessee shall pay utilities, real estate taxes and miscellaneous expenses totaling approximately \$319,006.

The applicant has indicated that the lease agreement is an arms-length agreement, and they have provided two letters of rent reasonableness.

Operating Budget

The applicant has submitted an operating budget for the first year in 2012 dollars, which is summarized below:

<u>Year One</u>	<u>CHHA</u>	<u>LTHHCP</u>	<u>Combined</u>
Revenues	\$9,597,458	\$5,973,923	\$15,571,381
Expenses	<u>5,937,571</u>	<u>5,978,201</u>	<u>11,915,772</u>
Gain/ (Loss):	\$3,659,887	\$ (4,278)	\$ 3,655,609

Expenses and utilization for the LTHHCP is detailed as follows:

Year One

<u>LTHHCP</u>	<u>Total Costs</u>	<u>Visits/Hours</u>	<u>Cost per Visit</u>
Nursing	\$1,227,246	7,541	\$162.74
Physical Therapy	\$381,741	2,195	\$173.91
Speech Pathology	\$47,755	222	\$215.11
Occupation Therapy	\$11,929	86	\$138.71
Home Health Aide	\$753,291	31,930	\$23.59
Medical Social Services	\$87,069	1,135	\$76.71
Personal Care	<u>\$3,469,170</u>	216,000	\$16.06
Total	\$5,978,201		

* Reflects hourly data

<u>CHHA</u>	<u>Total Costs</u>	<u>Visits/Hours</u>	<u>Cost per Visit</u>
Nursing	\$3,479,054	12,823	\$271.31
Physical Therapy	\$1,186,356	9,711	\$122.16
Speech Pathology	\$272,904	1,117	\$244.31
Occupation Therapy	\$33,947	278	\$122.11
Home Health Aide	\$843,434	12,196	\$69.16
Medical Social Services	\$117,124	499	\$234.71
Personal Care (Visits)	\$4,752	44	\$108.00
Total	\$5,937,571		

* Reflects hourly data

Utilization by payor source for the CHHA and LTHCCP for the first year is as follows:

	<u>CHHA</u>	<u>LTHHCP</u>
Medicare	89.10%	0%
Medicaid	5.40%	100%
Private Pay	3.00%	0%
Charity Care	2.50%	0%

Expense and utilization assumptions are based on the existing Family Care Certified Services of Nassau CHHA and LTHHCP Program's historical experience and cost reports. Revenues are reflective of current payment episodic payment rates and current reimbursement rates in treating high acuity patients with a case weight of 2.42 with LUPA Blend.

Capability and Feasibility

There are no project costs associated with this application. The operational purchase price of \$1,475,000 at which \$150,000 was paid in equity to the seller, and \$850,000 will be satisfied via equity from Kenrick Cort. The residual of \$475,000 will be paid through a promissory note for a term of 2 years at a rate of 3.25%, paid for by Kenrick Cort. Presented on BFA Attachment A is the net worth financial summary of Kenrick Cort, indicating there is sufficient equity for the purchase price.

Working capital requirements estimated at \$1,985,962 based on two months' of first year expenses will be provided by cash equity in the amount of \$992,981 from Ken Cort, and \$992,981 at a rate of 7% for a term of three years. A letter of interest has been provided. Presented as BFA Attachment A, is Kenrick Cort's net worth statement, which indicates the ability to meet the purchase price and working capital requirements. Also, presented as BFA Attachment D is the pro-forma balance sheet for Tri-Borough Certified Health Systems of New York, LLC, which show the entity, will start off with a positive equity position of \$992,981.

The budget projects an excess of revenues over expenses of \$3,655,609 during the first year subsequent to the change in operator.

The submitted budget is based on Family Aides Certified Services of Nassau, Suffolk, Inc. operations of its CHHA and LTHHCP. Medicaid and Medicare revenues are based on upon the current payment methodologies and regional historical rates. The submitted budget appears reasonable.

Presented as BFA Attachment C is the financial summary of Family Aides Certified Services of Nassau, Inc., which indicates that the facility has maintained an average positive working capital position and an average positive net assets position. Also, Family Aides Services of Nassau generated annual gross profit of \$1,958,023 and \$1,512,100 for 2010 and 2011, respectively.

Presented as BFA Attachments D and E, are Tri-Borough Home Care, LTD, December 31, 2011, financial summary and June 30, 2012, internal financial summary, which shows a positive average working capital position of \$2,671,034 and an average operating loss of \$67,513. Net assets were \$3,944,863 as of June 30, 2012.

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Net Worth Financial Summary, Kenrick Cort
BFA Attachment B	Pro-forma Balance Sheet, Tri-Borough Certified Health Systems of New York, LLC
BFA Attachment C	Financial Summary, Family Aides Certified Services of Nassau, Inc.
BFA Attachment D	Financial Summary for 2011, Tri-Borough Home Care, LTD
BFA Attachment E	Internal Financial Summary as of June 30, 2012, Tri-Borough Home Care, LTD.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to purchase and become successor operator of an existing certified home health agency and long-term care program, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

121325 E

Tri-Borough Certified Health Systems of
New York, LLC d/b/a Tri-Borough Certified
Health Systems of New York

APPROVAL CONTINGENT UPON:

1. Submission of an executed promissory note that is acceptable to the Department of Health. [BFA]
2. Submission of a corrected executed asset purchase agreement with the proper named entity listed that is acceptable to the Department of Health. [BFA]
3. Submission of an executed building lease that is acceptable to the Department of Health. [BFA]
4. Submission of a working capital loan that is acceptable to the Department of Health. [BFA]

APPROVAL CONDITIONED UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 121328-E
Tri-Borough Certified Health Systems of the Hudson Valley, LLC
d/b/a Tri-Borough Certified Health Systems of the Hudson Valley

County: Westchester (Mt. Kisco)
Purpose: Establishment

Program: Certified Home Health Agency
Submitted: April 20, 2012

Executive Summary

Description

Tri-Borough Certified Health Systems of the Hudson Valley, LLC, a limited liability company created to pursue this application, requests approval to purchase and become the operator of Datahr Home Health Care, Inc. (Datahr), a special needs certified home health agency (CHHA) which services Dutchess, Putnam, and Westchester counties.

As background, the acquisition of Datahr's CHHA by Family Aides Certified Services of Nassau, Suffolk, Inc. (Family Aides) was contingently approved by the Public Health and Health Planning Council (PHHPC) on June 16, 2011, via CON #051081-E. The transaction was originally entered into on October 1, 2002, but was delayed due to legal difficulties surrounding William Schnell, the sole shareholder of Family Aides. Through a trust agreement, the court appointed Robert Silbering as trustee and granted him legal authority over Family Aides. Under this authority, 100% of the corporation stock was transferred into Nassau CHHA Grantor Trust, which was approved by the Public Health Council on June 10, 2009, under CON #072196-E. The sale has not yet been consummated, as Family Aides is waiting for approvals from the Office of the Attorney General (OAG) and from the appropriate judicial district of the Supreme Court before the sale and transfer can be finalized. According to the applicant, the legal documents have been submitted to the OAG and following receipt of their "no objection" letter, the proper legal documents will be submitted to the appropriate judicial district of the Supreme Court for their approval.

The sole member of Tri-Borough Certified Health Care Systems of the Hudson Valley, LLC is Kenrick Cort. Mr. Cort is the sole stockholder, director and officer of Tri-Borough Home Care, Ltd., a proprietary corporation operating a licensed home care services agency (LHCSA) in Nassau, Bronx, Kings and New York, Queens and Richmond Counties.

Also on this agenda for PHHPC action is a concurrent filing by Mr. Cort (CON #121325-E), which seeks to establish Tri-Borough Certified Health Systems of New York, LLC as the

operator of the Family Aides CHHA serving Nassau County and their long-term home health care program serving Nassau, Queens and Bronx counties.

Effective May 1, 2012, a new Episodic Payment System (EPS) reimbursement methodology to reimburse CHHA providers for services provided to Medicaid patients receiving home care services took effect. The EPS is based on a price for 60-day episodes of care, which will be adjusted by patient acuity and regional wage differences. The EPS was recommended by the Medicaid Redesign Team (MRT proposal # 5) and authorized in the 2011-12 enacted budget. The EPS is designed to address the issue of rapid growth in Medicaid costs per patient by better aligning payments with needed services and is part of a broad effort to promote the development of care management arrangements for Medicaid recipients.

DOH Recommendation
Contingent approval.

Program Summary
Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Financial Summary
The transfer of assets by Datahr to Family Aides is awaiting approval from the Court System. There are no project costs associated with this proposal. The applicant will acquire the assets of the CHHA for \$25,000.

Budget:	<i>Revenues:</i>	\$ 2,921,028
	<i>Expenses:</i>	<u>2,810,235</u>
	<i>Gain/(Loss):</i>	\$ 110,793

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. Submission of a working capital commitment that is acceptable to the Department of Health. [BFA]
2. Submission of an executed building lease that is acceptable to the Department of Health. [BFA]
3. Submission of an executed assignment of lease that is acceptable to the Department of Health. [BFA]
4. Submission of the approval for Family Aides Certified Services of Nassau, Suffolk, Inc. to purchase Datahr Home Care Inc. from the Justice of the Supreme Court, acceptable the Department of Health. [BFA]

Approval conditional upon:

1. The provision of CHHA services is limited to the special needs population of patients with mental retardation and developmental disabilities, with the understanding that the New York State Department of Health will monitor the utilization statistics for ongoing compliance with the condition. [CHHA]

Council Action Date

February 7, 2013.

Programmatic Analysis

Background

Tri-Borough Certified Health Systems of the Hudson Valley, LLC d/b/a Tri-Borough Certified Health Systems of the Hudson Valley proposes to become the new owner and operator of a Datahr Home Health Care, Inc., a special needs CHHA through an Asset Purchase Agreement and Assignment and Assumption Agreement with Family Aides Certified Services of Nassau/Suffolk, Inc. Family Aides Certified Services of Nassau/Suffolk, Inc. obtained PHHPC approval to acquire Datahr Home Health Care, Inc., through CON # 051081 at the October 27, 2011 meeting. The transaction approved under CON # 051081 is pending with the Attorney General's Office for approval of the transfer of this agency from a not-for-profit corporation to a proprietary corporation.

Tri-Borough Certified Health Systems of the Hudson Valley seeks approval to become the new operator of the special needs CHHA approved to serve the OPWDD population in Dutchess, Putnam and Westchester counties. Datahr Home Health Care, Inc. currently operates under a Management and Administrative Services Agreement with Family Aides Certified Services of Nassau/Suffolk, Inc.

The applicant proposes to operate the CHHA from an office located at 120 Kisco Avenue, Mt. Kisco, New York 10549 and serve the following counties:

Dutchess

Putnam

Westchester

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Medical Supplies, Equipment, and Appliances
Physical Therapy	Occupational Therapy	Speech Language Pathology
Personal Care	Respiratory Therapy	Medical Social Services
Nutrition	Homemaker	Housekeeper

The sole Member and sole Manager of Tri-Borough Certified Health Systems of the Hudson Valley is:

Kenrick L. Cort – President/CEO

Affiliations:

- President/CEO, Tri-borough Home Care, Ltd.
- President/CEO, ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
- President/CEO, ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Tri-borough Home Care, Ltd.
ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

ISIS Home Health Care, Inc., Fort Myers, FL was fined eleven thousand dollars (\$11,000.00) resulting from two survey deficiencies; one thousand dollars (\$1,000.00) for not following the Plan of Treatment and ten thousand dollars (\$10,000.00) for not following the Plan of Care, 10 patients total. ISIS Home Health Care, Inc. resolved the fine September 6, 2012.

ISIS Home Health Care, Inc., Fort Myers, FL was fined ten thousand dollars (\$10,000.00) resulting from not completing their quarterly reports for the 3rd and 4th quarter in 2008. ISIS Home Health Care, Inc. resolved the fine October 6, 2009.

The information provided by the State of Florida regulatory agency has indicated that facilities affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the appropriate character and competence under Article 36 of the Public Health Law.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Total Project Cost and Financing

There are no project costs associated with this application.

Asset Purchase Agreement

The applicant has submitted a draft asset purchase agreement, the terms of which are summarized below:

<i>Date:</i>	January 31, 2012
<i>Seller:</i>	Family Aides Certified Services of Nassau, Suffolk, Inc.
<i>Purchaser:</i>	Tri-Borough Certified Health Systems, LLC n/k/a Tri-Borough Certified Health Systems of New York, LLC Tri-Borough Certified Health Systems of the Hudson Valley, LLC
<i>Assets Transfer</i>	Transfer, assign, and convey all rights, title and interest in the Datahr Purchase Agreement, its transferrable and assignable contracts and agreements
<i>Excluded Assets:</i>	Cash, marketable securities, equipment leased by seller, accounts & notes receivable, non-transferable permits and licenses, stock records, minutes, all trademarks and names (shall be permitted to use the name "Family Care Certified Services of Nassau, a division of Tri-Borough Certified Health Systems, LLC,) web-sites, e-mail addresses, telephone numbers, deposits, pre-paid expenses, customer advances, all furniture, fixtures, equipment and assets used by the seller, all claims and rights of recovery relating to Purchase Assets.
<i>Assumed Liabilities:</i>	Those accruing on or after the closing date.
<i>Purchase Price:</i>	\$25,000
<i>Payment:</i>	\$25,000 at closing

The \$25,000 purchase price will be provided from Kenrick Cort's personal assets.

The applicant has submitted an original affidavit, acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently there are no Medicaid liabilities.

Assignment and Assumption Agreement

The applicant has submitted a draft assignment and assumption agreement, the terms of which are summarized below:

Assignor: Tri-Borough Certified Health Systems, LLC n/k/a Tri-Borough Certified Health Systems of New York, LLC
Assignee: Tri-Borough Certified Health Systems of the Hudson Valley, LLC
Assets Assigned: Assignor's right, title and interest in, to and under the Purchase Agreement
Obligations Assigned: Accepts the transfer and the assignment of the Purchase Agreement and assumes and agrees to keep, perform and fulfill all the terms, covenants, conditions and obligations of the Purchase Agreement.

LEASE RENTAL AGREEMENT - Assignment of Lease

The applicant has submitted a letter of interest to enter into an Assignment of Lease at the proposed site, the terms of which are summarized below:

Premises: Suite E 1,186 gross square feet located at 120 Kisco Avenue, Mt. Kisco, NY
Landlord: Medcomp Technologies, Inc.
Lessee/Assignor: Family Aides Certified Services of Nassau, Suffolk, Inc.
Assignee: Tri-Borough Certified Health Systems of Hudson Valley, LLC
Term: 10 year term at \$26,220 per year (\$22.11 per sq. ft.) renewable yearly

Provisions: Taxes, utilities and Maintenance

The lease is an arm's length arrangement.

Operating Budget

The applicant has submitted the first and third year incremental operating budgets, in 2012 dollars, as summarized below:

Description	<u>First Year</u>	<u>Third Year</u>
Medicaid	\$292,103	\$368,720
Medicare	2,226,397	2,810,371
Other	<u>402,528</u>	<u>508,109</u>
Total Revenues	\$2,921,028	\$3,687,200
Total Expenses	<u>\$2,810,235</u>	<u>\$3,264,070</u>
Net Income or (Loss)	\$110,793	\$423,130

Utilization by payor source for the first & third year is anticipated as follows:

Medicaid Managed Care	10%
Medicare Managed Care	80%
Other	8%
Charity Care	2%

Utilization and expense assumptions are based on evaluations by the applicant.

Expense projections are based on projected case load and case mix.

The Medicaid average episode payment is expected to be \$6,178, based upon the Hudson Valley Wage Index Factor of 1.125693 and an average case mix of 1.

The Medicare average episodic payment of \$2,611.10 is predicated on the calendar year 2012 national standardized 60-day episode payment rate of \$2,192.07, adjusted for the following: home health market basket update of 1.015; reduced for the nominal change in case mix of .94940; plus the wage index for the service area of 1.3063; at average case mix of 1.

Capability and Feasibility

There are no project costs associated with this application.

Tri-Borough Certified Health Systems of the Hudson Valley, LLC will pay \$25,000 for the purchase of Family Aides Certified Services of Nassau, Suffolk, Inc.'s Certified Home Health Agency (CHHA), which services Dutchess, Putnam and Westchester counties. The sole member, Kenrick Cort, will satisfy the purchase price at the time Family Aides Certified Services of Nassau, Suffolk, Inc., obtains approval from the Supreme Court in the appropriate judicial district to complete the sale and transfer of Datahr Home Health Care Inc.'s assets.

Working Capital requirements are estimated at \$544,012, which appears reasonable based on two months of third year expenses. Half of the working capital or \$272,006 will be contributed from Kenrick Cort, sole member, with the remaining \$272,006 being borrowed from Capital One Bank for three years at a 7% interest rate. Presented as BFA Attachment A is Kenrick Cort's net worth statement, which indicates the ability to meet the purchase price and working capital requirements. Presented as BFA Attachment B is the pro-forma balance sheet for Tri-Borough Certified Health Systems of Hudson Valley, LLC, which show the entity, will start off with \$297,006 in equity.

The budget projects an operating surplus of \$110,793 and \$423,130 in the first and third years, respectively. Medicare and Medicaid revenues are based upon the current payment methodologies, and commercial payors were based on regional historical rates. The budget appears reasonable.

Present as BFA Attachments C and D are Tri-Borough Home Care, LTD, December 31, 2011 financial summary and June 30, 2012 internal financial summary, which shows a positive average working capital position of \$2,671,034 and an average operating loss of \$67,513. The applicant points out that in 2012, Tri-Borough Home Care LTD realized savings through better utilization of the labor as revenues increased 51.9% on an annualized basis from 2011. Net assets were \$3,944,863 as of June 30, 2012.

It appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

<h2>Attachments</h2>

- | | |
|------------------|--|
| BFA Attachment A | Net Worth of Sole Member, Tri-Borough Certified Health Systems of the Hudson Valley, LLC |
| BFA Attachment B | Pro-forma Balance Sheet, Tri-Borough Certified Health Systems of the Hudson Valley, LLC |
| BFA Attachment C | Financial Summary for 2011, Tri-Borough Home Care, LTD |
| BFA Attachment D | Internal Financial Summary as of June 30, 2012, Tri-Borough Home Care, LTD |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to purchase and become the operator of Datahr Home Health Care, Inc., a special needs certified health agency which serves Dutchess, Putnam and Westchester counties, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

121328 E

Tri-Borough Certified Health Systems of the Hudson Valley, LLC d/b/a Tri-Borough Certified Health Systems of the Hudson Valley

APPROVAL CONTINGENT UPON:

1. Submission of a working capital commitment that is acceptable to the Department of Health. [BFA]
2. Submission of an executed building lease that is acceptable to the Department of Health. [BFA]
3. Submission of an executed assignment of lease that is acceptable to the Department of Health. [BFA]
4. Submission of the approval for Family Aides Certified Services of Nassau, Suffolk, Inc. to purchase Datahr Home Care Inc. from the Justice of the Supreme Court, acceptable the Department of Health. [BFA]

APPROVAL CONDITIONED UPON:

1. The provision of CHHA services is limited to the special needs population of patients with mental retardation and developmental disabilities, with the understanding that the New York State Department of Health will monitor the utilization statistics for ongoing compliance with the condition. [CHHA]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



STATE OF NEW YORK - DEPARTMENT OF HEALTH

MEMORANDUM

TO: Public Health and Health Planning Council
FROM: James E. Deering, General Counsel
DATE: January 7, 2013
SUBJECT: Proposed Restated Certificate of Incorporation for the Pluta Cancer Center Foundation, Inc.

The attached proposed Restated Certificate of Incorporation of Pluta Cancer Center Foundation, Inc. ("the Foundation"), dated November 8, 2012, is being submitted for Public Health and Health Planning Council approval. The Foundation is restating its Certificate of Incorporation to replace the existing beneficiary, Pluta Cancer Center, Inc., with the Pluta Cancer Center now owned by the University of Rochester. The University of Rochester acquired the assets of Pluta Cancer Center, Inc. in a transaction completed on December 28, 2012. The Foundation's ability to file the certificate and solicit funds for such purpose depends on the approval of the Public Health and Health Planning Council pursuant to Public Health Law § 2801-a(1) and (6).

In addition to the proposed Restated Certificate of Incorporation, the following documents and information are attached in support of the Foundation's request for approval:

1. The Foundation's Amended and Restated bylaws.
2. In lieu of a letter from the intended beneficiary, the Acquisition Agreement among the Foundation, the Pluta Cancer Center and University of Rochester (on behalf of Strong Memorial Hospital) which provides that the University of Rochester will accept the funds raised by the Foundation.
3. A letter agreement from the University of Rochester and the Pluta Cancer Center Foundation granting to the Foundation additional time to obtain PHHPC approval of the change.
4. Disclosure information regarding the Foundation's board of directors.

The proposed Restated Certificate of Incorporation is in legally acceptable form.

Attachments

RESTATED CERTIFICATE OF INCORPORATION

OF

PLUTA CANCER CENTER FOUNDATION, INC.

Under Section 805 of the Not-For-Profit Corporation Law

THE UNDERSIGNED, in accordance with Section 805 of the Not-For-Profit Corporation Law, does hereby certify:

1. The name of the Corporation is **"PLUTA CANCER CENTER FOUNDATION, INC."**

2. The certificate of incorporation was filed by the Department of State on May 21, 2009.

3. The certificate of incorporation as now in full force and effect is hereby amended to effect the following changes authorized in Subdivision (b)(2), Subdivision (b)(3) and Subdivision (b)(6) of Section 801 of the Not-For-Profit Corporation Law, respectively: to change its corporate purposes; to change the description of the transferee of assets upon a dissolution of the Corporation; and to change the location of the office of the Corporation.

(a) Current Section 3 of the certificate of incorporation is amended and restated in its entirety to read as follows:

"The Corporation is formed and shall be operated exclusively for the charitable purpose of supporting and benefiting the University of Rochester, a New York education corporation and such other organizations described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Code") and Section 509(a)(1) or Section 509(a)(2) of the Code that are subsidiaries of or controlled by the University of Rochester, that operate

hospital facilities within the scope of Article 28 of the New York State Public Health Law, and that provide medical and/or radiation oncology services and related services to the community (the "Beneficiaries"). It is intended that the Corporation will primarily support and benefit the Pluta Cancer Center, an extension clinic of Strong Memorial Hospital of the University of Rochester.

In furtherance of the foregoing purposes, and subject to any limitations provided in the Not-For-Profit Corporation Law or any other statute of the State of New York, the Corporation shall have the power, either directly or indirectly, either alone or in conjunction or cooperation with others, to do any and all lawful acts and things and to engage in any and all lawful activities which may be necessary, useful, suitable, desirable, or proper for the furtherance, accomplishment, fostering, or attainment of any and all of the purposes for which the Corporation is organized, together with the power to solicit and receive grants and contributions from private and public sources, and to aid or assist other organizations whose activities are such as to further, accomplish, foster or attain any of such purposes. Notwithstanding anything herein to the contrary, the Corporation shall exercise only such powers as are in furtherance of the purposes of supporting and benefiting the Beneficiaries, which purposes are set forth in Section 501(c)(3) of the Code and the Treasury Regulations promulgated thereunder, as the same now exist or as they may be hereafter amended from time to time."

(b) Current Section 4 of the certificate of incorporation is amended and restated in its entirety to read as follows:

“The Corporation is organized and shall be operated exclusively for the charitable purpose of supporting and benefiting the Beneficiaries. The Corporation shall carry out its stated purposes within the meaning and intent of Section 509(a)(3) of the Code, and is not formed for pecuniary profit or financial gain. The Corporation shall not operate to support or benefit organizations other than the Beneficiaries.”

(c) Current Section 9 of the certificate of incorporation is renumbered as Section 8 and is amended and restated in its entirety to read as follows:

“The Corporation may be dissolved only upon (i) authorization of the Board of Directors at a special meeting called for that purpose and (ii) approval by the members of the Corporation in accordance with the Not-For-Profit Corporation Law of the State of New York. In the event of the dissolution or the winding-up of the Corporation, all of the remaining assets and property of the Corporation shall, after necessary expenses thereof, be distributed to the University of Rochester for purposes of supporting oncology services and, in particular, the Pluta Cancer Center, provided that it shall then qualify under Section 501(c)(3) of the Code, or if it shall not so qualify as of the time of dissolution, to such other organization or organizations that are qualified under Section 501(c)(3) of the Code and are organized and operated exclusively for charitable, scientific, or educational purposes, to be used in such manner as in the judgment of a Justice of Supreme Court of the State of New York will best accomplish the general purposes for which this Corporation was formed and, in all events, in accordance with the requirements of Section 509(a)(3) of the Code and the Treasury Regulations promulgated thereunder. Subject to the restrictions contained in the preceding sentence, the

corporations, funds, or foundations to receive said property shall be recommended by the existing Board of Directors and approved by the members of the Corporation.”

(d) Current Section 11 of the certificate of incorporation is renumbered as Section 10 and is amended and restated in its entirety to read as follows:

“The Secretary of State of the State of New York is hereby designated the agent of the Corporation upon whom process against the Corporation may be served. The post office address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him as agent of the Corporation is:

c/o Pluta Cancer Center Foundation, Inc.
200 Red Creek Drive, Suite 200
Rochester, New York 14623”

(e) The certificate of incorporation as amended hereby is restated in its entirety to read as follows:

1. The name of the Corporation is **“PLUTA CANCER CENTER FOUNDATION, INC.”**

2. The Corporation is a corporation as defined in subparagraph (a)(5) of Section 102 of the Not-For-Profit Corporation Law and shall be a Type B Corporation pursuant to Section 201 of the Not-For-Profit Corporation Law.

3. The Corporation is formed and shall be operated exclusively for the charitable purpose of supporting and benefiting the University of Rochester, a New York education corporation and such other organizations described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the “Code”) and Section 509(a)(1) or Section 509(a)(2) of the Code that are subsidiaries of or controlled by the University of Rochester, that operate hospital facilities within the scope of Article 28 of the New York State Public Health Law, and

that provide medical and/or radiation oncology services and related services to the community (the "Beneficiaries"). It is intended that the Corporation will primarily support and benefit the Pluta Cancer Center, an extension clinic of Strong Memorial Hospital of the University of Rochester.

In furtherance of the foregoing purposes, and subject to any limitations provided in the Not-For-Profit Corporation Law or any other statute of the State of New York, the Corporation shall have the power, either directly or indirectly, either alone or in conjunction or cooperation with others, to do any and all lawful acts and things and to engage in any and all lawful activities which may be necessary, useful, suitable, desirable, or proper for the furtherance, accomplishment, fostering, or attainment of any and all of the purposes for which the Corporation is organized, together with the power to solicit and receive grants and contributions from private and public sources, and to aid or assist other organizations whose activities are such as to further, accomplish, foster or attain any of such purposes. Notwithstanding anything herein to the contrary, the Corporation shall exercise only such powers as are in furtherance of the purposes of supporting and benefiting the Beneficiaries, which purposes are set forth in Section 501(c)(3) of the Code and the Treasury Regulations promulgated thereunder, as the same now exist or as they may be hereafter amended from time to time.

4. The Corporation is organized and shall be operated exclusively for the charitable purpose of supporting and benefiting the Beneficiaries. The Corporation shall carry out its stated purposes within the meaning and intent of Section 509(a)(3) of the Code, and is not formed for pecuniary profit or financial gain. The Corporation shall not operate to support or benefit organizations other than the Beneficiaries.

5. The office of the Corporation where the books and records of account will be kept is to be located in the County of Monroe, State of New York.

6. All income and earnings of the Corporation shall be used exclusively for its corporate purposes. No part of the net income or net earnings of the Corporation shall inure to the benefit or profit of or be distributable to its members, directors, officers, or other private persons. Notwithstanding the foregoing, the Corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purposes of the Corporation set forth in Paragraphs 3 and 4 hereof. No director of the Corporation shall receive any salary, other compensation, or pecuniary profit of any kind for services as such director other than reimbursement of actual and necessary expenses incurred in the performance of his duties.

7. Notwithstanding any other provision of this Certificate, the Corporation shall not carry on any activities not permitted to be carried on by a corporation exempt from federal income taxation under Section 501(c)(3) of the Code, as amended, or by a corporation, contributions to which are deductible under Section 170(b)(2) of the Code. No substantial part of the activities of the Corporation shall be the carrying on of propaganda or otherwise attempting to influence legislation. The Corporation shall not participate in or intervene in (including the publication or distribution of statements) any political campaign on behalf of any candidate for public office.

8. The Corporation may be dissolved only upon (i) authorization of the Board of Directors at a special meeting called for that purpose and (ii) approval by the members of the Corporation in accordance with the Not-For-Profit Corporation Law of the State of New York. In the event of the dissolution or the winding-up of the Corporation, all of the

remaining assets and property of the Corporation shall, after necessary expenses thereof, be distributed to the University of Rochester for purposes of supporting oncology services and, in particular, the Pluta Cancer Center, provided that it shall then qualify under Section 501(c)(3) of the Code, or if it shall not so qualify as of the time of dissolution, to such other organization or organizations that are qualified under Section 501(c)(3) of the Code and are organized and operated exclusively for charitable, scientific, or educational purposes, to be used in such manner as in the judgment of a Justice of Supreme Court of the State of New York will best accomplish the general purposes for which this Corporation was formed and, in all events, in accordance with the requirements of Section 509(a)(3) of the Code and the Treasury Regulations promulgated thereunder. Subject to the restrictions contained in the preceding sentence, the corporations, funds, or foundations to receive said property shall be recommended by the existing Board of Directors and approved by the members of the Corporation.


9. Nothing contained in the Certificate of Incorporation shall authorize the Corporation to establish, operate or maintain a hospital, a home care services agency, a hospice, a health maintenance organization, or a comprehensive health services plan, as provided for by Articles 28, 36, 40 and 44, respectively, of the Public Health Law, to provide hospital service or health related service, to establish, operate or maintain an adult care facility, as provided for by Article 7 of the Social Services Law, or to solicit any funds, contributions or grants, from any source, for the establishment or operation of any adult care facility.

10. The Secretary of State of the State of New York is hereby designated the agent of the Corporation upon whom process against the Corporation may be served. The post office address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him as agent of the Corporation is:

c/o Pluta Cancer Center Foundation, Inc.
200 Red Creek Drive, Suite 200
Rochester, New York 14623

4. This restated certificate of incorporation was authorized and approved by
vote of a majority of the board of directors.

IN WITNESS WHEREOF, the undersigned, has signed and acknowledged this
Restated Certificate of Incorporation under penalties of perjury this 8th day of November, 2012.



Name: Nicholas A. Scargone, Attorney-in-fact
Address: c/o Hiscock & Barclay, LLP
2000 HSBC Plaza
100 Chestnut Street
Rochester, New York 14604

RESTATED CERTIFICATE OF INCORPORATION

OF

PLUTA CANCER CENTER FOUNDATION, INC.

Under Section 805 of the Not-For-Profit Corporation Law

**Nicholas A. Scarfone, Esq.
Hiscock & Barclay, LLP
2000 HSBC Plaza
100 Chestnut Street
Rochester, New York 14604**

STATE OF NEW YORK
SUPREME COURT : MONROE COUNTY

In the Matter of the Application
of

PLUTA CANCER CENTER FOUNDATION, INC.
Petitioner,

For an order approving the Restated Certificate
of Incorporation pursuant to Section 805 of the
Not-For-Profit Corporation Law

ORDER APPROVING
RESTATED CERTIFICATE
OF INCORPORATION

Index No. 12/13170

Upon reading and filing the petition of Pluta Cancer Center Foundation, Inc., for an Order approving the Restated Certificate of Incorporation, with the exhibits annexed, verified the 3 day of December, 2012, and it appearing that the Attorney General of the State of New York has no objection to approval of said Petition, it is hereby

ORDERED that the Petition and Restated Certificate of Incorporation, be and the same each are hereby approved.

ENTER

12/12



Justice of the Supreme Court
of the State of New York

THE ATTORNEY GENERAL HAS NO OBJECTION
TO THE GRANTING OF JUDICIAL APPROVAL
HEREON/ACKNOWLEDGES RECEIPT OF
STATUTORY NOTICE AND DEMANDS SERVICE
OF THE FILED CERTIFICATE SAID NO OBJECTION
IS CONDITIONED ON SUBMISSION OF THE
MATTER TO THE COURT WITHIN 30 DAYS HEREAFTER.


ASSISTANT ATTORNEY GENERAL

11-15-2012
DATE

2012 DEC -4 PM 4:23

RECORDED
MONROE COUNTY CI

PLUTA CANCER CENTER FOUNDATION, INC.

AMENDED AND RESTATED

BY-LAWS

ARTICLE I

GENERAL

Section 1. Name. This not-for-profit corporation shall be known as **PLUTA CANCER CENTER FOUNDATION, INC.** (the “Corporation”).

Section 2. Mission. The Corporation is formed and shall be operated exclusively for the charitable purpose of supporting and benefiting the University of Rochester, a New York education corporation (the “University”), and such other organizations described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the “Code”) and Section 509(a)(1) or Section 509(a)(2) of the Code that are subsidiaries of or controlled by the University, that operate hospital facilities within the scope of Article 28 of the New York State Public Health Law, and that provide medical and/or radiation oncology services and related services to the community. It is intended that the Corporation will primarily support and benefit the Pluta Cancer Center, an extension clinic of Strong Memorial Hospital. Pursuant to an Acquisition Agreement dated October 18, 2012, the University has agreed to operate the facility formerly operated by Pluta Cancer Center, Inc., as an extension clinic of Strong Memorial Hospital, an unincorporated division of the University. The University is an organization described in Section 170(b)(1)(A) (other than in clauses (vii) and (viii)) of the Code. The

Corporation shall carry out its stated purposes at all times within the meaning and intent of Section 509(a)(3) of the Code.

Section 2. Principal Office. The principal office of the Corporation shall be located at 200 Red Creek Drive, Suite 200, Rochester, New York 14623, and the Corporation may also have offices at such other places within or without the State of New York as the Board of Directors may from time to time determine or the business of the Corporation may require.

ARTICLE II

MEMBERS

The Corporation is a "Type B" not-for-profit corporation and shall have members. Any action or vote required or permitted to be taken by members under the laws of the State of New York shall be taken by action or vote of the board of directors. The individuals constituting the board of directors at any particular time shall automatically be the "members" of the Corporation under New York State's Not-For-Profit Corporation Law and such individuals shall have all of the rights and powers which may be possessed and exercised by members under applicable law and in accordance with these By-Laws.

ARTICLE III

BOARD OF DIRECTORS

Section 1. General. The property, business, and affairs of the Corporation shall be vested in the Corporation and managed by a self-perpetuating Board of Directors (the "Board"), which shall have all the powers and duties necessary or appropriate for the administration of the

affairs of the Corporation as are permitted by law, the Certificate of Incorporation of the Corporation, and these By-Laws.

Section 2. Number. The Board shall consist of not less than three (3) and not more than eleven (11) directors. The number of directors shall be determined by action of the board of directors and may be increased or decreased only by action of a majority of the entire Board, provided, however, that no decrease shall shorten the term of any incumbent director, unless such incumbent director is removed in accordance with Section 5 of this **ARTICLE III**.

Section 3. Election and Term. Directors of the Corporation shall be elected by action of the board of directors at the annual meeting of the board of directors. At all times, at least one (1) of the Directors of the Corporation shall be an individual nominated by the University. The University's nominee may not be rejected by the Board, except for cause. In the event of such rejection, the President will immediately notify the University, which shall nominate an alternative individual to fill the position. Unless a director earlier resigns or is earlier removed in accordance herewith, each director shall serve until such director's successor shall have been elected and qualified at the next succeeding annual meeting of the board of directors.

Section 4. Resignation. A director may resign from the Corporation at any time by presenting to the President a written letter of resignation. Such letter shall be presented to the Board by the President at the next meeting of the Board following receipt of such letter. Such resignation shall be effective upon receipt by the President unless otherwise specified in the letter of resignation. The acceptance of a resignation shall not be necessary to make it effective; however, no resignation shall discharge any accrued obligation or duty of a director.

Section 5. Removal. Except as otherwise provided in this Section 5 of this **ARTICLE III**, any director may be removed with or without cause at any time by action of the Board at any meeting called by such Board, provided that notice of the proposed resolution to remove the director has been stated in the notice of the meeting. Notwithstanding anything herein to the contrary, any director of the Corporation that was nominated by the University in accordance with Section 3 of this **ARTICLE III** may not be removed without cause.

Section 6. Vacancies and Newly-Created Directorships. Whenever a vacancy shall occur in the Board for any reason or a new directorship shall be created, it may be filled by vote of a majority of the directors then in office, regardless of their number, subject, however, to the restriction set forth in Section 3 of this **ARTICLE III** at all times at least one (1) of the Directors of the Corporation shall be an individual nominated by the University. In the event of a vacancy in a position filled by a nominee of the University, the University shall nominate a replacement to fill such vacancy. A director so elected shall hold office until the next annual meeting of the board of directors at which the election of directors is in the regular course of business, and until such director's successor is elected and qualified.

Section 7. Compensation. No director, as such, shall receive any compensation from the Corporation for service performed; however, by resolution of the Board, directors may be reimbursed for reasonable and necessary expenses incurred in the performance of their official duties. Nothing herein contained shall be construed to preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

ARTICLE IV
MEETINGS

Section 1. Annual Meeting. The annual meeting of the Board shall be held at the time and place designated by the Board for the purpose of electing officers and receiving the annual reports of the officers and committees of the Corporation, and transacting such other business as may properly come before the meeting.

Section 2. Regular and Special Meetings. Regular meetings of the Board may be held without notice at such time and place as the Board shall from time to time determine. Special meetings of the Board shall be held upon notice to the directors and may be called by the President at any time and by any director upon written demand of not less than twenty percent (20%) of the entire Board. Such requests shall state the purpose or purposes of the proposed meeting. Business transacted at special meetings shall be confined to the purpose or purposes stated in the notice of the meeting.

Section 3. Place of Meetings. The Board shall hold its meetings at the principal office of the Corporation or at such other places, either within or without the State of New York, as it may from time to time determine.

Section 4. Notice of Meetings of the Board; Observer.

(a) Regular meetings of the Board shall be held without notice. Written notice of any annual or special meeting of the Board, stating the place, date, and time of the meeting, and in the case of a special meeting, the purpose or purposes for which the meeting is called, shall be given either personally, by facsimile or other electronic transmission, or by mail to each director not less than ten (10) days before the meeting. If mailed, notice is given when

deposited in the United States mail, with postage thereon prepaid, directed to the director at such director's address as it appears on the record of directors or, if such director shall have filed with the Secretary a written request that notices be mailed to such director at some other address, then directed to such director at such other address. A majority of the directors present, whether or not a quorum is present, may adjourn any meeting to another specified time and place. Notice of the adjournment shall be given to all directors who are absent at the time of the adjournment.

(b) The then current Director of the James P. Wilmot Cancer Center at the University of Rochester Medical Center (the "Observer") shall have observer rights with respect to the Board. The Observer shall not be a director of the Corporation and shall have no voting rights, but shall (i) receive notice of each meeting of the Board at the same time and in the same manner that the members of the Board receive notice, (ii) have the right to attend all such meetings, including executive sessions thereof, (iii) have the right to participate in all discussions and deliberations at all such meetings, and (iv) receive a copy of any proposed action by written consent of the Board at the same time and in the same manner that the members of the Board receive it. The foregoing notwithstanding, the Board may ask the Observer to leave a meeting of the Board while the following are discussed: (x) any transaction in which a conflict may exist between the University of Rochester or any affiliate thereof and the Corporation; or (y) legal proceedings, where the Corporation's counsel advises that the Observer's presence may result in a waiver of attorney-client privilege.

Section 5. Waiver of Notice. Notice of a meeting need not be given to any director who submits a signed waiver of notice whether before or after the meeting, or who attends the

meeting without protesting, prior thereto or at its commencement, the lack of notice to such director.

Section 6. Quorum and Vote. Except as otherwise provided by law or in the Certificate of Incorporation, a majority of the entire Board shall constitute a quorum for the transaction of business or of any specified item of business. Except as otherwise specifically provided herein, the vote of a majority of the Board present at the time of a vote, if a quorum is present at such time, shall be the act of the Board.

Section 7. Presumption of Assent. A director who is present at the meeting of the Board in which action on any corporate matters shall be taken shall be presumed to have entered into the action unless such director votes against such action or abstains from voting because of a conflict of interest.

Section 8. Chairman. At all meetings of the Board, the President or, in his absence, the Vice President (or the Executive Vice President if there is more than one Vice President, or in his absence another Vice President nominated by the President), or in the absence of the President and the Vice President(s), a chairman chosen by the Board, shall preside.

Section 9. Action of Directors Without a Meeting. Any action required or permitted to be taken by the Board or any Committee thereof may be taken without a meeting if all of the members of the Board or Committee consent in writing to the adoption of a resolution authorizing the action.

Section 10. Meetings by Conference Telephone. Any one or more of the directors may participate in a meeting of the Board or any Committee thereof by means of a conference telephone or similar communications equipment allowing all persons participating in the meeting

to hear each other at the same time. Participation by such means shall constitute presence in person at the meeting.

ARTICLE V COMMITTEES

Section 1. General. The Board, by resolution adopted by a majority of the entire Board, may designate from among its members an Executive Committee and other standing committees, each consisting of three (3) or more directors. Each Committee shall serve at the pleasure of the Board.

Section 2. Executive Committee. If an Executive Committee is so appointed, it shall, in the interim between the meetings of the Board, exercise all powers of the Board to the extent permitted by law and the Certificate of Incorporation, except that the Executive Committee shall have no power or authority to remove officers from office.

ARTICLE VI OFFICERS

Section 1. Number. The officers of the Corporation shall be a President, Secretary, and Treasurer, and such other officers as the Board may elect. Any two or more offices may be held by the same person, except the office of President and Secretary.

Section 2. Election and Term. The officers of the Corporation shall be elected by the Board at the annual meeting. Each officer shall hold office until such officer's successor has been elected and qualified at the next succeeding annual meeting of the Board, unless the officer resigns or is removed in the manner hereinafter provided.

Section 3. Removal. Any officer may be removed at any meeting by the Board, with or without cause.

Section 4. Vacancies. In the event of the death, resignation, or removal of an officer, the Board may elect a successor to fill the unexpired term.

Section 5. Compensation. Compensation for all officers shall be fixed from time to time by the Board. Upon submission of a proper claim, officers shall be reimbursed for their reasonable expenses incurred in the performance of their duties. No officer shall be prevented from receiving such compensation by reason of the fact that such officer is also a director.

Section 6. President. The President shall be the chief executive officer of the Corporation; he shall preside at all meetings of the Board and of the Executive Committee, if any; he shall have responsibility for the supervision and management of the business and affairs of the Corporation, subject to the control of the Board; and he shall see that all orders and resolutions of the Board are carried into effect. The President shall have the power to sign and execute all contracts and instruments of conveyance in the name of the Corporation, to sign checks, drafts, notes, and orders for the payments of money, and to appoint and discharge agents and employees, subject to the approval of the Board. The President shall perform all the duties usually incident to the office of President.

Section 7. Vice Presidents. During the absence or disability of the President, the Vice President or, if there are more than one, the Executive Vice President, shall perform the duties and exercise all the powers of the President. Each Vice President shall perform such other duties as the Board or the President may from time to time prescribe.

Section 8. Secretary. The Secretary shall attend all meetings of the Board, record all votes and minutes of all proceedings in a book to be kept for that purpose, give or cause to be given notice of all annual and special meetings of the Board and all other notices required by law or by these By-Laws, keep in safe custody the seal of the Corporation and affix it to any instrument when so authorized by the Board or the President, keep all the corporate books and records of the Corporation as required by law or otherwise in a proper and safe manner, and perform all duties incident to the office of Secretary and such other duties as from time to time may be prescribed by the Board or the President.

Section 9. Treasurer. The Treasurer shall have the custody of the corporate funds, securities, evidences of indebtedness, and other valuable documents; keep full and accurate accounts of receipts and disbursements in the corporate books; deposit all money and other valuables in the name and to the credit of the Corporation in such depositories as may be designated by the Board; disburse the funds of the Corporation as may be ordered or authorized by the Board and preserve proper vouchers for such disbursements; render to the President and Board at the regular meetings of the Board, or whenever they require it, an account of all transactions as Treasurer and of the financial condition of the Corporation; and render a full financial report at the annual meeting of the Corporation if so requested; be furnished by all corporate officers and agents at such Treasurer's request with such reports and statements as such Treasurer may require as to all financial transactions of the Corporation; and perform such other duties as from time to time may be prescribed by the Board or the President.

Section 10. Sureties and Bonds. In case the Board shall so require, any officer, employee, or agent of the Corporation may be required by the Board to execute a bond in such

sum and with such surety or sureties as the Board may direct, conditioned upon the faithful performance of such officer's, employee's, or agent's duties to the Corporation and including responsibility for negligence and for the accounting for all property, funds, or securities of the Corporation which may come into such officer's, employee's or agent's hands.

Section 11. Delegation of Duties. In the absence or disability of any officer, or for any other reason deemed sufficient by the Board, the Board may delegate such officer's powers or duties to any other officer.

ARTICLE VII

EXECUTION OF INSTRUMENTS

All corporate instruments and documents shall be signed or countersigned, executed, verified, or acknowledged by the President or by such other officer or officers or other person or persons as the Board may from time to time designate.

ARTICLE VIII

DIRECTORS' AND OFFICERS' LIABILITY AND INDEMNIFICATION

Section 1. Indemnification.

(a) Any person made or threatened to be made a party to any action or proceeding, other than one by or in the right of the Corporation to procure a judgment in its favor, whether civil or criminal, by reason of the fact that such person, such person's testator or intestate, was a director or officer of this Corporation, shall be indemnified by this Corporation to the full extent permitted by law against amounts paid in settlement and reasonable expenses, including attorneys' fees, actually and necessarily incurred by such person, such person's testator

or intestate as a result of such action or proceeding, or any appeal therein, if such director or officer acted in good faith, for a purpose which he reasonably believed to be the best interests of the Corporation and in criminal actions or proceedings, had no reasonable cause to believe that his conduct was unlawful.

(b) Any person made or threatened to be made a party to any action or proceeding by or in the right of the Corporation to procure a judgment in its favor, whether civil or criminal, by reason of the fact that such person, such person's testator or intestate, is or was a director or officer of this Corporation, shall be indemnified by this Corporation to the full extent permitted by law against amounts paid in settlement and reasonable expenses, including attorneys' fees, actually and necessarily incurred by such person, such person's testator or intestate in connection with the defense of such action or proceeding, or in connection with any appeal therein, if such director or officer acted in good faith, for a purpose which he reasonably believed to be the best interests of the Corporation except that no indemnification under this paragraph shall be made in respect of (1) a threatened action, or a pending action which is settled or otherwise disposed of, or (2) any claim, issue, or matter as to which such person shall have been adjudged to be liable to the Corporation, unless and only to the extent that a court determines that such person is fairly and reasonably entitled to indemnity. The right of indemnification provided in this **ARTICLE VIII** shall not be deemed exclusive of any other rights to which a director or officer seeking indemnification or advancement of expenses may be entitled as provided in the Certificate of Incorporation or as provided by (1) a resolution of the Board or (2) an agreement providing for such indemnification, it being expressly intended that these By-Laws authorize the creation of other rights in any such manner.

Section 2. Insurance. The Board shall have the power to purchase and maintain insurance: (i) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of its directors and officers under the provisions of this **ARTICLE VIII**; (ii) to indemnify directors and officers in instances in which they may be indemnified by the Corporation; and (iii) to indemnify in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this **ARTICLE VIII**, provided the contract of insurance covering such directors and officers provides, to the extent required by law, for a retention amount and for co-insurance.

Section 3. Repeal or Modification. No repeal or modification of this **ARTICLE VIII**, including, without limitation, any repeal or modification of this **ARTICLE VIII** occurring upon the merger, consolidation, or dissolution of the Corporation, shall adversely affect, repeal, or modify any right of indemnification for any act or omission which occurred or is alleged to have occurred while such right of indemnification was in place.

ARTICLE IX

FISCAL MANAGEMENT

Section 1. Fiscal Year. The fiscal year of the Corporation shall begin on the first (1st) day of January of every year, except that the first fiscal year of the Corporation shall begin at the date of incorporation and end the next following December 31st. The commencement date of the fiscal year herein established shall be subject to change by the Board.

Section 2. Books and Accounts. The books and accounts of the Corporation shall be kept under the direction of the Treasurer in accordance with generally accepted accounting practices.

Section 3. Auditing and Reports. At the close of each fiscal year, the books and records of the Corporation shall be audited in accordance with generally accepted accounting practices, and the Board shall direct the President and Treasurer to present a full and correct statement of the affairs of the Corporation at the annual meeting of the Board and filed with the Secretary and other agencies as legally required.

**ARTICLE X
BY-LAW CHANGES**

Except as otherwise provided in this **ARTICLE X**, the By-Laws may be adopted, amended, or repealed only by action of the board of directors. Notwithstanding anything herein to the contrary, the following provisions may not be amended or repealed except upon the unanimous vote or unanimous written consent of the Board (including the nominee of the University): (i) Section 3 of **ARTICLE III** and Section 6 of **ARTICLE III** requiring that at all times at least one (1) of the Directors of the Corporation be an individual nominated by the University and otherwise pertaining to such nomination; (ii) **ARTICLE II** defining "members" of the Corporation; (iii) Section 5 of **ARTICLE III** addressing the removal of any director of the Corporation nominated by the University; (iv) Paragraph (b), Section 4 of **ARTICLE IV** defining and providing certain rights to an Observer (as defined therein); and (v) this **ARTICLE X**. Notice of any proposed action to amend or repeal any provision listed in the preceding sentence shall be given personally, by facsimile or other electronic transmission, or by mail to the directors and the Observer not less than ten (10) days before the proposed action is taken.

Notice of the action shall be given to the then current Board as soon as practicable following such action.

ARTICLE XI
REFERENCES

Reference to the Certificate of Incorporation in these By-Laws shall include all amendments thereto or changes thereof unless specifically excepted.

All pronouns and any variations thereof in these By-Laws shall be deemed to refer to masculine, feminine, or neuter, singular or plural, as the identity of the person or persons referred to may require.

THESE AMENDED AND RESTATED BY-LAWS ADOPTED BY the Directors of the Corporation at a meeting held this 15th day of October, 2012 and shall be effective as of the date the Corporation's Restated Certificate of Incorporation dated November 8, 2012 is filed by the New York Secretary of State.



WALTER PARKES, Secretary

ACQUISITION AGREEMENT
BY AND AMONG
THE UNIVERSITY OF ROCHESTER
ON BEHALF OF STRONG MEMORIAL HOSPITAL,
AND
PLUTA CANCER CENTER, INC.
AND
PLUTA CANCER CENTER FOUNDATION, INC.

DATED: OCTOBER 18, 2012

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*U of R
Pluta Cancer Center, Inc. (Pluta)
Pluta Cancer Center Foundation, Inc. (PCCF)*

ACQUISITION AGREEMENT

This Acquisition Agreement, ~~hereinafter referred to~~ as "Agreement", dated October 18, 2012, is by and among the University of Rochester, a New York education corporation, on behalf of the Strong Memorial Hospital, an unincorporated division with offices located at 601 Elmwood Avenue, Rochester, New York, 14627, hereinafter referred to as "Hospital" or "University", the Pluta Cancer Center, Inc., a New York not-for-profit corporation with offices located 125 Red Creek Drive, Rochester, New York, 14623, hereinafter referred to as "Pluta", and the Pluta Cancer Center Foundation, Inc., a New York not-for-profit corporation with offices located at 125 Red Creek Drive, Rochester, New York 14623, hereinafter referred to as "PCCF". Hospital, PCCF and Pluta are referred to herein collectively as "the Parties" and individually as a "Party".

WHEREAS, University is duly authorized to operate Strong Memorial Hospital, an acute care hospital which is a division of the University of Rochester and a division of the University of Rochester Medical Center; and

WHEREAS, Pluta is duly authorized to operate a diagnostic and treatment center; and

WHEREAS, PCCF is duly authorized to operate as a charitable, tax exempt, foundation; and

WHEREAS, Pluta was formed in 2001 to continue the operation of the Pluta Cancer Center of Genesee Hospital; and

WHEREAS, PCCF was formed for the purpose of supporting the mission of Pluta; and

WHEREAS, Pluta and Hospital share an interest in providing compassionate and patient-family centered care, and believe that a combination of their two organizations will benefit the communities they serve; and

WHEREAS, Pluta and the Hospital share an interest in ensuring Pluta's long-term economic vitality and preserving the legacy of the Pluta family as reflected in the mission and operations of Pluta; and

WHEREAS, Pluta has been operating at a loss for several years and is unable to use the non-liquid assets to generate sufficient revenue to cover its operating costs; and

WHEREAS, Pluta and Hospital have therefore been exploring a possible business collaboration whereby Hospital would acquire all of the assets and assume most of the liabilities of Pluta, and continue the operations of Pluta under the Pluta name; and

WHEREAS, Pluta and Hospital entered into a Confidentiality Agreement dated April 10, 2012, regarding the confidentiality of their discussions and negotiations, hereinafter referred to as the "Confidentiality Agreement"; and

WHEREAS, the Parties entered into a Memorandum of Understanding dated July 18, 2012; and

WHEREAS, Pluta, Hospital and PCCF have agreed to an affiliation plan regarding the consolidation of Pluta's programs and personnel into Hospital, the acquisition of Pluta's assets by Hospital, Hospital's assumption of some of the liabilities of Pluta, and PCCF's continued support for Pluta's mission and the cancer programs it provides, hereinafter referred to as the "Acquisition", as specified herein; and

WHEREAS, Hospital intends to establish Pluta's current campus as an extension clinic of Hospital, subject to regulatory and board approval; and

WHEREAS, Hospital intends to use commercially reasonable efforts to grow Pluta's operations, including its services to those with breast cancer, and intends to include Pluta's current site in clinical trials, as appropriate; and

WHEREAS, Hospital intends to implement an electronic medical record system at Pluta's current site after it is established as an extension clinic of Hospital; and

WHEREAS, the Parties identify the goals of the Acquisition as: providing financial stability to Pluta; allowing patients access to clinical trial opportunities and more advanced radiation technology for complex and challenging cancer problems; allowing Pluta patients access to new sequence technology and infrastructure at Hospital which will provide the ability to profile tumors for clinical care and research purposes; achieving significant cost savings and operational efficiencies; and allowing Pluta to recruit needed medical staff; and

WHEREAS, on the basis of the terms and conditions of this Agreement, the governing boards of each of the Parties has determined that the missions of their respective institutions will be enhanced following the consolidation contemplated by this Agreement; and

WHEREAS, the Parties believe that their commitment to the Acquisition will help them achieve their goals and objectives in the context of anticipated significant changes in the state and national health care delivery and reimbursement system; and

WHEREAS, the Parties wish to set forth in this Agreement the terms and conditions upon which the Acquisition will take place.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and intending to be legally bound hereby, the Parties hereby agree as set forth below:

ARTICLE I
CERTAIN DEFINITIONS

“Assumed Contracts” means the contracts listed on Schedule 3.2(i), attached hereto and incorporated by reference to this Agreement.

“Assumed Liabilities” means those liabilities of Pluta as reflected in the Balance Sheet, including without limitation the Assumed PCCF Obligation, as agreed to in Article III. For purposes of illustration, and not by limitation, Assumed Liabilities include the liabilities listed in Exhibit 3.2(ii) hereof.

“Assumed PCCF Obligation” means the liability of Pluta to PCCF as reflected in the Balance Sheet and identified therein as “Loan Payable to Foundation”, in accordance with Section 3.3 hereof.

“Balance Sheet” means the balance sheet of Pluta as of the Effective Date, as finally determined by Pluta’s accountants and approved by the Parties as provided in Section 3.5 hereof.

“Claims” means claims, actions, suits, proceedings or investigations.

“Closing” shall have the meaning ascribed to such term in Section 9.1.

“Code” shall mean the Internal Revenue Code of 1986, as amended.

“Effective Date” means the date on which the Closing of the transactions contemplated by this Agreement occurs.

“Leased Premises” shall mean the premises of Pluta, located at 125 Red Creek Drive, Rochester, New York, 14623.

“Material” means in the light of context and circumstance, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the item or representation would have been changed or influenced by the inclusion, omission or correction of the item.

“Material Adverse Effect” means a Material adverse effect on the business, assets, financial condition, operations or prospects of the entity concerned.

“Ordinary Course of Business” means practices which are reasonably consistent with the ongoing day-to-day conduct and administration of the business of the entity in question as evidenced by past practice(s) or the reasonable activities of similarly situated entities.

“Patient” shall mean any patient who is the subject of records owned by Pluta as of the Closing.

“PCCF Promissory Note” means the promissory note issued by Pluta to PCCF as described in Section 3.3 hereof. “Purchased Assets” shall mean: (A) all leasehold improvements and fixtures constituting real property located at 125 Red Creek Drive, Rochester, New York 14623; and (B) all of the tangible and intangible personal property and rights of any kind whatsoever, including without limitation, goodwill and going concern value, owned by Pluta and used in or useful to its diagnostic and treatment facility located at 125 Red Creek Drive, Rochester, New York, 14623, including: (i) all accounts receivable, whether or not collected as of the Effective Date, and all other monies due and payable to Pluta resulting from professional services rendered on or prior to the Effective Date, including insurance company “risk pool” funds; (ii) all service marks, trademarks, trade names, and copyright to the “Pluta Cancer Center”, including all logos associated with the “Pluta Cancer Center”; and (iii) all other tangible and intangible property owned by Pluta and reflected in the Balance Sheet. The Purchased Assets shall include, but shall not be limited to, the assets described in Exhibit 1 attached hereto. The Purchased Assets shall exclude all Patient medical records and all service marks, trademarks, trade names, and copyright to the “Pluta Cancer Center Foundation”.

Notwithstanding the foregoing, Purchased Assets shall not include cash and cash equivalents in the amount of \$25,000, which shall be retained by Pluta as a reserve against the costs of dissolution. Any cash or cash equivalents in excess of such amount shall be transferred to the Hospital. All dissolution expenses shall be approved by the University of Rochester Medical Center’s Chief Financial Officer, which approval shall not be unreasonably withheld, and any remaining cash or cash equivalent after all expenses have been paid shall be transferred to the Hospital.

ARTICLE II PLAN OF ACQUISITION

2.1 Acquisition. On the Effective Date, Pluta will sell to Hospital, and Hospital will buy from Pluta, all of the Purchased Assets in exchange for the consideration set forth in Article III below. Except for the foregoing specific liabilities, the Hospital shall not assume and shall have no responsibility for any other liability relating to the operation of Pluta prior to the Effective Date or the operation of Pluta necessary to wind up and dissolve its 401(k) Plan or the organization after the Effective Date. Furthermore, Hospital shall not assume any successor

liability, including but not limited to, any successor liability for any tax matters, employee and labor relation matters, Medicaid and Medicare issues, environmental compliance, and employee benefit plans.

2.2 Other Transactions At Closing.

2.2.1 Lease. Upon the Effective Date, Hospital shall assume the lease for the Leased Premises, pursuant to an Assignment and Assumption of Lease substantially in the form set forth in Exhibit 2.2.1 hereto.

2.2.2 Surrender of Pluta's License. Upon the Effective Date, Pluta shall surrender its Article 28 license to the New York State Department of Health.

2.2.3 Continuation of Pluta's Programs and Mission. From and after the Effective Date, Hospital will be responsible for the operation of Pluta as an extension clinic of Hospital, including, except as provided in Section 3.3, and Article XI hereof, the power and responsibility for deciding upon any changes in programs which might be necessary or desirable. Hospital shall have the fiscal and fiduciary responsibility for the operation of such programs and services from and after the Effective Date.

ARTICLE III
FINANCIAL OBLIGATIONS AND CONSIDERATION

3.1 Cost of Acquisition. Except in the event of a material breach of any obligation under this Agreement or a Material misrepresentation herein or hereunder by any Party hereto, each Party shall be responsible for paying its own costs for legal due diligence, financial due diligence, and other legal and accounting services the Party engages. Furthermore, each Party shall be responsible for any other internal and external costs incurred in connection with this Agreement.

3.2 Consideration. As consideration for the Purchased Assets, Hospital shall assume Pluta's obligations under the Assumed Contracts and the Assumed Liabilities as provided herein. Hospital shall not assume any liability other than the Assumed Contracts and Assumed Liabilities, which liabilities shall remain liabilities of Pluta. Hospital shall also continue Pluta's current arrangements with the vendors and independent contractors listed on Schedule 3.2(iii), provided however, that Hospital may, in its discretion, terminate any arrangements if such arrangements are no longer needed. Notwithstanding the above, Hospital intends to continue the yoga and Tai Chi services currently offered by Pluta.

3.3 Agreements relating to Assumed PCCF Obligation. The amount of the Assumed PCCF Obligation shall reflect the following:

3.3.1 The parties acknowledge that: (i) as of October 9, 2012 Pluta was indebted to PCCF in the amount of \$1,031,654.68; (ii) from October 10, 2012 to the Effective Date, PCCF intends to advance funds to Pluta from time to time from the date of this Agreement through the Effective Date in such amounts as Pluta and PCCF determine to be necessary to continue the day-to-day operations of Pluta, contingent upon the prior consent of the University of Rochester Medical Center's CFO; (iii) the additional advances described in the immediately preceding subclause will include, but may not be limited to, payments that Pluta is required to make pursuant to its personnel policies to its employees for unused paid time off as of the Effective Date and employer contributions to Pluta's 401(k) Plan, to the extent that Pluta does not have sufficient liquid assets to pay those obligations without such an advance; and (iv) Pluta does not intend to repay to PCCF any amount of the PCCF Obligation prior to Closing.

3.3.2 The principal amount of the Assumed PCCF Obligation shall be reflected in a five year, no interest promissory note from Pluta to PCCF, attached hereto as Exhibit 3.3.2 and incorporated by reference to this Agreement. Hospital shall assume the PCCF Note pursuant to the terms and conditions of the Assignment and Assumption of Assumed Liabilities, attached hereto as Exhibit 9.2.7.

3.4 Additional Consideration. As further consideration for the Purchased Assets, the University agrees that it shall continue, as provided in Article XI hereof, Pluta's operations at 125 Red Creek Drive, Rochester, New York, 14623, for a period of not less than five years from the expiration of Pluta's current lease at such location. Furthermore, Hospital agrees that it shall use the name "Pluta Cancer Center" or a name of similar import in connection with the extension clinic established at 125 Red Creek Drive, Rochester, New York 14623 and that such name or a name of similar import will be prominently displayed and used in all public communication. In the event the extension clinic is moved, Hospital shall continue to use the name "Pluta Cancer Center" or a name of similar import in connection with the services provided at the new location. Signage and all public announcements and communications will identify the clinic as an extension clinic of Strong Memorial Hospital.

3.5 Procedure to Pay and Finalize Purchased Assets and Assumed Liabilities. Within five (5) days after the Effective Date, Pluta shall deliver to the Hospital its unaudited Balance Sheet prepared by it in good faith as of the Effective Date ("Interim Balance Sheet"), or as close in time as reasonably practicable to the Effective Date. Pluta shall prepare such balance sheet on such basis and applying the same accounting principles, policies and practices as employed by Pluta on the date hereof in the Ordinary Course of Business.

Within 30 days after the Effective Date, Pluta shall finalize its financial statement for the period ending on the Effective Date (which financial statement shall include the Balance Sheet) and deliver the same to Bonadio & Co., LLP, (the "Auditor"). Pluta shall request that the Auditor deliver its unqualified opinion that Pluta's financial statements (including its Balance Sheet) present fairly, in all Material respects, Pluta's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles (the "Unqualified Opinion"). Pluta shall provide a copy of such financial statement to the Hospital concurrently with delivery to the Auditor.

Pluta shall provide or cause to be provided to the Auditor such workpapers and other documents as the Auditor may reasonably request, and shall provide copies of all such documents concurrently to the Hospital. Pluta and the Hospital shall cooperate to provide to the Auditor such other information as may be requested by the Auditor, including making the former management employees of Pluta available to discuss the financial statement with the Auditor. Pluta shall advise the Hospital of, and the Hospital shall be entitled to participate in, all substantive discussions between Pluta and the Auditor in connection with the financial statement.

The Balance Sheet, with respect to which the Auditor has provided its Unqualified Opinion (the "Audited Balance Sheet"), shall finally and conclusively resolve all issues relating to existence and book value of the Purchased Assets and the Assumed Liabilities.

The following liabilities shall be paid by Pluta or PCCF at, or prior to, the Effective Date: Special Women's Fund, Tony Labaize Spec. Men's Fund, Wages Payable, 401(k) Payable, United Way Payable, FSA Payable, HSA Payable, Prior Year Clean Up. If necessary, PCCF may, subject to the approval of Hospital, increase the amount of the loan by the amount necessary to pay such liabilities.

ARTICLE IV TERMINATION

4.1 Events of Termination. This Agreement may be terminated by written notice of termination only as follows:

4.1.1 Mutual Consent. By mutual consent of the Parties; and/or

4.1.2 Breach by Pluta or PCCF. By Hospital if Pluta or PCCF: (a) shall have materially misstated any representation or is in Material breach of any warranty contained herein, or (b) is in Material breach of any covenant, undertaking or restriction contained herein, and such misstatement or breach has not been cured by the Effective Date, and Hospital is not in breach of its obligations hereunder; and/or

4.1.3 Breach by Hospital. By Pluta or PCCF if Hospital: (a) shall have materially misstated any representation or is in Material breach of any warranty contained herein, or (b) is in Material breach of any covenant, undertaking or restriction contained herein, and such misstatement or breach has not been cured by the Effective Date, and the terminating party is not in breach of its obligations hereunder; and/or

4.1.4 Failure of Approval Process. By Pluta or Hospital if there is a failure to receive one or more of the required governmental approvals, including that of the New York Supreme Court, the New York Department of Health, or the consent of a creditor whose consent is required.

4.2 Consequences of Termination. In the event of the termination of this Agreement pursuant to the provisions of Section 4.1 above, this Agreement shall have no further effect and such termination shall be without any liability on the part of any of Parties, their governing boards or officers with respect of this Agreement, except for any breach of this Agreement by such party, and termination by a party shall be without prejudice to its rights to recover damages for any such breach by another party. Notwithstanding the above, the Parties agree that any claim against the Hospital for a Material breach of any warranty or a Material misstatement of any representation shall be brought within one (1) year after the Effective Date.

ARTICLE V APPROVALS

5.1 Corporate Approvals. The governing board of each Party shall take all necessary corporate actions to duly authorize the Acquisition and other transactions contemplated herein.

5.2 Preparation for Closing. Prior to the Closing, each Party will fulfill each of the conditions precedent to obligations of such Party hereto set forth in Section 9.4, and to do each and every act and thing as may be necessary or reasonably desirable to consummate the Acquisition contemplated hereby and to consummate the implementation of the Acquisition, including obtaining the written consents of any third parties that are necessary to comply with the provisions of this Agreement. Each Party shall not take any action that is likely to impair the Parties' ability to consummate the Acquisition contemplated in this Agreement, nor shall any Party omit to take any action the omission of which is likely to impair such ability.

5.3 Notice of Developments; Acts and Omissions Impairing Acquisition. From the date hereof to the Effective Date, the Parties shall work together in good faith to consummate the Acquisition contemplated hereby. Each Party shall notify the other Parties in writing of any

Material problems or adverse developments with respect to the businesses or operations of the noticing Party.

5.4 Regulatory Matters. The Parties shall file such requests for rulings or other documents, seek such approvals and undertake such other actions as the officers of each of the Parties shall, with the advice of their legal counsel and certified public accountants, deem necessary or advisable in order to ensure that each has the approval of all necessary or desirable federal, state or other regulators in order to consummate the formation and implementation of this Acquisition, including:

5.4.1 Tax Exemption. Each Party shall use its respective best efforts to assure the retention of applicable exemptions from federal, state and local taxes of the Party and its affiliates, and the continued tax-exempt status of interest on any bond financing to which it or its affiliates are a party.

5.4.2 Certificate of Need. The Hospital shall obtain approval from the New York State Department of Health to operate an extension clinic encompassing the services and programs currently delivered by Pluta at Pluta's location.

5.4.3 Attorney General and Supreme Court. Pluta shall make any necessary filings and obtain any required consents with respect to the Acquisition from the New York Department of Law and the New York Supreme Court.

5.5 Approvals Required under Existing Contractual Obligations. The Parties shall obtain all necessary approvals required under any existing contractual and financial obligations to permit them to fulfill their obligations under this Agreement.

ARTICLE VI REPRESENTATIONS AND WARRANTIES OF UNIVERSITY

University hereby represents and warrants to Pluta and PCCF, as of the date hereof and the Effective Date as follows:

6.1 Organization and Good Standing. University is an education corporation duly organized, validly existing, and in good standing under the laws of the State of New York, and has all requisite corporate power and authority to carry on its business as it is now being conducted, and to own and operate the properties and assets now owned and operated by it. University is an organization described in Sections 501(c)(3) and 170(b)(1)(A)(ii) of the Code.

To the best of its knowledge, no event or condition has occurred which poses a Material risk to the tax-exempt status of University.

6.2 Authorization. The execution, delivery and performance by University of this Agreement and each instrument executed and to be executed in connection herewith, and its consummation of the Acquisition provided for herein: (i) have been duly authorized by all necessary corporate action; (ii) do not violate its Charter or bylaws; (iii) and assuming that all consents set forth on Schedule 6.4 and 7.6 are obtained, will not result in a violation of, or constitute, with or without due notice or lapse of time or both, a default, or give rise to any right of termination, cancellation or acceleration, under any of the terms, conditions or provisions of any Material contract to which it is a party or is bound; and (iv) will not violate any order, writ, injunction, decree, or judgment, or to the best of its knowledge, any statute, treaty, rule or regulation applicable to it which is Material to its current operation.

6.3 Binding Effect. This Agreement and each document and instrument executed and to be executed by or on behalf of University in connection herewith have been duly executed and delivered by it and, assuming due authorization, execution and delivery hereof by Pluta and PCCF, constitute the legal, valid and binding obligations of University enforceable against it in accordance with the terms hereof, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject, as to enforceability, to general principles of equity.

6.4 Consents and Approvals. Except as set forth in Schedule 6.4, no consent of any person, or third-party entity, and no approval or authorization of, or declaration or filing with, any governmental or regulatory body or other person is required for the valid authorization, execution, delivery and performance by University of this Agreement.

6.5 Litigation. There are no Claims pending or to the best of University's knowledge, threatened against University, that potentially exceed the scope of and amount of insurance policies currently maintained by University, that would prevent it from performing its obligations under this Agreement, that would prevent it from consummating and implementing the Acquisition described in the Agreement or that would create any Material Adverse Effect for Pluta or PCCF.

6.6 Compliance with Law. University has not failed to comply with any injunction, judgment, writ, decree or order or, to the best of its knowledge, any law, statute, ordinance, requirement, regulation or rule applicable to it or otherwise relating to its operations, including, without limitation, any federal or state anti-kickback or anti-referral laws or statutes, which failure would prevent it from performing its obligations under this Agreement, prevent it from

consummating and implementing the Acquisition described in the Agreement, or create any Material Adverse Effect for Pluta or PCCF.

6.7 Insurance. University has paid when due all fire and casualty, liability, workers' compensation and other insurance premiums under its insurance policies.

6.8 Medicare and Medicaid. Hospital is presently qualified for participation in and is a participant in good standing in the health insurance program for the aged and disabled created under Title XVIII of the Social Security Act, as amended ("Medicare") and in the New York Medicaid Program supported by grants from the federal government under Title XIX of the Social Security Act, as amended ("Medicaid"). To the best of its knowledge, the operation of Hospital is and has at all times been in substantial compliance with the conditions and standards of participation in, and the rules and regulations of the Medicare and Medicaid programs and such other third party reimbursement programs in which Hospital participates. There are no Material disputes, audits, investigations, inquiries or Claims pending or, to the best of its knowledge, threatened involving it or any of its employees and such reimbursement programs, and, to the best of its knowledge, there is no basis for any such dispute or Material Claim such that it would prevent it from performing its obligations under this Agreement, prevent it from consummating and implementing the Acquisition described in this Agreement, or create any Material Adverse Effect for Pluta or PCCF.

ARTICLE VII REPRESENTATIONS AND WARRANTIES OF PLUTA AND PCCF

Pluta and PCCF, as of the date hereof and the Effective Date, hereby individually and independently represent and warrant to University as follows:

7.1 Organization and Good Standing. Each of Pluta and PCCF are not-for-profit corporations duly organized, validly existing and in good standing under the laws of the State of New York, and have all requisite corporate powers and authority to lease and operate their properties and to carry on their businesses as now being conducted. Pluta is an organization described in Sections 501(c)(3) and 509(a)(2) of the Code; PCCF is an organization described in Sections 501(c)(3) and 509(a)(3) of the Code. To the best of their knowledge, no event or condition has occurred which poses a Material risk to their tax-exempt or public charity status.

7.2 Ownership of Pluta. Neither Pluta nor PCCF have any members nor outstanding capital or subvention certificates.

7.3 Subsidiaries. Neither Pluta nor PCCF have any subsidiaries or equity ownership in any other entity.

7.4 Authorization. The execution, delivery and performance by them of this Agreement and each instrument executed and to be executed by it in connection herewith and the consummation by them of the Acquisition provided for herein: (i) have been duly authorized by all necessary corporate action on their part; (ii) do not violate their respective Certificates of Incorporation or bylaws; (iii) assuming that all consents set forth on Schedule 6.4 and 7.6 are obtained, will not result in a violation of, or constitute with or without due notice or lapse of time or both, a default, or give rise to any right of termination, cancellation or acceleration, under any of the terms, conditions or provisions of any Material contract to which either party is a party or is bound; and (iv) will not violate any order, writ, injunction, decree, judgment, or to the best of their respective knowledge, statute, treaty, rule or regulation applicable to them which is Material to their respective current operations.

7.5 Binding Effect. This Agreement and each document and instrument executed and to be executed by or on behalf of each of them in connection herewith has been duly executed and delivered and, assuming due authorization, execution and delivery hereof by University, constitute legal, valid and binding obligations enforceable against each of them in accordance with and subject to the terms hereof, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject, as to enforceability, to general principles of equity.

7.6 Consents and Approvals. Except as set forth on Schedule 7.6, no consent of any person and no approval or authorization of, or declaration or filing with, any governmental body or other person is required for the valid authorization, execution, delivery and performance by Pluta and PCCF of this Agreement.

7.7 Litigation. There are no Claims pending or to the best of Pluta's or PCCF's knowledge, threatened against it, that potentially exceed the scope and amount of insurance policies currently maintained by it, that would prevent it from consummating and implementing the Acquisition described in the Agreement or that would create any Material Adverse Effect for University.

7.8 No Material Omission. To the best knowledge of each of the Responsible Officers (defined as the top two officers of Pluta), there is no other matter that should be disclosed herein where failure to disclose would have a material adverse effect on the Hospital's decision to proceed with this Agreement.

7.9 Property. Pluta is the sole owner or lessee under valid and existing leases, of the Purchased Assets. Pluta has good and marketable title or valid leasehold interests to the Purchased Assets, free and clear of all assessments, Claims, charges, liens, pledges, Claims, security interests and encumbrances, except as disclosed on Schedule 7.9. There are no liabilities, debts, obligations, liens, charges, security interests, Claims, restrictions or encumbrances of any nature, whether absolute, accrued, contingent or otherwise, whether due or to become due affecting the Property that would prevent them from performing their obligations under this Agreement, prevent them from consummating and implementing the Acquisition described in this Agreement or create any Material Adverse Effect for University. The Purchased Assets do not directly or indirectly secure the debt of any person except as disclosed on Schedule 7.9.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, PLUTA EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND OR NATURE, EXPRESS OR IMPLIED, AS TO THE CONDITION, VALUE OR QUALITY OF THE PURCHASED ASSETS OR THE PROSPECTS (FINANCIAL AND OTHERWISE), RISKS AND OTHER INDICIA OF THE PURCHASED ASSETS AND PLUTA SPECIFICALLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF MERCHANTABILITY, USAGE, SUITABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WITH RESPECT TO THE PURCHASED ASSETS, OR ANY PART THEREOF, OR AS TO THE WORKMANSHIP THEREOF, OR THE ABSENCE OF ANY DEFECTS THEREIN, WHETHER LATENT OR PATENT, OR COMPLIANCE WITH ENVIRONMENTAL LAWS, OR AS TO THE CONDITION OF, THE PURCHASED ASSETS OR ANY PART THEREOF.

TO THE BEST OF ITS KNOWLEDGE, HOWEVER, PLUTA DOES POSSESS TITLE AND THE RIGHT TO TRANSFER THE PURCHASED ASSETS TO HOSPITAL AS DESCRIBED HEREIN.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, PLUTA FURTHER SPECIFICALLY DISCLAIMS ANY REPRESENTATION OR WARRANTY REGARDING THE ABSENCE OF HAZARDOUS SUBSTANCES OR LIABILITY OR POTENTIAL LIABILITY ARISING UNDER ENVIRONMENTAL LAWS. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, PLUTA EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND REGARDING THE CONDITION OF THE PURCHASED ASSETS OR THE SUITABILITY OF THE PURCHASED ASSETS AND NO MATERIAL OR INFORMATION PROVIDED BY OR COMMUNICATIONS MADE BY PLUTA WILL CAUSE OR CREATE ANY WARRANTY, EXPRESS OR IMPLIED AS TO THE CONDITION, VALUE OR QUALITY OF THE PURCHASED ASSETS.

7.10 Agreements. To the best of its knowledge and except as set forth in Schedule 7.10, each of Pluta and PCCF have each performed all of the obligations required to be performed by it to date in all Material respects and is not in Material default under any Material contract and to the best of its knowledge, no event has occurred which, with the passage of time or the giving of notice or both would result in the occurrence of a Material default by it under any such contract. To the best of its knowledge, no third party to any contract with it, is in Material default thereunder and to the best of its knowledge, no event has occurred which, with the passage of time or the giving of notice or both, would result in the occurrence of a Material default by a third party under any contract.

7.11 Financial Status. The most recent audited financial statements of each of Pluta and PCCF, as previously delivered to University, are true and correct in all Material respects, fairly present their financial condition as of the date indicated thereon and do not distort its ownership and operation of its assets and business as of the date indicated thereon, and the results of its operations for the period covered thereby, and were prepared in accordance with generally accepted accounting principles consistently applied. To the best of its knowledge, all of its assets and liability are disclosed in the financial statements, as and to the extent required under generally accepted accounting principles. Since the date of the most recent audited financial statements delivered to University, there has not been a Material Adverse Effect sufficient to prevent it from performing its obligations under this Agreement, prevent it from consummating and implementing the Acquisition described in this Agreement or create a Material Adverse Effect for University.

7.12 Necessary Licensure. To the best of its knowledge, Pluta has all permits, licenses, orders, approvals including, diagnostic and treatment, pharmacy, laboratory and other ancillary department licenses, CON approvals, and provider agreements (collectively referred to as "Licenses") from each governmental entity required for it to conduct its businesses as presently conducted, and it is in substantial compliance with all requirements for maintenance of such Licenses. To the best of its knowledge, all such Licenses are in full force and effect and free from material restriction, waiver or limitation and no suspension or cancellation is threatened and no such licenses will be materially and adversely affected by the consummation of the Acquisition contemplated herein.

7.13 Insurance. Pluta has paid when due all fire and casualty, liability, and other insurance premiums under its insurance policies.

7.14 Medicare and Medicaid. Pluta is qualified for participation in and is a participant in good standing in the health insurance program for the aged and disabled created under Title XVIII of the Social Security Act, as amended ("Medicare") and in the New York Medical Assistance Program supported by grants from the federal government under Title XIX of the

Social Security Act, as amended ("Medicaid"). To the best of its knowledge, the operation of Pluta is and has at all times been in substantial compliance with the conditions and standards of participation in, and the rules and regulations of, the Medicare and Medicaid programs and such other third party reimbursement programs in which it participates. There are no Material disputes, audits, investigations, inquiries or Claims pending or, to the best of its knowledge, threatened involving Pluta or any of its employees or independent contractors and such reimbursement programs, and, to the best of its knowledge, there is no basis for any such dispute or Material Claim such that would prevent it from performing its obligations under this Agreement, prevent it from consummating and implementing the Acquisition described in this Agreement or create any Material Adverse Effect for University.

7.15 Environmental Compliance. To the best of its knowledge, the ownership, use, maintenance and operation by each of Pluta and PCCF of the Property and the conduct of its businesses comply with and has at all times complied in all Material respects with all applicable provisions of federal, state, local or municipal laws, rules, orders, regulations, statutes, ordinances, codes, decrees and requirements of any governmental entity regulating, relating to or imposing a liability or standards of conduct concerning environmental protection or workplace safety matters. No notices of violations of any environmental law or workplace safety standards has been received by it in the last five years, and there are no writs, injunctions, decrees, orders or judgments outstanding, no Claims pending, or, to the best of its knowledge, threatened relating to its ownership, use, maintenance or operation nor, to the best of its knowledge, is there any basis for such Claims being instituted or filed, which would prevent it from performing their obligations under this Agreement, prevent them from consummating and implementing the Acquisition described in this Agreement, or create any Material Adverse Effect for University.

7.16 Service Marks and Names. To the best of its knowledge, Pluta has the right, to transfer ownership of all service marks, trademarks, trade names, copyrights, and licenses which are utilized in the conduct of its business.

7.17 Zoning and Use. To the best of its knowledge, no present use or condition of the Property and the facilities operated by it violates any enforceable building or use restriction of record.

7.18 Hazardous Substances. To the best of its knowledge: (i) no portion of the Property operated by it is being used or at any previous time has been used, for the production, storage, deposit or disposal of toxic, dangerous or hazardous substances or pollutants, including nuclear fuel or wastes; and (ii) no hazardous substances or pollutants have ever been placed or located upon such Property, which hazardous substances or pollutants, if found upon such Property or found elsewhere and determined to have come from its Property would subject them to any Material damages, penalties or liabilities under any applicable federal, state or local law,

or under any civil action that would prevent it from performing its obligations under this Agreement, prevent it from consummating and implementing the Acquisition described in this Agreement or create a Material Adverse Effect for University. It is acknowledged that medical and associated hazardous wastes and substances have been and may still be stored at the Property. To the best of its knowledge, all storage of medical and associated hazardous wastes and substances and the disposal thereof are in Material compliance with all applicable governmental laws, rules and regulations.

7.19 Title to Purchased Assets. Pluta has good title to all the Purchased Assets, subject to no mortgage, pledge, lien, security interest, lease, charge, encumbrance or conditional sale or other title retention agreement, other than a loan which will be satisfied at or before Closing, or as disclosed on Schedule 7.9 hereto. The Purchased Assets constitute all of the assets used in the diagnostic and treatment facility of Pluta. Pluta will have and convey to Hospital on the Effective Date lawful possession and control of, and good title to, all the Purchased Assets, subject to no mortgage, pledge, lien, security interest, lease, charge, encumbrance or conditional sale or other title retention agreement, except as provided above.

ARTICLE VIII CONDUCT PRIOR TO CLOSING

8.1 Conduct of Business prior to Closing. Except as listed and described in Schedule 8.1, as otherwise expressly provided in this Agreement or as approved in writing by Hospital or Pluta (as the case may be), Hospital, PCCF and Pluta agree on behalf of itself that from the date hereof until the Closing:

(i) PCCF will prepare an amendment to its Certificate of Incorporation as provided in Exhibit 8.1(i) hereto in order to modify its purpose to benefit and support exclusively the Pluta Cancer Center in its capacity as an extension clinic of Strong Memorial Hospital of the University of Rochester, and shall obtain the approval of a Justice of the State Supreme Court, upon notice to the New York Attorney General, for the filing of such Amendment. In the event the New York State Department of Health requests any changes to PCCF's proposed Amendment to its Certificate of Incorporation, the Parties shall mutually agree upon any modifications to the amended Certificate of Incorporation.

(ii) PCCF shall amend its bylaws as provided in Exhibit 8.1(ii) hereto to be consistent with the amendment to its Certificate of Incorporation. The bylaws shall be further amended to modify the election of its officers and directors and to include a Hospital representative on the Board of the PCCF as a voting director, who shall be appointed at the sole discretion of Hospital; such appointment shall occur upon the Effective Date. Furthermore, the amended bylaws shall provide that the Director of the James P. Wilmot Cancer Center at the

University of Rochester Medical Center shall be invited to attend and be privileged to participate in all Board meetings, without vote. The amended bylaws shall be adopted and effective as of the Effective Date.

(iii) Pluta will ensure that it has an Extended Reporting Endorsement (also known as "Tail" coverage) to cover Claims or adverse medical incidents which occur prior to the Effective Date.

(iv) Each of the Parties will (i) carry on its business in substantially the same manner as heretofore carried on; and (ii) conduct its business in compliance with all material statutory and regulatory requirements of any federal, state, or local authority.

(v) Except as set forth herein, no Party will change its respective Charter, Certificate of Incorporation, or bylaws prior to the Closing.

(vi) Except as otherwise provided herein, Pluta will not without the prior written approval of Hospital (A) make any investment or loan; (B) make any capital expenditure in an amount in excess of \$50,000, or (C) enter into any contract in an amount in excess of \$50,000; (D) enter into any contract which would be assumed by the University.

(vii) Except as otherwise provided herein or in the Ordinary Course of Business or pursuant to existing contractual obligations, Pluta will not, without the express written consent of Hospital: (i) increase compensation payable or to become payable to any of its directors, trustees, officers or employees other than reasonable annual increases and market adjustments; (ii) enter into any new, or amend, or alter any existing bonus, incentive compensation, profit sharing, retirement, pension, group insurance, death benefit or other fringe benefit plan, trust agreement, or arrangement adopted by Pluta with respect to its employees; (iii) establish, adopt, enter into or amend any collective bargaining agreement; and (iv) except as may be required by applicable laws or Generally Accepted Accounting Principles, change its accounting methods, principles or practices in any Material respect. Notwithstanding the above, the Parties have agreed that Pluta may give its employees, excluding its CFO and CEO, a one-time merit bonus, provided that the total amount of such bonus shall not exceed \$65,370.

(viii) Other than the acquisition of the Optima CT580 RT-8 scanner (and all workstations, etc.), Pluta will not acquire or dispose of any asset, tangible or intangible, that would have a Material Adverse Effect on it or Hospital, other than in the Ordinary Course of Business or pursuant to its existing contractual obligations.

(ix) Other than in connection with the acquisition of the Optima CT580 RT-8 scanner (and all workstations, etc.), Pluta will not enter into or assume any indebtedness or any

mortgage, pledge, conditional sale or other title retention agreement that would have a Material Adverse Effect on it, nor shall it permit any liens, including any lien, encumbrance or charge of any kind to attach upon any of the Property, whether now owned or hereafter acquired that would have a Material Adverse Effect on it or Hospital, except in such Party's Ordinary Course of Business.

(x) Pluta shall use commercially reasonable efforts to maintain and keep its real and personal property in good order, subject to ordinary wear and tear.

(xi) Pluta will file a Closure Plan with the Department of Health at least 90 days prior to the Effective Date.

(xii) Pluta will secure approval under Sections 510 and 511 of the Not-for-Profit Corporation Law for the disposition by Pluta of substantially all of its assets to Hospital.

8.2 Certain Pre-closing Matters. During such times and in such manner as Hospital, PCCF or Pluta may reasonably request, Pluta, PCCF or Hospital will deliver such additional information relating to its businesses and properties as may be reasonably requested by the other Party.

8.3 Supplemental Disclosure. During the period between the date of this Agreement and the Closing, each Party shall have the continuing obligation to supplement any information contained herein with respect to any Material matter arising or discovered after the date hereof which, if existing or known on the date hereof, would have been required to be disclosed hereunder or would make any representation or warranty of the Party (to the extent required to be made as the Closing), untrue, incomplete or misleading; provided, however, that such disclosure shall not constitute a waiver or modification of the rights of the non-notifying Parties in respect thereof.

ARTICLE IX THE CLOSING

9.1 Closing. The Closing of the Acquisition contemplated by this Agreement, hereinafter referred to as the "Closing", shall be held at a mutually agreed upon time and place within two (2) days following the receipt of all of the approvals set forth under Article V of this Agreement or otherwise listed in Schedule 6.4 and 7.6 of this Agreement (other than confirmations of tax exemption. In the event Hospital or Pluta fail to obtain all of the necessary approvals and/or licenses required to consummate the Acquisition and to provide, without interruption, continuous medical care to Pluta's patients, the Closing shall be postponed until such approvals and/or licenses have been obtained.

9.2 Deliveries by Hospital: At the Closing, Hospital shall deliver or cause to be delivered to Pluta all of the following:

9.2.1 Copies of the resolution of the Board of Trustees of the University of Rochester authorizing the making, execution and delivery of this Agreement and consummation of the Acquisitions contemplated hereby, certified by the Secretary of the University.

9.2.2 All regulatory consents and approvals specified in Schedule 6.4 hereto (other than confirmations of tax exemptions).

9.2.3 Certificates, dated the date of the Closing, signed by the Chief Executive Officer of Hospital, stating that: (i) the representations and warranties of Hospital contained herein are true and correct in all material respects on and as of the date of the Closing with the same effect as if made on the date of the Closing; and (ii) Hospital has complied with all agreements and satisfied all of the conditions on its part to be performed or satisfied at or prior to the date of the Closing.

9.2.4. The name of the individual(s) nominated by Hospital to serve on the governing board of PCCF as voting director(s), and the name of the individual(s) who may attend and vote in place of the University's primary representative.

9.2.5 A release of Pluta from its bank debt obligation to Key Bank in form and substance mutually acceptable to the Hospital and Pluta. The Parties agree that Hospital's obligation shall be contingent upon Pluta's assistance and cooperation in securing such release.

9.2.6 An Assumption of Pluta's Lease on its Leased Premises substantially in the form provided in Exhibit 2.2.1 hereof.

9.2.7 An Assignment and Assumption of the Assumed Contracts and Assumed Liabilities, as provided in Exhibit 9.2.7.

9.2.8 Evidence reasonably satisfactory to Pluta and PCCF that Hospital has obtained the Certificate of Need described in Section 5.4.2 hereof.

9.3 Deliveries by Pluta and PCCF: At the Closing, Pluta and PCCF shall deliver or cause to be delivered to Hospital all of the following:

9.3.1 Copies of the resolutions of the governing boards of Pluta and PCCF authorizing the making, execution and delivery of this Agreement and the consummation of the Acquisition contemplated hereby, including the adoption of the Amended and Restated Bylaws and the adoption of the Amended PCCF Certificate of Incorporation, all certified by the Secretaries of Pluta and PCCF, and in form and substance satisfactory to Hospital and its counsel.

9.3.2 Amended and Restated Bylaws of PCCF incorporating the provisions described in this Agreement, in form and substance satisfactory to Hospital and its counsel. The Bylaws of PCCF shall be amended as set forth in Exhibit 9.3.3 hereto.

9.3.3 A proposed Certificate of Amendment of the Certificate of Incorporation of PCCF as set forth in Exhibit 8.1(i) hereto, with the approval of a Justice of the State Supreme Court to filing annexed thereto.

9.3.4 A copy of Pluta's Plan of Plan of Dissolution, approved by its board.

9.3.5 Certificates, dated the Effective Date, signed by the Chief Executive Officers of Pluta and PCCF stating that: (i) the representations and warranties contained herein are true and correct in all Material respects on and as of the date of the Closing with the same effect as if made on and as of the date of the Closing; and (ii) each has complied with all agreements and satisfied all of the conditions on its part to be performed or satisfied at or prior to the date of the Closing.

9.3.6 To the extent they have not previously been delivered by Pluta: (i) possession of the Purchased Assets; (ii) a Bill of Sale and Assignment therefore, as set forth in Exhibit 9.3.6 attached hereto; (iii) such other instruments of transfer, in such form as shall be reasonably necessary or appropriate to vest in Hospital good and valid title to the Purchased Assets; (iv) physical possession of Pluta's Patient medical records; (v) a record of Pluta's Patients which includes their addresses; and (vi) evidence of the insurance coverage required under Section 8.1(iv).

9.3.7 A copy of the New York State Department of Health's approval of Pluta's Closure Plan. All regulatory consents and approvals specified in Schedule 7.6 hereto (other than confirmations of tax exemption).

9.3.9 A copy of an Order of the State Supreme Court approving the Disposition of Substantially All of Pluta's Assets pursuant to Sections 510 and 511 of the Not-for-Profit Corporation Law.

9.3.10 The names of the individuals nominated by PCCF to serve on the advisory board of JPWCC.

9.3.11 The Interim Balance Sheet described in Section 3.5 hereof.

9.4 Conditions Precedent to the Closing. The obligations of each Party to effect the Acquisitions contemplated at the Closing shall be subject to the following conditions precedent:

9.4.1 In the case of Pluta and PCCF, to the condition that the representations and warranties of Hospital as contained in Article VI shall be true, complete and correct in all Material respects as of the date of the Closing. In the case of Hospital, to the condition that the representations and warranties of Pluta and PCCF contained in Article VII shall be true, complete and correct in all Material respects as of the date of the Closing.

9.4.2 All required corporate approvals pursuant to Section 5.1 have been received.

9.4.3 The approvals described in Sections 6.4 and 7.6 and Article V (other than confirmation of tax exemptions) have been received.

9.4.4 All covenants and agreements required hereunder have been complied with and performed by the Parties.

9.4.5 All opinions, consents, approvals, and other instruments described in Sections 9.2 and 9.3 have been delivered or received.

**ARTICLE X
FOUNDATION SUPPORT AFTER ACQUISITION
AND HOSPITAL SUPPORT OF PLUTA DISSOLUTION**

10.1 PCCF Support of Operations. After Hospital establishes an extension clinic at the current location of the Pluta Cancer Center and the Acquisition is completed, PCCF will provide financial support to the cancer programs and services offered there as an extension clinic of Hospital. Current funds and any funds raised by PCCF after the Effective Date shall be used solely for the benefit of Hospital's extension clinic and its patients. For nine (9) months after the Effective Date, PCCF will reimburse Hospital for ten percent (10%) of the salary and benefits of the prior President and Chief Executive Officer of Pluta, who, as a Hospital employee, will support PCCF's activities and will act as a liaison between Hospital and PCCF; provided, however, that such support shall continue for an additional three (3) months if such employee continues to act as a liaison between Hospital and PCCF and continues to support PCCF's

activities. PCCF shall also reimburse Hospital for fifteen percent (15%) of the salary and benefits of the prior Chief Financial Officer of Pluta, who shall continue to provide financial services to PCCF and shall oversee the termination of Pluta's 401(k) Plan and the dissolution of Pluta; PCCF's reimbursement shall continue as long as services are provided to PCCF and/or Pluta but the amount of PCCF's reimbursement may be reduced if the amount of the services are reduced. PCCF will also reimburse the Hospital for one hundred percent (100%) of the salary and benefits paid to the previous Director of Development of Pluta and seventy-five percent (75%) of the salary and benefits paid to the previous Development Coordinator of Pluta, who will continue to provide services to the Foundation. Such services may include activities related to PCCF's Emerald Ball and other fundraising events (such as the Tree of Hope, Fashion Show, the Annual Fund Drive, etc.), direct mailings on behalf of the Foundation, maintaining PCCF's fundraising database system, maintaining its donor base, etc. PCCF agrees that it will coordinate its fund raising efforts, including solicitation of its major donors, with Hospital in order to maximize philanthropic support for all Parties. In all other respects, the conduct of PCCF activities, including compliance with laws, shall be the responsibility of the PCCF governing board. Within five (5) days after the Effective Date, PCCF shall file its Certificate of Amendment of the Certificate of Incorporation of PCCF with the New York State Department of State and shall provide Hospital with a copy of such filing, including a copy of the filing receipt.

10.2 Hospital Support of Pluta Dissolution. In order to facilitate the dissolution of Pluta, the Hospital shall provide, for a reasonable period following the Effective Date, office space at Pluta's current location, equipment (including phones, computers and photocopiers), and administrative services, including the services of former employees of Pluta who are familiar with Pluta's operations. Upon mutual agreement among Hospital, Pluta and PCCF, PCCF will, in addition to the reimbursement for the services of former employees of Pluta as provided in Section 10.1 hereof, reimburse Hospital for such support, including a portion of the salary and benefits paid to previous employees of Pluta, who continue to provide services to Pluta in connection with its dissolution.

ARTICLE XI MEDICAL RECORDS, CONTINUATION OF CARE

11.1 Medical Records. Upon the Effective Date, Pluta shall transfer ownership of the Patient medical records to Hospital for safekeeping purposes and for continuation of care of Patients that elect to be treated by Hospital. Hospital shall retain Pluta's Patient medical records for the length of time required by law. In the event that a Patient or other appropriate person under state and federal law (including, without limitation, a parent or guardian of an infant, a guardian, committee for an incompetent, a conservator, or other person pursuant to court order) requests that a copy of a Patient's medical record be provided, Hospital shall forward a copy of the Patient's record, provided, however, that in all instances Hospital shall comply with all

provisions of law, state and federal, with respect to the confidentiality of records and release of information by Hospital, including without limitation, the applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, Title II, Subtitle F, and regulations from time to time promulgated thereunder ("HIPAA").

11.2 Continuation of Services. Hospital shall use its best efforts to continue, under the name "Pluta Cancer Center" or words of similar import, the programs and philosophy of care previously offered by Pluta, including its commitment to provide a family atmosphere for both patients and staff that treats patients with leading-edge technology and with the empathy, kindness and thoughtfulness you would expect from family, subject to appropriate modifications. Hospital shall offer continuous medical services to Pluta's former patients on and after the Effective Date. Pluta shall cooperate fully, and shall take all reasonable actions requested by Hospital, to assist in an orderly transition of the Patients from Pluta to Hospital.

11.3 Lease of Existing Premises. Hospital shall extend or renew Pluta's current lease on the premises located at 125 Red Creek Drive, Rochester, New York, 14623 for a period of not less than five years after the expiration of its current term. Hospital shall use such location throughout such renewal or extension period as the primary location of the programs and services described in Section 11.2 hereof.

11.4 Credentialing of Medical Staff. Subject to its credentialing process and board approval, the Hospital shall expeditiously credential all current Pluta medical staff members and, as promptly and seamlessly possible, transition such medical staff to the Hospital Staff on the Effective Date or as quickly thereafter as reasonably practicable.

11.5 Extension of EMR, Identity, Signage. As quickly as reasonably practicable after the Effective Date, Hospital shall implement its electronic medical record system at the Pluta location. Effective on the Effective Date, Hospital shall register, schedule and issue patient bills in such manner as clearly identifies Pluta Cancer Center, and describes Pluta Cancer Center as an extension clinic of the Hospital. As quickly as reasonably practicable, Hospital shall erect and install appropriate signage for the Pluta location which clearly identifies such location as the Pluta Cancer Center, and describes Pluta Cancer Center as an extension clinic of the Hospital.

ARTICLE XII EMPLOYEES

At or around the Closing, Hospital will offer employment to the then-existing employees of Pluta, provided that such employees have completed employment applications and fulfilled all of Hospital's employment criteria prior to the Effective Date. Hospital's offer of employment shall be at compensation levels and on other terms satisfactory to Hospital in Hospital's sole

discretion. Hospital retains whatever rights it may have to terminate any employee who accepts Hospital's offer of employment or to vary the terms of his or her employment. All employees shall be subject to the personnel policies of Hospital. Subject to Hospital's credentialing process and board approval, Hospital will credential all Pluta medical staff members and transition them to Hospital medical staff. Pluta shall use its best efforts to facilitate acceptance of Hospital's offer of employment by those employees of Pluta to whom Hospital makes such offer. Nothing in this Article is intended to create a private right of action in any existing employees of Pluta or any other person; it is a good faith expression of the Parties with respect to employment matters.

ARTICLE XIII

OVERSIGHT COMMITTEE; JAMES P. WILMOT CANCER CENTER ADVISORY BOARD

13.1 Oversight Committee. Hospital shall establish a committee ("Oversight Committee") to provide non-binding advice, oversight of operations and influence regarding future direction of services provided at Pluta's current site. The Oversight Committee shall include four (4) individuals appointed by the PCCF Board of Directors and four (4) members of University's senior administrators. The Oversight Committee shall receive presentations from the Director of the James P. Wilmot Cancer Center Advisory Board ("JPWCC"), initially on at least a quarterly basis; more frequent presentations will be presented if warranted.

13.2 James P. Wilmot Cancer Center Board. Upon the Effective Date, Hospital shall invite four (4) representatives of Pluta's current Board to become members of the James P. Wilmot Cancer Center Advisory Board. Hospital shall also amend the bylaws of the James P. Wilmot Cancer Center Advisory Board to include four (4) representatives of PCCF on the James P. Wilmot Cancer Center Advisory Board as voting directors, who shall be appointed at the sole discretion of PCCF. The amended bylaws shall be adopted and effective as of the Effective Date.

ARTICLE XIV

CONFIDENTIALITY/ANNOUNCEMENTS

The Parties agree that the contents of this Agreement and the nature of the status of the transactions and related matters described herein are confidential. The Parties shall retain in strictest confidence, except as and to the extent that such Party is obligated by law or required to consummate the transactions contemplated herein, and shall not use in competition with or in a manner otherwise detrimental to the interests of the other Parties, any confidential information, including, without limitation, information with respect to any of the Party's services, finances, processes, customers, clients, patients, or marketing plans or techniques; provided, however, that confidential information shall not include any information known generally to the public (other than as a result of unauthorized disclosure by a Party). The timing and the content of any

announcements concerning the Effective Date will occur upon, and be determined in advance by, mutual agreement and consent of the Parties. After the Effective Date, Pluta's former Director of Communications and Marketing will collaborate with the Hospital's Public Relations Department on public announcements regarding the extension clinic and programs offered there.

ARTICLE XV MISCELLANEOUS

15.1 Entire Agreement; Amendments. This Agreement, with the Exhibits and Schedules hereto, constitutes the entire understanding among the Parties hereto with respect to the subject matter contained herein and supersedes any prior understandings and agreements among them respecting such subject matter. This Agreement may be amended, supplemented, and terminated only by a written instrument duly executed by the Parties.

15.2 Section Headings. The section headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement.

15.3 Construction. The language used in this Agreement will be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Party. Any reference to any applicable law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. Whenever required by the context, any gender shall include any other gender, the singular shall include the plural and the plural shall include the singular. The words "herein", "hereof", "hereunder", and words of similar import refer to this Agreement as a whole and not to a particular section. Whenever the word "including" is used in this Agreement, it shall be deemed to mean "including, without limitation," "including, but not limited to," or other words of similar import such that the items following the word "including" shall be deemed to be a list by way of illustration only and shall not be deemed to be an exhaustive list of applicable items in the context thereof. Whenever the word "or" is used in this Agreement, it shall be deemed to be used in the conjunctive unless the context otherwise requires. Any reference in this Agreement to an Article, Section, Schedule or Exhibit are references to Articles, Sections, Schedules or Exhibits of this Agreement, unless the context otherwise requires. References to any "person" shall include references to such person and his or her respective successors and permitted assigns.

15.4 Severability. If any term or provision of this Agreement is held illegal, invalid, or unenforceable, such illegality, invalidity, or unenforceability will not, provided it is not so fundamental as to frustrate the basic expectations of any Party to this Agreement, affect any

other provision hereof, and this Agreement shall, in such circumstances, be deemed modified to the extent necessary to render enforceable the provisions thereof.

15.5 Expenses of Brokers, etc. No Party has employed any broker, finder or agent in connection with the Acquisition contemplated hereby.

15.6 Cooperation. Following the Closing, the Parties shall in good faith cooperate with each other so as to effectuate the purpose for which the Agreement was entered into and thereby advance the charitable purposes of the Parties. Each Party shall take such further actions and execute and deliver from time to time such further documents, instruments of assignment, conveyance and transfer, and shall take such other actions as may reasonably be required to accomplish the orderly transfer all of the assets, programs, personnel, records and operations of Pluta to the Hospital as contemplated by this Agreement.

15.7 Fraud and Abuse. The Parties agree that the benefits to each other hereunder do not require, are not payment for, and are not in any contingent upon the admission or referral of patients or any other arrangement for the provision of any item or service. The Parties intend and, in good faith believe, this Agreement complies with all applicable federal and state laws, regulations and proposed regulations governing Medicare and Medicaid fraud and abuse ("Medicare/Medicaid Laws"). Should any provision of this Agreement be deemed contrary to the Medicare/Medicaid Laws, then the Parties agree in good faith to renegotiate such provision to the mutual satisfaction of the Parties.

15.8 Changes in Law. In the event there are changes to or clarifications of federal, state or local statutes, regulations, or rules which would materially affect the operation of any Party, the Parties agree to examine this Agreement and to renegotiate any applicable provisions to accommodate the changes in law.

15.9 Notices. All notices and other communications hereunder shall be in writing and shall be deemed given to the person upon receipt if: (i) delivered personally; (ii) sent by facsimile with facsimile written receipt; (iii) sent by registered or express mail, postage prepaid; or (iv) sent by reputable courier services, charges prepaid to such party's address:

If to Strong Memorial Hospital:
Strong Memorial Hospital
601 Elmwood Avenue
Rochester, New York 14642
Attn: Steven I. Goldstein, CEO

With a copy to:
Office of Counsel to the Medical Center

University of Rochester
P.O. Box 278979
Rochester, New York 14627
Attn: Medical Center Counsel

If to Pluta:

Pluta Cancer Center
125 Red Creek Drive
Rochester, New York 14623
Attn: Kelly McCormick-Sullivan

If to PCCF:

Pluta Cancer Center Foundation, Inc.
200 Red Creek Drive, Suite 200
Rochester, New York 14623
Attn: Ronald Pluta, Board Chair

With a copy to:

George G. Mackey
Hiscock & Barclay, LLP
2000 HSBC Plaza
100 Chestnut Street
Rochester, NY 14604

or to such other address or telecopy number as any of the foregoing may have designated for that purpose by notice to the others.

15.10 Waiver. The failure by any Party to exercise any right under, or to object to the breach by any other Party of any term, provision or condition of this Agreement shall not constitute a waiver thereof and shall not preclude such Party from thereafter exercising that or any other right, or from thereafter objecting to that or any prior or subsequent breach of the same or any other term, provision or condition of the Agreement.

15.11 Governing Law. This Agreement, including any dispute or controversy arising out of or related to this Agreement or the breach thereof, shall be subject to, governed by, and construed in accordance with, the substantive and procedural laws of the State of New York.

15.12 Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original, but such counterparts shall together constitute one and the same Agreement.

15.13 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of each of the Parties hereto and their respective successors and assigns, provided,

however, that no Party may assign this Agreement or any rights herein or obligations without the prior written consent of other Parties, and any attempted assignment without such consent shall be void.

15.14 Survival of Agreement. The obligations set forth in Articles X, XI, XII, XIII, and Sections 15.6, and 15.7 shall survive the Closing.

IN WITNESS WHEREOF, this Agreement has been executed as of the date hereinabove set forth.

PLUTA CANCER CENTER INC.

By: Kelly M' McCormick-Sullivan
Kelly McCormick-Sullivan,
President/CEO

PLUTA CANCER CENTER FOUNDATION, INC.

By: Ron Pluta
Ron Pluta,
Chairman

STRONG MEMORIAL HOSPITAL,
A DIVISION OF
THE UNIVERSITY OF ROCHESTER

By: _____
Bradford C. Berk, M.D., Ph.D,
CEO, University of Rochester Medical Center
Senior Vice President for Health Sciences

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IN WITNESS WHEREOF, this Agreement has been executed as of the date hereinabove set forth.

PLUTA CANCER CENTER INC.

By: _____
Kelly McCormick-Sullivan,
President/ CEO

PLUTA CANCER CENTER FOUNDATION, INC.

By: _____
Ron Pluta,
Chairman

STRONG MEMORIAL HOSPITAL,
A DIVISION OF
THE UNIVERSITY OF ROCHESTER

By: BBerk
Bradford C. Berk, M.D., Ph.D,
CEO, University of Rochester Medical Center
Senior Vice President for Health Sciences

Bradford C. Berk, MD, PhD
CEO, University of Rochester Medical Center
University Senior Vice President for Health Sciences



UNIVERSITY of
ROCHESTER
MEDICAL CENTER

December 28, 2012

MEDICINE of THE HIGHEST ORDER

Ronald A. Pluta
Pluta Cancer Center Foundation
200 Red Creek Drive
Rochester, New York 14623

Jamie Bishop
Pluta Cancer Center
125 Red Creek Drive
Rochester, New York 14623

Dear Messrs. Bishop and Pluta,

This letter will set forth our legally binding agreement to modify the Acquisition Agreement entered into by the Pluta Cancer Center, Inc., the Pluta Cancer Center Foundation, Inc., and the University of Rochester, on behalf of Strong Memorial Hospital, dated October 18, 2012.

The parties have agreed that there will be a pre-closing on December 21, 2012 at 10:00 a.m. in order to accommodate those who wish to be away for the holiday season. The Effective Date for the Acquisition Agreement remains December 28, 2012. All of the documents, except for the Promissory Note and the Assignment and Assumption of the Promissory Note and the Assumed Liabilities, will be held in escrow, by each party, until December 28, 2012. The Promissory Note and the Assignment and Assumption of the Promissory Note and the Assumed Liabilities will be held in escrow by the University of Rochester until the conditions listed below have been fulfilled. The Promissory Note and the Assignment and Assumption of the Promissory Note and the Assumed Liabilities shall be released from escrow upon: (i) receipt of all governmental approvals, including the approval of the New York State Public Health Council, to amend the Foundation's Certificate of Incorporation in accordance with Section 8.1(i) and the form provided in Exhibit 8.1(i) of the Acquisition Agreement; (ii) filing of the Restated Certificate of Incorporation, dated November 8, 2012, by the New York Secretary of State; and (iii) delivery to the University of evidence satisfactory to the University that the above conditions have been met.

The parties have agreed that the Foundation will have additional time to obtain all of the approvals required to amend its Certificate of Incorporation. The Acquisition Agreement is hereby amended to the extent necessary to provide that the Foundation shall meet the obligations set forth in Section 8.1 (i) of the Acquisition Agreement by April 30, 2013. The Foundation will not have to obtain such approvals prior to Closing and evidence of such approvals shall not be a deliverable at the Closing. Section 10.1 is hereby amended to the extent necessary to provide that the Foundation shall have until April 30, 2013 to ensure

that the New York Secretary of State files the Foundation's Restated Certificate of Incorporation, dated November 8, 2012, and to provide the University with a copy of such filing.

The parties have agreed that the Foundation may further amend its By-Laws, to provide that the Amended and Restated By-Laws shall become effective as of the date that the Corporation's Restated Certificate of Incorporation, dated November 8, 2012, is filed by the New York Secretary of State. Notwithstanding the delay in the effective date of the Amended and Restated By-Laws of the Pluta Foundation, the parties have agreed that the Foundation's Board will invite one (1) University representative to become a voting Director on the Foundation's Board, effective December 28, 2012. Furthermore, the current Director of the James P. Wilmot Cancer Center at the University of Rochester shall have observer rights as previously agreed to by the parties, effective December 28, 2012.

The parties have agreed that the Acquisition Agreement shall be modified to the extent necessary to provide that the University shall not assume the Foundation loan until the New York Secretary of State files the Foundation's Restated Certificate of Incorporation, dated November 8, 2012.

The parties have acknowledged that the Foundation's covenant to: (i) amend its Certificate of Incorporation; (ii) obtain all necessary approvals; (iii) ensure that the New York Secretary of State files the Restated Certificate of Incorporation, dated November 8, 2012; (iv) adopt and amend its By-Laws; and (v) provide financial support to the extension clinic established at Pluta's current location, all in accordance with the terms and conditions of the Acquisition Agreement, was and continues to be a material inducement for the University to enter into the Acquisition Agreement, and specifically to assume the Foundation loan. The Foundation shall ensure that its Restated Certificate of Incorporation, dated November 8, 2012, is filed by the New York Secretary of State no later than April 30, 2013.

The amount of the Promissory Note and the amount of the Foundation loan shall be determined in accordance with the procedure set forth in Section 3.5 of the Acquisition Agreement.

The parties have agreed that Exhibit 9.3.5 (the Officer's Certificate) for the Pluta Cancer Center will not be modified. Exhibit 9.3.5 (the Officer's Certificate) for the Pluta Cancer Center Foundation will be modified to the extent necessary to provide that the Foundation will have until April 30, 2013 to obtain all necessary approvals and to ensure that the New York Secretary of State files its Restated Certificate of Incorporation, dated November 8, 2012. All representations and warranties of the Foundation set forth in Article VII of the Acquisition Agreement remain the same. All other covenants and obligations will remain the same.

The parties have agreed that the liability associated with the Flexible Spending Account ("FSA") will not be paid prior to the Effective Date. This liability will remain on Pluta's Balance Sheet, but will be paid directly by the Pluta Cancer Center, Inc. or the Pluta Cancer Center Foundation, Inc. The University will not pay this liability directly.

The parties have agreed that the capital lease obligation with Key Bank will be satisfied on December 28, 2012. It will not be satisfied at the pre-closing, scheduled for December 21, 2012.

The parties have agreed that in lieu of a list of all of the patient medical records, the parties will execute an acknowledgment that the Pluta Cancer Center has transferred, and the University has accepted, physical possession and ownership of all of the patient records physically located at the Pluta Cancer Center, 125 Red Creek Drive, Henrietta, New York on December 28, 2012.

This agreement may be executed in several counterparts, each of which shall be deemed an original, but such counterparts shall together constitute one and the same Agreement. All other terms and conditions of the Acquisition Agreement shall remain the same.

If you are in agreement with the terms and conditions set forth above, please sign and return one (1) copy to me. We are very excited about the transition of the Pluta Cancer Center to the University and we look forward to many years of collaboration with the Pluta Cancer Center Foundation. We enthusiastically welcome the Pluta family to our University.

Sincerely,

By: Brad Berk

Bradford C. Berk, M.D., Ph.D,
CEO, University of Rochester Medical Center
University Senior Vice President for Health Sciences

Agreed and accepted by:

PLUTA CANCER CENTER INC.

By: Jamie Bishop
Jamie Bishop
Chief Financial Officer

Date: 12/21/12

PLUTA CANCER CENTER FOUNDATION, INC.

By: Ronald A. Pluta
Ronald A. Pluta
President

Date: 12/21/12



RE: Establishment of an Art. 28 Foundation [DMS-ACTIVE.FID3493]

McCabe, Raymond N.

to:

Kendra C Jenkins

01/07/2013 11:32 AM

Cc:

"KMccormick-Sullivan@plutacancercenter.org", Jamie Bishop, "PLUTAFAM@aol.com", "Mackey, George G.", "Zambri, Melissa M."

Hide Details

From: "McCabe, Raymond N." <RMcCabe@hblaw.com> Sort List...

To: Kendra C Jenkins <kcj02@health.state.ny.us>,

Cc: "KMccormick-Sullivan@plutacancercenter.org" <KMccormick-Sullivan@plutacancercenter.org>, Jamie Bishop <JBishop@plutacancercenter.org>, "PLUTAFAM@aol.com" <PLUTAFAM@aol.com>, "Mackey, George G." <GMackey@hblaw.com>, "Zambri, Melissa M." <MZambri@hblaw.com>

Security:

To ensure privacy, images from remote sites were prevented from downloading. Show Images

Kendra,

I left you a voice mail this morning regarding the above matter. We are concerned about the timing of this approval. We had submitted the proposed Restated Certificate to your office on November 8 in the hopes that it could be considered by the PHC at its December meeting. When that did not happen, the Pluta Cancer Center and the University of Rochester went ahead with the scheduled closing of its transfer of assets on December 28. As a result, the University now operates the Pluta Cancer Center facility. The parties closed the transaction with the expectation that the Restated Certificate would be recommended for approval by the appropriate PHC committee at its January 17 meeting and approved by the full PHC at its February meeting. We are advised by Colleen Frost at the PHC that, in order to be included in the mailing to the committee, she must have the recommendation of Legal Affairs by Wednesday, January 9.

We have provided all of the information called for in your checklist with the exception of information relating to the "initial" directors, which we provide in this e-mail. Please note that the Foundation was formed in 2009, and in connection with therewith, the Foundation has already provided information relating to the initial directors of the Foundation. Those initial directors continue to serve as directors of the Foundation. Below, we update that information and provide information regarding the Foundation's other directors.

Initial Directors (still in office):

- Ronald A. Pluta, resides at 2990 East Avenue, Rochester, New York 14610. Mr. Pluta is the Managing Member of Calkins Corporate Park, LLC, 200 Red Creek Drive, 14623. Mr. Pluta a founding director of the Pluta Cancer Center Foundation and the Pluta Cancer Center.
- Mary K. Pluta, resides at 2990 East Avenue, Rochester, New York 14610. She is a community volunteer. Mrs. Pluta is a founding director of the Pluta Cancer Center Foundation and the Pluta Cancer Center.
- Barbara Pluta-Randall, resides at 15 Lake LaComa Drive, Pittsford, New York 14534. Ms. Pluta-Randall is employed part-time as a registered nurse and instructor at the Highlands at Pittsford (a senior living facility), 500 Hahnemann Trail, Pittsford, NY 14534. She is a founding director of the

Foundation and a founding director of the Pluta Cancer Center.

Other Directors:

- William Strassburg, is the Vice President, Strategic Planning for Wegman's Food Markets, 1500 Brooks Ave., Rochester, NY 14624. He resides t 96 N. Country Club Lane, Rochester, NY 14618. In addition to serving as a director of the Foundation, Mr. Strassburg is chair of the Children's Success Fund, Vice Chair of the Tournament Owners Association LPGA, Secretary of the Oak Hill Country Club and a director of the Seneca Zoo Society and Center for Governmental Research.

- Douglas Emblidge is a news anchor at WHAM television, Channel 13 in Rochester, 4225 West Henrietta Road, Rochester, NY 14623. He resides at 5547 Lakewood Drive, Canandaigua, NY 14623. In addition to serving as a director of the Foundation, Mr. Emblidge is a director of Daystar, and the New York Wine and Culinary Center Foundation.

- Steve McCluski was senior vice president and chief financial officer of Bausch & Lomb until his retirement in 2007. He resides at 10 Grandhill Way, Pittsford, NY 14534. In addition to serving as a director of the Foundation, Mr. McCluski is a director of the Ithaca College Board of Trustees, Daystar for Medically Fragile Children, and the James P. Wilmot Cancer Center Advisory Board. He is also President of the Monroe Golf Club. Mr. McCluski is the University's appointee to the Foundation Board.

Please call me at your earliest convenience if you need anything further.

Thank you again for your consideration.

Ray

Raymond N. McCabe
Partner

 Hiscock

1100 M&T Center • 3 Fountain Plaza • Buffalo, NY 14203
D: (716) 566-1408 • F: (716) 566-4013 • E: RMcCabe@hblaw.com

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Federal Tax Disclosure and Confidentiality Notice:

In accordance with IRS requirements, we inform you that any Federal tax advice contained in this communication is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

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From: McCabe, Raymond N.
Sent: Friday, January 04, 2013 2:10 PM
To: 'Kendra C Jenkins'
Cc: 'KMcCormick-Sullivan@plutacancercenter.org'; 'Jamie Bishop'; 'PLUTAFAM@aol.com'; Mackey, George G.; Zambri, Melissa M.
Subject: RE: Establishment of an Art. 28 Foundation [DMS-ACTIVE.FID3493]

Kendra,

Please refer to my e-mail to you of earlier this afternoon (reproduced below). I advised in that e-mail that I would address items contained in the Department's "Establishment of an Article 28 Foundation" checklist by separate email. I note that the proposed action involves changing the purposes of an existing Article 28 foundation and not the establishment of a new foundation. Our responses to the checklist below reflect this distinction.

1. The Checklist requests a copy of the proposed Certificate of Incorporation. A copy of the proposed Restated Certificate of incorporation was attached to my prior e-mail.
 - 1(a). The Checklist asks whether the certificate specifically identifies the Article 28 beneficiary. The Article 28 beneficiary is identified in Section 3(a) of the proposed Restated Certificate;
 - 1(b). The Checklist asks whether the certificate includes certain language to the effect that the nothing contained in the certificate authorizes the foundation to provide services described in Articles 28, 36, 40 and 44 of the Public Health Law. This language is contained in Section 9 of the Restated Certificate.
2. The Checklist requests a copy of the proposed Bylaws of the foundation. A copy of the currently effective Bylaws of the Pluta Cancer Center Foundation are attached to this e-mail.
3. The Checklist request a letter from the intended beneficiary acknowledging that it will accept the funds raised by the Foundation. Our prior e-mail included a copy of the agreement among the Pluta Cancer Center Foundation, the University of Rochester and the Pluta Cancer Center obligating the Foundation to amend its certificate of incorporation to provide for support of the operations of the University in connection with the Cancer Center's facility and to provide continuing support to those operations. Our prior e-mail also included a copy of a letter agreement from the University and the Pluta Cancer Center Foundation granting to the Foundation additional time to obtain PHC approval of the change.
4. The Checklist requests a generalized description of the fundraising activities to be undertaken by the foundation. The Foundation conducts fundraising events, including an annual gala, a fashion show and a golf tournament. The Foundation also solicits donations for contributions from certain members of the community identified by the Pluta Cancer Center Foundation's board.
5. The checklist asks for certain information regarding the foundations "initial" board of directors. Short biographies of the current directors of the Pluta Cancer Center Foundation will be provided separately.

6. The checklist asks for identification of the organizational relationship between the foundation and the Article 28 Beneficiary. Because the University operates the Wilmot Cancer Center in addition to taking over the Pluta Cancer Center, the Pluta Cancer Center Foundation and the University have cross-representation on the Wilmot Cancer Center and Pluta Cancer Center boards. The University designates one member of the Foundation's Board of directors, and the President of Strong Memorial Hospital is invited to attend each meeting of the Foundation (personally, or by designee). The Foundation board designates four members of the Advisory Board of the Wilmot Cancer Center. In addition, the Foundation and the University each appoint four members of a Pluta Cancer Center Oversight Committee, which oversees the operations of facility previously operated by Pluta Cancer Center, Inc. which has been taken over by the University.

7. The checklist asks for a list of any entities which control or are controlled by the foundation and the nature of such relationships. The Pluta Cancer Center Foundation is not controlled by, and does not control, any other entity.

As I noted in our conversations and my prior e-mail, it is critically important to the Foundation and the University that the proposed Restated Certificate of Incorporation be approved at the January committee meeting and full PHC meeting scheduled for February 17. Please feel free to call if you have any questions or concerns which might cause this request not to be included on agenda for the PHC's January committee meeting and February Council meeting.

Thank you again for your consideration.

Ray

From: McCabe, Raymond N.
Sent: Friday, January 04, 2013 12:34 PM
To: 'Kendra C Jenkins'
Cc: KMCCormick-Sullivan@plutacancercenter.org; Jamie Bishop; 'PLUTAFAM@aol.com'; Mackey, George G.; Zambri, Melissa M.
Subject: RE: Establishment of an Art. 28 Foundation [DMS-ACTIVE.FID3493]

Kendra,

Thank you for taking the time to speak with me this morning and for sending the checklist. As we discussed, attached is the Proposed Restated Certificate of Incorporation to the Foundation's Certificate of Incorporation, which would change the corporation's purposes from supporting the Pluta Cancer Center, Inc. to supporting the University of Rochester.

With respect to your request for a letter from the University, I think that your request is covered by the attached Acquisition Agreement among the Foundation, the Pluta Cancer Center and U or R (on behalf of Strong Memorial Hospital) (the "Agreement"). That Agreement provides that, not only will the U or R accept the funds, the proposed Restated Certificate of Incorporation is an essential element of the deal among the parties. The proposed Restatement is part of a larger transaction under which Pluta Cancer Center has transferred all of its operating assets to Strong Memorial Hospital (an unincorporated division of the U or R), the University has assumed all of the Cancer Center's obligations, and the Foundation has agreed to continue its support the Cancer Center's operations, as conducted by the University. A copy of the Agreement is attached. I respectfully direct your attention to Section 8.1 in which the parties agree that the Foundation will change its purposes to supporting the cancer programs

of the U of R at the site previously controlled by Pluta Cancer Center, and Section 10.1 which obligates the Foundation to provide that support. This Agreement was signed by an authorized officer of the University as well as an officer of the Foundation and the Cancer Center. The Department has approved a closure plan for the Pluta Cancer Center and has issued a Certificate of Need to the U of R with respect to the Cancer Center facility.

The Agreement contemplated that the Foundation would have secured PHC approval of the Amendment prior to the scheduled closing date of December 28, 2012. Pursuant to a letter agreement signed by the U of R, the Foundation and the Cancer Center at closing, the parties closed the transaction on December 28, 2012, with the understanding that the Foundation would secure approval of the attached Amendment promptly after the closing and would cause it to be filed by the Secretary of State. A copy of that letter is also attached. Currently, the U of R operates the facility previously operated by Pluta Cancer Center, Inc. The Pluta Cancer Center, Inc. is currently inactive and is in the process of winding up its affairs.

Your e-mail attached a checklist of items to be provided with respect to the Establishment of an Article 28 Foundation. I will address those items in a separate e-mail.

I hope that the attached, and the e-mail to follow are sufficient for your office to recommend approval of the proposed amendment at the PHC committee meeting scheduled for January 17 and the meeting of the full Council on February 7. If this information is not sufficient, please let me know as quickly as possible.

Thank you for your prompt consideration.

Ray

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, on this 7th day of February, 2013, approves the filing of the Restated Certificate of Incorporation of Pluta Cancer Center Foundation, Inc. dated November 8, 2012.

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services – Northeast Westchester
Address: Brewster
County: Putnam
Structure: For-Profit Corporation
Application Number: 2061-L

Description of Project:

ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services – Northeast Westchester, a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The applicant has authorized 1,500 shares of stock, which are owned as follows:

ADG Health Care Holdings Inc. Profit Sharing Plan – 1,500 shares

The trustees of ADG Health Care Holdings Inc. Profit Sharing Plan comprise the following individuals:

Anthony F. Guarna – Member President, ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services – NE Westchester (Non Medical Companion Care)	Deborah J. Cooper-Guarna – Member Compliance Manager, Interactive Data Corporation
	Affiliation: <ul style="list-style-type: none">• Board Member, ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services – NE Westchester (Non Medical Companion Care)

The Board of Directors of ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services – Northeast Westchester comprises the following individuals:

Anthony F. Guarna – Member (Previously Disclosed)	Deborah J. Cooper-Guarna – Member (Previously Disclosed)
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A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 16 Mt Ebo Road South, STE 14a, Brewster, New York 10509.

Westchester	Putnam	Dutchess	Orange
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The applicant proposes to provide the following health care services:

Nursing Housekeeper	Personal Care	Home Health Aide	Homemaker
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Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: January 7, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: A-Plus Care HHC, Inc.
Address: Brooklyn
County: Kings
Structure: For-Profit Corporation
Application Number: 2017-L

Description of Project:

A-Plus Care HHC, Inc., a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The applicant has authorized 200 shares of stock which are owned as follows: Karl Bikhman owns 100 shares and Anna Domashitsky owns 100 shares.

The Board of Directors of A-Plus Care HHC, Inc. comprises the following individuals:

Karl Bikhman, Esq., President Attorney, Bikhman & Vinbaytel, PC	Anna Domashitsky, R.N., Secretary Staff Nurse, Revival Home Health Care
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A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A Certificate of Good Standing was received for Karl Bikhman.

The Office of the Professions of the State Education Department indicates no issues with the license of the health care professional associated with this application.

The applicant proposes to serve the residents of the following counties from an office located at 833 McDonald Avenue, 2nd Floor, Brooklyn, New York 11218:

New York	Kings	Queens	Bronx	Richmond
Westchester				

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care
Homemaker	Housekeeper	

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 8, 2012

Division of Home & Community Based Care
Character and Competence Staff Review

Name of Agency: ASC of New York, LLC dba Affordable Senior Care of New York
Address: Brooklyn
County: Kings
Structure: For-Profit
Application Number: 1946-L

Description of Project:

ASC of New York, LLC dba Affordable Senior Care of New York, a limited liability company, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The proposed member of ASC of New York, LLC dba Affordable Senior Care of New York comprises the following individuals:

Laszlo Friedman – President/CEO – 90% SPA Director, Creative Industries of America, Inc.	Yuliya (Julia) Friedman, HHA, PCA – 10% Home Health Aide, I & Y Senior Care, Inc.
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The Office of the Professions of the State Education Department indicates no issues with the licensure of the health professional associated with this application.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 135 Ocean Parkway, Suite 14U, Brooklyn, New York 11218:

Bronx	Kings	Nassau	New York
Richmond	Queens		

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Physical Therapy
Homemaker	Housekeeper		

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: January 14, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Christine Home Care Services, Inc.
Address: Richmond Hill
County: Queens
Structure: Not For Profit
Application Number: 1878-L

Description of Project:

Christine Home Care Services, Inc., a not-for-profit corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The members of the Board of Directors of Christine Home Care Services, Inc. comprise the following individuals:

Christine Persaud, Chairperson
Director, Liberty Home Care Nurses Employment Agency, Inc.
Affiliations:
Liberty Home Care Nurses Employment Agency, Inc.
Caring Home Care (1997 – 2010)

Surindra Prasad, Secretary
Manager, Liberty Home Care Nurses Employment Agency, Inc.

Romeo Prasad, Treasurer
Supervisor, Liberty Home Care Nurses Employment Agency, Inc.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 103-44 121st Street, 2nd Floor, Richmond Hill, New York 11419:

New York Bronx Queens Kings Nassau

The applicant proposes to provide the following health care services:

Nursing Home Health Aide Personal Care Homemaker Housekeeper

A review of the operations of the following agencies was performed as part of this review:

Liberty Home Care Nurses Employment Agency, Inc.
Caring Home Care (2002 - 2010)

The information provided by the Division of Home and Community Based Services has indicated that the home care agencies reviewed have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 8, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Eden Home Care Services, Inc.
Address: Brooklyn
County: Kings
Structure: For-Profit Corporation
Application Number: 2015-L

Description of Project:

Eden Home Care Services, Inc., a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The applicant has authorized 200 shares of stock, which are owned as follows:

Jeffery A. St Clair, Esq. – 20 shares
Principle, St. Clair & Associates at Law

Teri N. Punch-Borderon, RN – 20 shares
Staff Nurse, Long Island Jewish Medical
Center

Arnel P. Borderon – 20 shares
Associate LAN Administrator, Kings County Supreme
Court

Wayne D. Peters – 20 shares
CEO, Elway Restaurant Consultants, Inc.

Jacqueline D. Kings-Peters, RN – 20 shares
Director of Clinical Services, Center for Nursing &
Rehabilitation LTHHCP

Cathleen S. St Clair, PA – 20 shares
Physician Assistant, New York Methodist
Hospital

Joey H. Peters – 40 shares
Journey Man/Foreman, Local Union 580

Glendon J. Riley – 20 shares
Police Officer, Nassau County Police
Department

Pamela J. Riley, RN, Nurse Practitioner – 20 shares
Case Manager, New York Presbyterian System Select
Health

The Board of Directors of Eden Home Care Services, Inc. comprises the following individuals:

Wayne D. Peters – President
(Previously Disclosed)

Glendon J. Riley – Vice President – Operations
(Previously Disclosed)

Arnel P. Borderon – Vice President – Marketing
(Previously Disclosed)

Joey H. Peters – Treasurer
(Previously Disclosed)

Jeffrey S. St. Clair, Esq. – Secretary/General Counsel
(Previously Disclosed)

Jacqueline Peters, RN – Clinical Director
(Previously Disclosed)

The Office of the Professions of the State Education Department indicates no issues with the licensure of the health professional associated with this application.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A Certificate of Good Standing has been received for the Jeffery A. St Clair, Esq.

The applicant proposes to serve the residents of the following Counties from an office located at 699 Jerome Street, Brooklyn, New York 11207:

Bronx	Kings	New York	Queens
Richmond	Nassau		

The applicant proposes to provide the following health care services:

Nursing	Personal Care	Home Health Aide	Homemaker
Housekeeper	Physical Therapy	Occupational Therapy	Speech-Language Pathology
Nutrition	Medical Social Services	Respiratory Therapy	

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: January 11, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: JC Beginnings, Inc. d/b/a Senior Helpers
Address: Smithtown
County: Suffolk
Structure: For Profit Corporation
Application Number: 2082-L

Description of Project:

JC Beginnings, Inc. d/b/a Senior Helpers, a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law. JC Beginnings, Inc. d/b/a Senior Helpers is an existing non-medical companion care agency and a franchise.

The applicant has authorized 200 shares of stock which are owned as follows:

Gayle Lindroth, 100 shares President, Senior Helpers Owner, Lindroth International, Inc. (diabetic supply company)	Glen Lindroth, 100 shares Vice President, Senior Helpers
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The members of the Board of Directors of JC Beginnings, Inc. d/b/a Senior Helpers comprise the following individuals:

Gayle Lindroth, Chairperson (disclosed above)	Glen Lindroth, Vice Chairperson (disclosed above)
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A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 308 West Main Street, Suite 202, Smithtown, New York 11787:

Nassau	Suffolk
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The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care
Homemaker	Housekeeper	

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department

Recommendation: Contingent Approval
Date: November 8, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Millennium Concepts, Inc. d/b/a Exclusive Care
Address: Bronx
County: Bronx
Structure: For-Profit Corporation
Application Number: 2006-L

Description of Project:

Millennium Concepts, Inc. d/b/a Exclusive Care, a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The applicant has authorized 200 shares of stock, which are owned as follows:

Anthony Riccobono – 110 Shares
Executive Director, First Care of New York, Inc.

Joseph Riccobono – 60
Assistant Administrator, First Care of New York, Inc.

Affiliations:

- Owner/Operator, First Care of New York, Inc.

Affiliations:

- Owner/Operator, First Care of New York, Inc.

Maria R. Riccobono – 30 Shares
Director of Operations, First Care of New York, Inc.

Affiliations:

- Owner/Operator, First Care of New York, Inc.

The Board of Directors of Millennium Concepts, Inc. d/b/a Exclusive Care comprises the following individuals:

Anthony Riccobono – President, Secretary,
Treasurer
(Previously Disclosed)

Joseph Riccobono, Vice President
(Previously Disclosed)

Maria R. Riccobono – Vice President
(Previously Disclosed)

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following Counties from an office located at 2488 Grand Concourse, Suite 334, Bronx, New York 10458:

Bronx
Richmond

Kings
Nassau

New York

Queens

The applicant proposes to provide the following health care services:

Nursing

Personal Care

Home Health Aide

A ten year review of the operations of First Care of New York, Inc. was performed as part of this review.

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval

Date: January 11, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Ochlor, Incorporated d/b/a Right at Home
Address: Brooklyn
County: Kings
Structure: For-Profit Corporation
Application Number: 2013-L

Description of Project:

Ochlor, Incorporated d/b/a Right at Home, a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

Ochlor, Incorporated has proposed to operate as a Franchisee of Right at Home.

The applicant has authorized 200 shares of stock, which are owned as follows:

Walter E. Ochoa, PCA, HHA – 200 Shares
Owner/President, Right at Home Brooklyn

The Board of Directors of Ochlor, Incorporated d/b/a Right at Home comprises the following individual:

Walter E. Ochoa, PCA, HHA
(Previously Disclosed)

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A search of the individual named above on the New York State Home Care Registry revealed that the individual is certified as a PCA and HHA, and has no convictions or findings.

The applicant proposes to serve the residents of the following counties from an office located at 7102 20th Avenue, Front Store, Brooklyn, New York 11204.

Kings New York Queens Richmond

The applicant proposes to provide the following health care services:

Nursing Personal Care Homemaker

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: January 11, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: SonicLeibs, Inc. d/b/a Synergy HomeCare
Address: New York
County: New York
Structure: For-Profit Corporation
Application Number: 1979-L

Description of Project:

SonicLeibs, Inc. d/b/a Synergy HomeCare, a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

SonicLeibs, Inc. has proposed to operate as a Franchisee of Synergy HomeCare.

The applicant has authorized 200,000 shares of stock, which are owned as follows:

David S. Muson – 142,499 shares
President/Owner, SonicLeibs, Inc. d/b/a Synergy HomeCare

Affiliations:

- President/Owner, Synergy HomeCare of Hudson County (New Jersey)

57,501 shares of stock remain outstanding.

The Board of Directors of SonicLeibs, Inc. d/b/a Synergy HomeCare comprises the following individual:

David S. Muson – President/Chairman
(Previously Disclosed)

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 708 Third Avenue, 6th Floor, New York, New York 10017:

Bronx	Kings	New York	Queens
Richmond	Westchester		

The applicant proposes to provide the following health care services:

Nursing	Personal Care	Home Health Aide	Homemaker
Housekeeper	Physical Therapy	Occupational Therapy	Speech-Language Pathology
Nutrition	Medical Social Services		

A ten year review of the operations of Synergy HomeCare of Hudson County was performed as part of this review for the time periods specified.

The information provided by the State of New Jersey regulatory agency has indicated that facility affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval

Date: November 5, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: SR Homecare of NY, Inc.
Address: Brooklyn
County: Kings
Structure: For-Profit Corporation
Application Number: 1907-L

Description of Project:

SR Homecare of NY, Inc., a business corporation, requests approval to obtain licensure as a home care services agency under Article 36 of the Public Health Law.

The applicant has authorized 200 shares of stock which are owned as follows: Susan Rabinovich owns 180 shares and Janette Shtaynberg owns 20 shares.

The Board of Directors of SR Homecare of NY, Inc. comprises the following individuals:

Susan Rabinovich, HHA, President Currently: Unemployed Formerly: Home Attendant, Helping Hands Attendant Services (4/99 – 6/09) Affiliation: New Millennium Home Care, Inc.	Janette Shtaynberg, HHA, PCA, Board Member Home Health Aide, Helping Hands Attendant Services
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A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 150 Ocean Parkway, Brooklyn, New York 11218:

New York	Kings	Queens	Bronx	Richmond
Westchester				

The applicant proposes to serve the residents of the following counties from a second office located in the New Rochelle Region:

Nassau	Suffolk	Rockland	Orange	Putnam
Sullivan	Ulster	Dutchess		

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care
Physical Therapy	Occupational Therapy	Respiratory Therapy
Speech Language Pathology	Audiology	Medical Social Services
Nutrition	Homemaker	Housekeeper

A review of the operations of the following agency was performed as part of this review for the time period indicated:

New Millennium Home Care, Inc. (6/09 – 5/10)

The information provided by the Division of Home and Community Based Services has indicated that the home care agency reviewed has provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval

Date: January 14, 2013

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: St. Vincent de Paul Residence
d/b/a St. Vincent de Paul LHCSA
Address: New York
County: New York
Structure: Not for Profit
Application Number: 1812L

Description of Project:

St. Vincent de Paul Residence d/b/a St. Vincent de Paul LHCSA, a not-for-profit corporation, requests approval to obtain licensure as a home care agency under Article 36 of the Public Health Law.

This application is requesting approval to establish a licensed home care services agency (LHCSA) associated with a new Assisted Living Program (ALP). This LHCSA will be associated with St Vincent de Paul Residence Assisted Living Program. This project was granted contingent approval to proceed under the 330 ALP RFA.

The governing body of the ultimate member (parent) corporation, Providence Health Services, consists of the following board members:

Cardinal Timothy Dolan Archbishop, Archdiocese of New York (Religious Organization)	Bishop Robert Brucato Retired
Bishop Dennis J. Sullivan Vicar General, Archdiocese of New York (Religious Organization)	Monsignor Gregory A. Mustaciuolo, Esq. Chancellor, Archdiocese of New York (Religious Organization)

The governing body of the member (parent) corporation, Catholic Health Care System, d/b/a Archcare consists of the following board members:

Francis J. Serbaroli, Esq. (Chairperson) Partner, Greenberg Traurig, LLP (Law Firm)	Karl P. Adler, MD (Vice-Chairperson / Secretary) CEO, New York Medical College (Medical School) Additional Affiliations: St. Vincent's Hospital, St. Clare's / St. Vincent's Midtown Hospital, Our Lady of Mercy Hospital, St. Agnes Hospital, Benedictine Hospital, St. Francis Hospital, Center for Comprehensive Health Practice (D&TC)
Thomas M. O'Brien (Vice-Chairperson) Self Employed Banking Consultant	Manfred Altstadt, CPA Retired COO, Mutual of America (Insurance Corp)
Joseph P. Anderson Retired CEO, Schaller Anderson, Inc. (Health Care Management / Administrative Services)	Monsignor William Belford Diocesan Administrator / Parish Priest, Archdiocese of New York (Religious Organization)
John T. Dunlap, Esq. Partner, Dunnington, Bartholow, and Miller, LLP (Law Firm)	Monsignor Charles J. Fahey, LMSW Retired Professor, Fordham University (Higher Education) Additional Affiliations: Village Center for Care, d/b/a VillageCare (RHCF, CHHA, and LTHHCP), Isabella Geriatric Center, Inc. (RHCF and LTHHCP)

Thomas J. Fahey, MD Retired Senior VP, Memorial Sloan Kettering Cancer Center (Cancer Health Care), Retired Associate Dean, Cornell University Medical College (Medical College)	Eric P. Feldmann, Real Estate Broker CEO / Executive Director, Sisters of Charity Housing Development Corporation (Affordable Housing)
Scott La Rue, Registered Dietician / Nutritionist CEO / President, Catholic Health Care System, d/b/a Archcare (NFP Health Care System)	John Marinelli Managing Director, Arc Partners, Inc. (Consulting Firm)
Monsignor Gregory A. Mustaciolo, Esq. (Previously disclosed)	Kathryn K. Rooney, Esq. Retired Intern / Counsel to Senator Marchi, NYS Senate (State Government Legislature) Additional Affiliations: Richmond University Medical Center (Hospital), Homemakers of Staten Island, Inc., d/b/a Safe Harbor Healthcare Services (LHCSA)
Bishop Dennis J. Sullivan (Previously disclosed)	

The governing body of St. Vincent de Paul Residence consists of the following trustees:

Francis J. Serbaroli, Esq. (Chairperson) (Previously disclosed)	Karl P. Adler, MD (Vice-Chairperson / Secretary) (Previously disclosed)
Thomas M. O'Brien (Vice-Chairperson) (Previously disclosed)	Manfred Altstadt, CPA (Previously disclosed)
Joseph P. Anderson (Previously disclosed)	Monsignor William Belford (Previously disclosed)
John T. Dunlap, Esq. (Previously disclosed)	Monsignor Charles J. Fahey, LMSW (Previously disclosed)
Thomas J. Fahey, MD (Previously disclosed)	Eric P. Feldmann, Real Estate Broker (Previously disclosed)
Scott La Rue, Registered Dietician / Nutritionist (Previously disclosed)	John Marinelli (Previously disclosed)
Monsignor Gregory A. Mustaciolo, Esq. (Previously disclosed)	Kathryn K. Rooney, Esq. (Previously disclosed)
Bishop Dennis J. Sullivan (Previously disclosed)	Gerald T. Sweeney Cigna, Vice-President IT

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant has confirmed that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with the consultation of legal counsel, and it is concluded that proceeding with the proposal is appropriate.

A Certificate of Good Standing has been received for the attorneys.

The applicant proposes to serve Bronx County from an office located at: 900 Interval, Bronx, New York 10459

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Physical Therapy
Occupational Therapy	Respiratory Therapy	Audiology	Speech-Language Pathology
Nutrition	Housekeeper	Homemaker	Medical Social Services

A 10 year review of the operations of the following facilities was performed as part of this review

- Calvary Hospital, Inc.
Calvary Hospital, Inc. (CHHA)
Calvary Hospital Home Health Agency and Hospice Care (Hospice),
- St. Vincent's Hospital,
- St. Clare's/St Vincent's Midtown Hospital
- Our Lady of Mercy Hospital
- St. Agnes Hospital
- Benedictine Hospital
- St. Francis Hospital
- Richmond University Medical Center
- Center for Comprehensive Health Practice (D&TC)
- Carmel Richmond Healthcare and Rehabilitation Center (RHCF),
- Ferncliff Nursing Home (RHCF),
- Kateri Residence (RHCF),
- Mary Manning Walsh Nursing Home (RHCF),
- St. Vincent DePaul Residence (RHCF),
- St. Teresa's Nursing and Rehabilitation Center (RHCF),
- Terence Cardinal Cooke Health Care Center (RHCF),
- Catholic Managed Long Term Care, Inc., d/b/a Archcare Senior Life (PACE Program)
- Catholic Special Needs Plan, LLC, d/b/a Archcare Advantage (Medicare Advantage Special Needs Plan)
- Village Center for Care d/b/a VillageCare (RHCF, CHHA, LTHHCP)
- Isabella Geriatric Center, Inc. (RHCF, LTHHCP)
- Homemakers of Staten Island, Inc. d/b/a Safe Harbor Healthcare Services (LHCSA)

The information provided by the Division of Hospital Certification and Surveillance indicated that the hospitals and diagnostic and treatment center provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

An enforcement action was taken against St. Vincent's Hospital in 2006 citing violations in medical resident working hours regulations. This action was resolved with a \$6,000 civil penalty. An additional enforcement action was taken against St. Vincent's Hospital in 2007 citing violations in medical resident working hours regulations. This action was resolved with a \$25,000 civil penalty. An additional enforcement action was taken against St. Vincent's Hospital in 2007 citing the elopement of two psychiatric patients, one of which committed suicide. This action was resolved with a \$6,000 civil penalty. An additional enforcement action was taken against St. Vincent's Hospital in 2008 citing violations in medical resident working hours regulations. This action was resolved with a \$12,000 civil penalty.

The Information provided by the Bureau of Quality and Surveillance has indicated that the residential health care facilities reviewed have provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

An enforcement action was taken against Kateri Residence in 2009 based on a March, 2008 survey citing violations in Quality of Care; and Quality of Care: Accidents. The action was resolved with a \$4000 civil penalty.

An enforcement action was taken against Mary Manning Walsh Nursing Home in 2005 based on May 2002, and September 2003, surveys citing violations in Quality of Care; and Quality of Care: Medication Errors. The action was resolved with a \$3000 civil penalty.

An enforcement action was taken against St. Teresa's Nursing Home in in 2004 based on an August, 2003 survey citing violations in Quality of Care: Accidents. The action was resolved with a \$2000 civil penalty.

An enforcement action was taken against Terence Cardinal Cooke Health Care Center in 2005 based on an April, 2005 survey citing violations in Resident Assessment and Care Planning; Comprehensive Care Plans; Quality of Care: Accidents; Organization and Administration: Governing Body; and Organization and Administration: Nurse Aide Certification and Training. The action was resolved with a \$4000 civil penalty. An additional enforcement action was taken against Terence Cardinal Cooke Health Care Center in 2007 based on a February, 2007 survey citing violations in Quality of Care: Accidents; and Organization and Administration. The action was resolved with a \$3000 civil penalty. An additional enforcement action was taken against Terence Cardinal Cooke Health Care Center in 2009 based on a March, 2008 survey citing violations in Quality of Care: Accidents; Organization and Administration; and Organization and Administration: Governing Body. The action was resolved with a \$6000 civil penalty. An additional enforcement action was taken against Terence Cardinal Cooke Health Care Center in 2011 based on an April, 2010 survey citing violations in Quality of Care: Highest Practicable Potential. The action was resolved with a \$2000 civil penalty.

An enforcement action was taken against Village Center for Care, d/b/a VillageCare Rehabilitation and Nursing Center, in 2004 based on an April, 2003 survey citing violations in Quality of Care: Accidents. The action was resolved with a \$2000 civil penalty. An additional enforcement action was taken against Village Center for Care, d/b/a VillageCare Rehabilitation and Nursing Center, in 2009 based on an April, 2008 survey citing violations in Quality of Care. The action was resolved with a \$2000 civil penalty.

The information provided by the Division of Home and Community Based Services indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

An enforcement action was taken against Village Center for Care, d/b/a VillageCare Long Term Home Health Care Program in 2005 based on April 2005 and June 2005 surveys, citing violations in Policies and Procedures of Service Delivery; Patient Care; and Governing Authority. This action was resolved with a \$3000 civil penalty, \$1500 of which was suspended.

An enforcement action was taken against Village Center for Care, d/b/a VillageCare Certified Home Health Agency in 2005 based on an August 2005 survey, citing violations in Policies and Procedures of Service Delivery; and Governing Authority. This action was resolved with a \$4000 civil penalty.

The Division of Managed Long Term Care reviewed the compliance history of the affiliated Medicare Advantage Special Needs Plan, and PACE Program, and determined that the plans have provided a substantially consistent high level of care.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval

Date: December 11, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Tri-Borough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd.
Address: Hempstead
County: Nassau
Structure: For-Profit
Application Number: 2069-L

Description of Project:

Tri-Borough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd., a for-profit corporation, requests approval for a change in ownership of a licensed home care services agency under Article 36 of the Public Health Law.

Family Aides, Inc. was previously approved as a home care services agency by the Public Health Council at its November 14, 2008 meeting and subsequently licensed as 1662L001 and 1662L002, 1662L003, 1662L004 and 1662L005. The change of ownership is for the agencies currently licensed as 1662L002 and 1662L005.

On September 8, 2011 Family Aides, Inc. solely owned by Family Aides Grantor Trust, with Robert Silbering, Esq. as the sole Trustee, entered into an Asset Sale Agreement with Tri-Borough Home Care, Ltd.

Family Aides, Inc. has entered into a management agreement with Tri-Borough Home Care, Ltd. which was approved by the Department of Health on August 27, 2012.

The applicant has authorized 200 shares of stock, which are owned as follows:

Kenrick L. Cort – 50 Shares
President/CEO, Tri-borough Home Care, Ltd.

Affiliations:

- President/CEO, Tri-borough Home Care, Ltd.
- President/CEO, ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
- President/CEO, ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

150 shares remain unissued.

The Board of Directors of Tri-Borough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd. comprises the following individual:

Kenrick L. Cort, Chief Executive Officer, President, Secretary, Treasurer

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to continue to serve the residents of the following counties from an office located at 235 N. Main Street, Spring Valley, New York 10977:

Dutchess	Orange	Putnam	Sullivan
Westchester	Ulster	Nassau	Suffolk
Rockland			

The applicant proposes to continue to serve the residents of the following counties from an office located at 50 Clinton Street, Hempstead, New York 11550:

Nassau	Suffolk	Queens	Westchester
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The applicant proposes to continue to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Medical Social Services
Occupational Therapy	Physical Therapy	Nutrition	Speech-Language Pathology
Homemaker	Housekeeper		

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Tri-borough Home Care, Ltd.
ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

ISIS Home Health Care, Inc., Fort Myers, FL was fined eleven thousand dollars (\$11,000.00) resulting from two survey deficiencies; one thousand dollars (\$1,000.00) for not following the Plan of Treatment and ten thousand dollars (\$10,000.00) for not following the Plan of Care, 10 patients total. ISIS Home Health Care, Inc. resolved the fine September 6, 2012.

ISIS Home Health Care, Inc., Fort Myers, FL was fined ten thousand dollars (\$10,000.00) resulting from not completing their quarterly reports for the 3rd and 4th quarter in 2008. ISIS Home Health Care, Inc. resolved the fine October 6, 2009.

The information provided by the State of Florida regulatory agency has indicated that facilities affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 14, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Tri-Borough Health Careers, LLC d/b/a Metro Care Home Services,
a division of Tri-Borough Health Careers, LLC
Address: Brooklyn
County: Kings
Structure: Limited Liability Company
Application Number: 2070-L

Description of Project:

Tri-Borough Health Careers, LLC d/b/a Metro Care Home Services, a division of Tri-Borough Health Careers, LLC a limited liability company, requests approval for a change in ownership of a licensed home care services agency under Article 36 of the Public Health Law.

Metrocare Home Services, Inc. was previously approved as a home care services agency by the Public Health Council at its November 14, 2008 meeting and subsequently licensed as 1661L001.

Metrocare Home Services, Inc. solely owned by Metrocare Grantor Trust, with Robert Silbering, Esq. as the sole Trustee, entered into an Asset Sale Agreement with Tri-Borough Health Careers, LLC.

Metrocare Home Services, Inc. has entered into a management agreement with Tri-Borough Health Careers, LLC which was approved by the Department of Health on December 19, 2011.

The sole member of Tri-Borough Health Careers, LLC d/b/a Metro Care Home Services, a division of Tri-Borough Health Careers, LLC comprises:

Kenrick L. Cort – 100%
President/CEO, Tri-borough Home Care, Ltd.

Affiliations:

- President/CEO, Tri-borough Home Care, Ltd.
- President/CEO, ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
- President/CEO, ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 883 Flatbush Avenue, Brooklyn, New York 11206:

Bronx	Kings	New York	Queens
Richmond	Westchester		

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Medical Social Services
Occupational Therapy	Physical Therapy	Nutrition	Speech-Language Pathology
Homemaker	Housekeeper		

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Tri-borough Home Care, Ltd.
ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

ISIS Home Health Care, Inc., Fort Myers, FL was fined eleven thousand dollars (\$11,000.00) resulting from two survey deficiencies; one thousand dollars (\$1,000.00) for not following the Plan of Treatment and ten thousand dollars (\$10,000.00) for not following the Plan of Care, 10 patients total. ISIS Home Health Care, Inc. resolved the fine September 6, 2012.

ISIS Home Health Care, Inc., Fort Myers, FL was fined ten thousand dollars (\$10,000.00) resulting from not completing their quarterly reports for the 3rd and 4th quarter in 2008. ISIS Home Health Care, Inc. resolved the fine October 6, 2009.

The information provided by the State of Florida regulatory agency has indicated that facilities affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval
Date: November 14, 2012

Division of Home & Community Based Services
Character and Competence Staff Review

Name of Agency: Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers,
a division of Tri-Borough Home Care, Ltd.
Address: Brooklyn
County: Kings
Structure: For-Profit
Application Number: 2103-L

Description of Project:

Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers, a division of Tri-Borough Home Care, Ltd., a for-profit corporation, requests approval for a change in ownership of a licensed home care services agency under Article 36 of the Public Health Law.

Metrocare Givers, Inc. was previously approved as a home care services agency by the Public Health Council at its November 14, 2008 meeting and subsequently licensed as 1681L001.

Metrocare Givers, Inc. solely owned by Metrocare Givers Grantor Trust, with Robert Silbering, Esq. as the sole Trustee, entered into an Asset Sale Agreement with Tri-Borough Home Care, Ltd.

Metrocare Givers, Inc. has entered into a management agreement with Tri-Borough Home Care, Ltd. which was approved by the Department of Health on May 17, 2012.

The applicant has authorized 200 shares of stock, which are owned as follows:

Kenrick L. Cort – 50 Shares
President/CEO, Tri-borough Home Care, Ltd.

Affiliations:

- President/CEO, Tri-borough Home Care, Ltd.
- President/CEO, ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)
- President/CEO, ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

150 shares remain unissued.

The Board of Directors of Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers, a division of Tri-Borough Home Care, Ltd. comprises the following individual:

Kenrick L. Cort, Chief Executive Officer, President, Secretary, Treasurer

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The applicant proposes to serve the residents of the following counties from an office located at 50 Clinton Street, Hempstead 1414 Utica Avenue, Brooklyn, New York 11203:

Bronx	Kings	New York	Queens
Richmond	Westchester		

The applicant proposes to provide the following health care services:

Nursing	Home Health Aide	Personal Care	Medical Social Services
Occupational Therapy	Physical Therapy	Nutrition	Speech-Language Pathology
Homemaker	Housekeeper		

A ten year review of the operations of the following facilities was performed as part of this review for the time periods specified (unless otherwise specified):

Tri-borough Home Care, Ltd.

ISIS Home Health Care, Inc., Fort Myers, FL (2005 – Present)

ISIS Home Health Care, Inc., Sunrise, FL (2008 – Present)

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

ISIS Home Health Care, Inc., Fort Myers, FL was fined eleven thousand dollars (\$11,000.00) resulting from two survey deficiencies; one thousand dollars (\$1,000.00) for not following the Plan of Treatment and ten thousand dollars (\$10,000.00) for not following the Plan of Care, 10 patients total. ISIS Home Health Care, Inc. resolved the fine September 6, 2012.

ISIS Home Health Care, Inc., Fort Myers, FL was fined ten thousand dollars (\$10,000.00) resulting from not completing their quarterly reports for the 3rd and 4th quarter in 2008. ISIS Home Health Care, Inc. resolved the fine October 6, 2009.

The information provided by the State of Florida regulatory agency has indicated that facilities affiliated with this application have provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

Contingency

Submission of any and all information requested by the Division of Legal Affairs, in a form and manner acceptable to the Department.

Recommendation: Contingent Approval

Date: November 14, 2012

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following applications for licensure, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

<u>NUMBER:</u>	<u>FACILITY:</u>
2061-L	ADG Health Care Holdings, Inc. d/b/a ComForcare Senior Services-Northeast Westchester (Westchester, Putnam, Dutchess and Orange Counties)
2017-L	A-Plus Care HHC, Inc (New York, Kings, Queens, Bronx, Richmond and Westchester Counties)
1946-L	ASC of New York, LLC d/b/a Affordable Senior Care of New York (Bronx, Kings, Nassau, New York, Richmond and Queens Counties)
1878-L	Christine Home Care Services, Inc. (New York, Bronx, Queens, Kings and Nassau Counties)
2015-L	Eden Home Care Services, inc. (Bronx, Kings, New York, Queens, Richmond and Nassau Counties)

2082-L JC Beginnings, Inc. d/b/a Senior Helpers
(Nassau and Suffolk Counties)

1995-L Life Quality Homecare Agency, Inc.
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

2006-L Millennium Concepts, Inc. d/b/a Exclusive Care
(Bronx, Kings, New York, Queens, Richmond and
Nassau Counties)

2013-L Ochlor, Incorporated d/b/a Right at Home
(Kings, New York, Queens and Richmond Counties)

1979-L SonicLeibs, Inc. d/b/a Synergy HomeCare
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

1907-L SR Homecare of NY, Inc.
(New York, Kings, Queens, Bronx, Richmond, and
Westchester Counties)

1812-L St. Vincent de Paul Residence d/b/a St. Vincent de
Paul LHCSA
(Bronx County)

2153-L Garden Homecare, LLC
(Erie County)

2076-L Ideal Care SP, LLC
(Ulster, Dutchess, Orange, Sullivan and Greene
Counties)

1881-L Marian Care, Inc.
(Nassau, Suffolk, and Queens Counties)

2070-L Tri-Borough Health Careers, LLC d/b/a Metro Care
Home Services, a division of Tri-Borough Health
Careers, LLC
(Bronx, Kings, New York, Queens, Richmond and
Westchester Counties)

- 2069-L TriBorough Home Care, Ltd. d/b/a Family Pediatric Home Care, a division of Tri-Borough Home Care, Ltd. (Dutchess, Orange, Putnam, Sullivan Westchester, Ulster, Nassau, Suffolk, and Rockland Counties)
- 2013-L Tri-Borough Home Care, Ltd. d/b/a Metrocare Givers, a division of Tri-Borough Home Care, Ltd. (Bronx, Kings, New York, Queens, Richmond and Westchester Counties)

**New York State Department of Health
Public Health and Health Planning Council**

February 7, 2012

**APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION
OF HEALTH CARE FACILITIES**

CATEGORY 6: Applications for Individual Consideration/Discussion

CON Applications

Ambulatory Surgery Center – Establish

Exhibit #20

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	121346 E	White Plains Ambulatory Surgery, LLC d/b/a White Plains Ambulatory Surgery Center, Inc. (Westchester County)	Contingent Approval

Residential Health Care Facility – Establish/Construct

Exhibit #21

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	122194 B	SSS Operating, LLC d/b/a Atlantic Harbor Center for Rehabilitation and Nursing (Suffolk County)	To be presented at the Special Establishment/Project Review Committee on 2/7/13 No Recommendation



Public Health and Health Planning Council

Project # 121346-E
White Plains Ambulatory Surgery, LLC
d/b/a White Plains Ambulatory Surgery Center

County: Westchester (White Plains)
Purpose: Establishment

Program: Ambulatory Surgery Center
Submitted: April 25, 2012

Executive Summary

Description

White Plains Ambulatory Surgery Center, LLC., a to-be-formed limited liability company, requests approval to be established as the new operator of Westchester Ambulatory Surgery Center, Inc., a freestanding multi-specialty ambulatory surgery center (ASC) located at 226 Westchester Avenue, White Plains.

The current and proposed ownership of White Plains Ambulatory Surgery Center is as follows:

Current	
<i>Westchester Ambulatory Surgery Center, Inc.</i>	
SHAREHOLDERS:	
-- Mike Gioscia	71.12%
-- Mark LaMastro	14.44%
-- Ed Sottile	14.44%
Proposed	
<i>White Plains Ambulatory Surgery Center, LLC</i>	
MEMBERS:	
-- Glen Lau, MD.	90%
-- Medical Shorefronts of Westchester, LLC	10%

Glen Lau, MD., will be the sole member of Medical Shorefronts of Westchester, LLC.

The existing operators of Westchester Ambulatory Surgery Center, Inc. have submitted a proposed d/b/a certificate to the State Department of Health requesting that the Center be known as Westchester Ambulatory Surgery Center, Inc. d/b/a White Plains Ambulatory Surgery Center. The applicant has indicated that there will not be an administrative services agreement associated with this application.

DOH Recommendation

Contingent approval, with an expiration of the operating certificate five years from the date of its issuance, should the operator not comply with the conditions of approval granted this CON.

Need Summary

This project is a change in ownership that will not result in any alterations to capacity or services. The applicant does not anticipate any change to its current operations. It is projected that there will be 2,500 visits in the first year of operation following the change in ownership.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

The purchase price for the operations is \$864,000 and will be met via cash reserves from the proposed operator.

Budget:	<i>Revenues:</i>	\$ 7,112,500
	<i>Expenses:</i>	<u>6,052,376</u>
	<i>Gain/(Loss):</i>	\$ 1,060,124

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health to provide annual reports to the Department beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who need follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided, and
 - Number of nosocomial infections recorded during the year in question. [RNR]
2. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a plan and signed agreement, acceptable to the Department, to provide services to the Medicaid eligible population that supports the projected payor mix as indicated in the CON application. [RNR]
4. Submission of an executed lease assignment that is acceptable to the Department of Health. [BFA]
5. Submission of executed Articles of Organization of White Plains Ambulatory Surgery Center, LLC, acceptable to the Department. [CSL]
6. Submission of an executed Operating Agreement of White Plains Ambulatory Surgery Center, LLC, acceptable to the Department. [CSL]
7. Submission of executed Articles of Organization of Medical Forefronts of Westchester, LLC, acceptable to the Department. [CSL]
8. Submission of an executed Operating Agreement of Medical Forefronts, LLC, acceptable to the Department. [CSL]

Approval conditional upon:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The submission of annual reports for a period of no less than five years, acceptable to the Department, demonstrating that actual utilization and payor mix experience is substantially consistent with that projected in the CON application with respect to Medicaid and charity care. [RNR]
3. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
4. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
5. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
6. The clinical space must be used exclusively for the approved purpose. [HSP]

Council Action Date

February 7, 2013.

Need Analysis

Background

White Plains Ambulatory Surgery Center, Inc. requests approval to become the operator of Westchester Ambulatory Surgery Center, Inc., located at 226 Westchester Avenue, White Plains, 10604, in Westchester County.

Analysis

Westchester Ambulatory Surgery Center, Inc. d/b/a White Plains ASC is an operating freestanding multi-specialty ambulatory surgery center. This change in ownership will result in no changes to capacity or services.

The number of projected visits is as follows:

First Year:	2,500
Third Year:	2,943

White Plains Ambulatory Surgery Center, Inc. has submitted a statement that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with consultation of the legal counsel, and concluded that proceeding with the proposal is acceptable. This statement is acceptable to the Department.

Conclusion

Westchester Ambulatory Surgery Center, Inc., d/b/a White Plains ASC, is an existing ambulatory surgery center in Westchester County. It is not anticipated that there will be any changes in its capacity or services following the change in ownership.

Recommendation

From a need perspective, contingent approval is recommended.

Programmatic Analysis

Background

Establish White Plains Ambulatory Surgery Center, LLC as the new operator of Westchester Ambulatory Surgery Center, Inc., an existing multispecialty surgery center operating at 226 Westchester, Avenue in Westchester.

Character and Competence

The members of the LLC are:

<u>Name</u>	
Glen Lau, MD	90%
Medical Forefronts of Westchester, LLC	10%
Glen Lau, MD (100%)	

Dr. Lau, a practicing physician, is the owner/operator of surgery centers in California, Nevada and one in New York.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Compliance with Applicable Codes, Rules and Regulations

The medical staff will ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements. The Center intends to review the list acceptable procedures annually and as needed to determine the appropriateness of adding new procedures consistent with individual physician expertise.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Asset Purchase Agreement

The applicant has submitted an executed asset purchase agreement for the acquisition of Westchester Ambulatory Surgery Center, Inc. d/b/a White Plains Ambulatory Surgery Center, which will be summarized below:

<i>Date:</i>	February 3, 2012
<i>Seller:</i>	Westchester Ambulatory Surgery Center, Inc. (WASC)
<i>Buyer:</i>	White Plains Ambulatory Surgery Center, LLC
<i>Assets Acquired:</i>	The Purchaser will acquire the following assets: the ASC business including the right to use the name "Westchester Ambulatory Surgery Center" and to WASC's knowledge, the name "White Plains Ambulatory Surgery Center" and any and all other trade names, logos, trademarks and service marks associated with the ASC business; all leasehold improvements, furniture, fixtures and equipment owned or leased by the ASC business; WASC's Medicare and Medicaid Provider Numbers and provider agreements to the extent transferable; WASC's forms, policies and procedures manuals, menus and patient healthcare and other records; computer software and other property; all patient security deposits and prepayments, if any, for future services held by WASC; all licenses, permits, consents and certificates of any regulatory, administrative or other governmental agency or body issued to or held by WASC necessary to or relating to the ownership or operation of the ASC; copies of all financial books and records in the possession of WASC relating to the ASC business; copies of all patient records relating to the ASC business; copies of all employee and payroll records; copies of all other books and records relating to the ASC Business; rights under WASC's profit sharing and 401(k) plans and related trusts and trust assets and all other assets of every nature and description owned by WASC and used in the WASC business.
<i>Excluded Assets:</i>	The Acquired assets shall not include any of the following: personal property; all real estate tax refunds relating to a period or periods prior to the Closing Date; books and records related to the organization, maintenance and existence of WASC including minutes of meetings of its Executive Board; related party debt; rights between or among WASC and WASC's Principals or their respective affiliates and rights of WASC under any contract which is not an assumed contract.

Assumed Liabilities: Upon the terms and subject to the condition of this agreement, at the Closing Buyer will assume and agree to perform and discharge all liabilities and obligations of WASC; it is the intent of the Parties hereto that the "Assumed Liabilities" shall mean all Assumed Liabilities as the same may change in the ordinary course of business from the date of this Agreement through and including the Closing Date and the assumption of the Assumed Liabilities by Buyer will be effected by execution and delivery by Buyer to WASC of duly executed Bill of Sale, Assignment and Assumption Agreement at the Closing.

Excluded Liabilities: The Buyer will not be assuming the following liabilities: income taxes of WASC or WASC's Principal's with respect to or attributable to the transactions contemplated by this agreement; any liabilities associated arising out of or relating to litigation under the caption Surgical Synergies, Inc. and Surgical Support Services, LLC v. Administrative Services of Westchester, LLC and litigation relating to the ASC business or the ownership or operation of the Acquired Assets arising out of facts or circumstances existing prior to the Closing Date to the extent reimbursed by WASC's existing insurance coverage.

Purchase Price: \$864,000

Payment of

Purchase Price: Down payment of \$100,000 and the remainder of \$764,000 will be paid at Closing in the form of equity.

The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments of fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. Currently, there are no outstanding liabilities.

Lease Rental Agreement

The applicant will occupy the site under a sublease agreement, of which they submitted a draft sublease assignment. The proposed sublease assignment is assigned below:

Premises: 11,000 square feet located at 226 Westchester Avenue, White Plains, New York

Sublessor: Administrative Services of Westchester, LLC

Sublessee: White Plains Ambulatory Surgery Center, LLC

Term: The term expires on May 14, 2021

Rental: May 15, 2012 through May 14, 2013- \$379,500 (\$34.50 per sq. ft.)

May 15, 2013 through May 14, 2014- \$396,000 (\$36.00 per sq. ft.)

May 15, 2014 through May 14, 2015- \$396,000 (\$36.00 per sq. ft.)

May 15, 2015 through May 14, 2016- \$407,880 (\$37.08 per sq. ft.)

May 15, 2016 through May 14, 2017- \$420,090 (\$38.19 per sq. ft.)

May 15, 2017 through May 14, 2018- \$432,740 (\$39.32 per sq. ft.)

May 15, 2018 through May 14, 2019- \$445,719 (\$40.52 per sq. ft.)

May 15, 2019 through May 14, 2020- \$459,030 (\$41.73 per sq. ft.)

May 15, 2020 through May 14, 2021- \$472,890 (\$42.99 per sq. ft.)

Provisions: The lessee will be responsible for taxes and utilities.

Operating Budget

The applicant has submitted an operating budget, in 2012 dollars, for the first year after the change in operator, summarized below:

Revenues	\$7,112,500
Expenses:	
Operating	\$5,597,180
Capital	<u>455,196</u>
Total Expenses	\$6,052,376
Net Income	<u>\$1,060,124</u>
Utilization: (procedures)	2,500
Cost Per Procedure	\$2,420.95

Utilization shown by payor source during the first year after the change in operator, is summarized below:

Commercial Fee-for-Service	20.00%
Commercial Managed Care	20.00%
Medicare Fee-for-Service	40.00%
Medicaid Fee-for-Service	5.00%
Medicaid Managed Care	10.00%
Self Pay	3.00%
Charity Care	2.00%

Expense and utilization assumptions are based on the historical experience of the current operator.

Capability and Feasibility

The purchase price of \$864,000 will be met via equity from personal funds of the proposed member of White Plains Ambulatory Surgery Center, LLC.

Working capital requirements are estimated at \$1,008,728, which is equivalent to two months of first year expenses. The proposed member of White Plains Ambulatory Surgery Center, LLC will provide equity from his personal resources to meet the working capital requirement. Presented as BFA Attachment A is the personal net worth statement of the proposed member of White Plains Ambulatory Surgery Center, LLC., which indicates the availability of sufficient funds to meet the purchase price and the working capital requirements. Presented as BFA Attachment B, is the pro-forma balance sheet of White Plains Ambulatory Surgery Center, LLC, which indicates a positive net asset position of \$1,008,728 as of the first day of operation.

The submitted budget projects a net income of \$1,060,124 during the first year after the change in operator. Revenues are based on current reimbursement methodologies for ambulatory surgery services. The submitted budget appears reasonable.

Presented as BFA Attachment C are the 2010 and 2011 certified financial statements of Westchester Ambulatory Surgery Center, Inc d/b/a White Plains Ambulatory Surgery Center. As shown on Attachment B, the facility had an average negative working capital position and an average negative net asset position from 2010 through 2011. Also, the facility incurred average net losses of \$1,661,482 from 2010 through 2011. The applicant indicated the reasons for the losses are as follows: the Company was overstaffed, the facility was slow in receiving payments, and the facility's managed care contracts had low reimbursement rates. The applicant implemented the following steps to improve operations: changed billing procedures and billing company whose sole business is billing for ASC's. The change in billing companies has resulted in quicker payments resulting in more efficient cash flow. The applicant also undertook a full evaluation of the current staff and upon completion of the evaluation, certain employees were relieved of their responsibilities, and the rest went through a vigorous training program. And existing managed care contracts have either been cancelled and/or renegotiated with higher rates of reimbursement.

Presented as BFA Attachment D, is the October 31, 2012 internal financial statements of White Plains Ambulatory Surgery Center. As shown on Attachment D, the facility had a positive working capital position and a positive net asset position through October 31, 2012. Also, the facility achieved a net income of \$1,012,855 through October 31, 2012. The facility improved operations in 2012 from 2010 through 2011.

Subject to the noted contingency, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Personal Net Worth Statement
BFA Attachment B	Pro-forma Balance Sheet
BFA Attachment C	Financial Summary for 2010 and 2011 certified financial statements of Westchester Ambulatory Surgery Center, Inc. d/b/a/ White Plains Ambulatory Surgery Center
BFA Attachment D	Financial Summary for October 31, 2012, internal financial statements for White Plains Ambulatory Surgery Center.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish White Plains Ambulatory Surgery, LLC as the new operator of Westchester Ambulatory Surgery Center, Inc, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

121346 E

FACILITY/APPLICANT:

White Plains Ambulatory Surgery, LLC d/b/a
White Plains Ambulatory Surgery Center, Inc.

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance is recommended contingent upon:

1. Submission of a signed agreement with an outside independent entity satisfactory to the Department of Health to provide annual reports to the Department beginning in the second year of operation. These reports shall include:
 - Data showing actual utilization including procedures;
 - Data showing breakdown of visits by payor source;
 - Data showing number of patients who need follow-up care in a hospital within seven days after ambulatory surgery;
 - Data showing number of emergency transfers to a hospital;
 - Data showing percentage of charity care provided, and
 - Number of nosocomial infections recorded during the year in question. [RNR]
2. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a plan and signed agreement, acceptable to the Department, to provide services to the Medicaid eligible population that supports the projected payor mix as indicated in the CON application. [RNR]
4. Submission of an executed lease assignment that is acceptable to the Department of Health. [BFA]
5. Submission of executed Articles of Organization of White Plains Ambulatory Surgery Center, LLC, acceptable to the Department. [CSL]
6. Submission of an executed Operating Agreement of White Plains Ambulatory Surgery Center, LLC, acceptable to the Department. [CSL]
7. Submission of executed Articles of Organization of Medical Forefronts of Westchester, LLC, acceptable to the Department. [CSL]
8. Submission of an executed Operating Agreement of Medical Forefronts, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The submission of a CON or other licensing extension application required by the Department prior to expiration date of the operating certificate issued pursuant to this CON, seeking extension of the operating certificate of the ambulatory surgery center. [PMU]
2. The submission of annual reports for a period of no less than five years, acceptable to the Department, demonstrating that actual utilization and payor mix experience is substantially consistent with that projected in the CON application with respect to Medicaid and charity care. [RNR]
3. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
4. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
5. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
6. The clinical space must be used exclusively for the approved purpose. [HSP]

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237



Public Health and Health Planning Council

Project # 122194-E

SSS Operating, LLC
d/b/a Atlantic Harbor Center for Rehabilitation and Nursing

County: Suffolk (Yaphank)
Purpose: Establishment

Program: Residential Health Care Facility
Submitted: October 25, 2012

Executive Summary

Description

SSS Operating, LLC d/b/a Atlantic Harbor Center for Rehabilitation and Nursing requests approval to be established as the new operator of John J. Foley Skilled Nursing Facility, an existing 264-bed County residential health care facility (RHCF) that includes a 12-bed AIDS unit and 60-slot adult day health care program (ADHCP), located at 14 Glover Drive, Yaphank. The County of Suffolk, which operates John J. Foley, entered into an asset purchase agreement with SSS Operating, LLC for the sale and acquisition of the facility's operating interest on July 30, 2012. A separate real estate company, SSS Realty, LLC, will acquire the facility's property.

Ownership of the operation before and after the requested change is as follows:

Before	
<i>John J. Foley Skilled Nursing Facility</i>	
MEMBER:	<u>Interest</u>
-- County of Suffolk	100%
After	
<i>SSS Operating, LLC d/b/a Atlantic Harbor Center for Rehabilitation and Nursing</i>	
MEMBERS:	<u>Interest</u>
-- Israel Sherman (B)	38.57%
-- Samuel Sherman (B)	26.94%
-- Zalmen Horowitz (A)	10.39%
-- Jeffrey Goldstein (B)	10.00%
-- Cheskel Berkowitz (A)	7.05%
-- Joel Zupnick (A)	7.05%

There are two types of members for the new operator, characterized as class A and Class B. The differentiation is that the class B members are the individuals that will be overseeing the day-to-day operations of the facility.

DOH Recommendation

Contingent approval.

Need Summary

The facility's utilization was below the 97% planning optimum for 2009, 2010, and 2011. Utilization was 94.5% in 2010 and decreased significantly to 77.91% in 2011, below the Long Island planning region's average occupancy of 92.27%. Public awareness of the potential sale and instability of the facility led to the decrease in facility utilization.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community. No changes in the program or physical environment are proposed in this application.

Financial Summary

The facility's assets have been sold in accordance with the Asset Purchase Agreement effective July 30, 2012. There are no project costs associated with this proposal.

Budget:	<i>Revenues:</i>	\$ 29,182,366
	<i>Expenses:</i>	<u>28,586,844</u>
	<i>Gain/(Loss):</i>	\$ 595,522

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this application.

Office of Health Systems Management

Approval contingent upon:

1. The submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
2. Submission of an executed Loan commitment for working capital that is acceptable to the Department of Health. [BFA]
3. Submission of an executed Personal Loan commitment for the purchase of the operations of the facility that is acceptable to the Department. [BFA]
4. Submission of a photocopy of an executed facility lease agreement, which is acceptable to the Department. [CSL]
5. Submission of a photocopy of the applicant's executed proposed articles of organization, which is acceptable to the Department. [CSL]
6. Submission of a photocopy of the applicant's executed proposed operating agreement, which is acceptable to the Department. [CSL]

Council Action Date

February 7, 2013.

Need Analysis

Background

Atlantic Harbor Center for Rehabilitation and Nursing seeks approval to purchase and be established as the operator of the John J. Foley Skilled Nursing Facility, a 264 bed, public residential health care facility located at 14 Glover Drive, Yaphank, 11980, in Suffolk County.

Analysis

Utilization at John J. Foley Skilled Nursing Facility was higher than Suffolk County for 2009 and 2010 but was lower in 2011, as shown in the table below:

<u>RHCF Utilization</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>
John J Foley Skilled Nursing Facility	95.10%	94.46%	77.91%
Suffolk County	95.43%	94.29%	93.05%
Long Island	94.79%	93.37%	92.27%

This county nursing home had open communications about the sale of this facility. Discussions also took place regarding the possible closure of the facility. As a result, many families were reluctant to place relatives into the facility and possibly face a transition to another provider. In addition, community referrals decreased for the same reason which also resulted in a decrease in admitted patients. It is expected that this situation will continue until a new operator/owner has been established. Once the change in ownership is finalized, the new owners plan to start a community outreach initiative that will inform local families and referral sources of the benefits of the facility and the programs it offers. It is anticipated that occupancy at John J. Foley will then return to former levels of approximately 95 percent annually.

<u>RHCF Bed Need</u>	<u>Long Island</u>
2016 Projected Need	16,962
Current Beds	16,000
Beds Under Construction	- 415
Total Resources	15,585
Unmet Need	1,377

Access

Regulations indicate that the Medicaid patient admissions standard shall be 75 percent of the annual percentage of all Medicaid admissions for Jefferson County in which Samaritan Senior Village will be located. Such planning area percentage shall not include residential health care facilities that have an average length of stay 30 days or fewer. If there are four or fewer residential health care facilities in the planning area, the applicable standard for a planning area shall be 75 percent of the planning area percentage of Medicaid admissions, whichever is less. In calculating such percentages, the Department will use the most current data which have been received and analyzed by the Department. An applicant will be required to make appropriate adjustments in its admission policies and practices so that the proportion of its own annual Medicaid patients admissions is at least 75 percent of the planning area percentage of Health Systems Agency percentage, whichever is applicable.

John J. Foley Skilled Nursing Facility 2009:	29.30%
John J. Foley Skilled Nursing Facility 2010:	70.80%
Suffolk County's 75% for 2009:	11.12%
Suffolk County's 75% for 2010:	20.26%

Conclusion

This project will not result in any changes in capacity or services. Long Island still has an unmet need of 1,377 residential health care facility beds. The proposed change of ownership will allow the facility to continue successfully operating in the Long Island planning region. Therefore, due to the ongoing need for RHCF care in the planning area

and because of the anticipated return of the facility's occupancy to formerly high levels, this change of ownership is recommended for contingent approval.

Recommendation

From a need perspective, approval is recommended.

<h2 style="margin: 0;">Programmatic Analysis</h2>

Facility Information

	<i>Existing</i>	<i>Proposed</i>
<i>Facility Name</i>	John J. Foley Skilled Nursing Facility	Atlantic Harbor Center for Rehabilitation and Nursing
<i>Address</i>	14 Glover Drive Yaphank, NY. 11980	Same
<i>RHCF Capacity</i>	264	Same
<i>ADHC Program Capacity</i>	60	Same
<i>Type Of Operator</i>	County	LLC
<i>Class Of Operator</i>	Public	Proprietary
<i>Operator</i>	County of Suffolk	SSS Operating, LLC <u>Managing Members:</u> Israel Sherman 38.57% Samuel Sherman 26.94% <u>Members</u> Zalmen Horowitz 10.39% Jeffrey Goldstein 10.00% Cheskel Berkowitz 7.05% Joel Zupnick 7.05%

Character and Competence

- FACILITIES REVIEWED:

Residential Health Care Facilities

Absolut Center for Nursing & Rehab @ Alleghany	05/2007 to present
Absolut Center for Nursing & Rehab @ Aurora Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Dunkirk	05/2007 to present
Absolut Center for Nursing & Rehab @ Eden	05/2007 to present
Absolut Center for Nursing & Rehab @ Endicott	05/2007 to present
Absolut Center for Nursing & Rehab @ Gasport	05/2007 to present
Absolut Center for Nursing & Rehab @ Houghton	05/2007 to present
Absolut Center for Nursing & Rehab @ Orchard Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Salamanca	05/2007 to present
Absolut Center for Nursing & Rehab @ Three Rivers	05/2007 to present
Absolut Center for Nursing & Rehab @ Westfield	05/2007 to present
Avalon Gardens Rehabilitation and Health Care Center	05/2003 to present
Elcor Nursing & Rehabilitation Center	06/2011 to present
Fort Tryon Center for Rehabilitation & Nursing	01/2003 to 12/2008
Franklin Center for Rehabilitation & Nursing	01/2003 to 12/2008
Nassau Extended Care Facility	09/2011 to present
Niagara Rehabilitation & Nursing Center	06/2012 to present

North Westchester Restorative Therapy and Nursing Center	01/2011 to 06/2011
Park Avenue Extended Care Facility	09/2011 to present
Sunharbor Manor	04/2006 to present
The Hamptons Center for Rehabilitation and Nursing	11/2007 to present
Throgs Neck Extended Care Facility	09/2011 to present
Townhouse Center for Rehabilitation and Nursing	09/2011 to present
<u>Licensed Home Care Services Agency (LHCSA)</u>	
Pella Care, LLC (LHCSA)	01/2005 to present

- **INDIVIDUAL BACKGROUND REVIEW:**

Israel Sherman is a licensed nursing home administrator in good standing. Mr. Sherman discloses the following ownership interests:

Sunharbor Manor	04/2006 to present
Absolut Center for Nursing & Rehab @ Alleghany	05/2007 to present
Absolut Center for Nursing & Rehab @ Aurora Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Dunkirk	05/2007 to present
Absolut Center for Nursing & Rehab @ Eden	05/2007 to present
Absolut Center for Nursing & Rehab @ Endicott	05/2007 to present
Absolut Center for Nursing & Rehab @ Gasport	05/2007 to present
Absolut Center for Nursing & Rehab @ Houghton	05/2007 to present
Absolut Center for Nursing & Rehab @ Orchard Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Salamanca	05/2007 to present
Absolut Center for Nursing & Rehab @ Three Rivers	05/2007 to present
Absolut Center for Nursing & Rehab @ Westfield	05/2007 to present
Elcor Nursing & Rehabilitation Center	06/2011 to present
Niagara Rehabilitation & Nursing Center	06/2012 to present
Avalon Gardens Rehabilitation and Health Care Center	05/2003 to present
Franklin Center for Rehabilitation & Nursing	11/2002 to 12/2008
Fort Tryon Center for Rehabilitation & Nursing	11/2002 to 12/2008

Samuel Sherman is the Chief Financial Officer of Sunharbor Manor and has been in that position since 2007. Prior to his employment at Sunharbor Manor, Mr. Sherman was the Billing Manager at Franklin Center for Rehabilitation and Nursing from 2000 through 2007. Mr. Sherman discloses the following ownership interests:

Sunharbor Manor	04/2006 to present
Absolut Center for Nursing & Rehab @ Alleghany	05/2007 to present
Absolut Center for Nursing & Rehab @ Aurora Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Dunkirk	05/2007 to present
Absolut Center for Nursing & Rehab @ Eden	05/2007 to present
Absolut Center for Nursing & Rehab @ Endicott	05/2007 to present
Absolut Center for Nursing & Rehab @ Gasport	05/2007 to present
Absolut Center for Nursing & Rehab @ Houghton	05/2007 to present
Absolut Center for Nursing & Rehab @ Orchard Park	05/2007 to present
Absolut Center for Nursing & Rehab @ Salamanca	05/2007 to present
Absolut Center for Nursing & Rehab @ Three Rivers	05/2007 to present
Absolut Center for Nursing & Rehab @ Westfield	05/2007 to present
Niagara Rehabilitation & Nursing Center	06/2012 to present

Zalmen Horowitz is the office manager at Aron Kahan Insurance Services and has been employed in that position since January 2007. Prior to his employment at the insurance agency, Mr. Horowitz was an assistant principal at the Kedushas Naftali school in Brooklyn, New York from 1997 through 2007. He discloses no ownership interests in health facilities.

Jeffrey Goldstein, a licensed nursing home administrator in good standing, and has been employed as the operations manager at Bay Park Center for Nursing and Rehabilitation since July 2007. Mr. Goldstein discloses the following ownership interests:

Niagara Rehabilitation & Nursing Center	06/2012 to present
Throgs Neck Extended Care Facility	09/2011 to present
Nassau Extended Care Facility	09/2011 to present
Park Avenue Extended Care Facility	09/2011 to present
Townhouse Center for Rehabilitation and Nursing	09/2011 to present
The Hamptons Center for Rehabilitation and Nursing	11/2007 to present

Cheskel Berkowitz is the president of HHCNY Inc., a healthcare staffing agency and has held that position for the previous ten years. He is also the president of Specialty Rx, Inc., a pharmaceutical company since June 2004. Mr. Berkowitz discloses the following ownership interests:

North Westchester Restorative Therapy and Nursing Center	01/2011 to 06/2011
Pella Care, LLC	01/2005 to present

Joel Zupnick is employed as the vice president of HHCNY, Inc., a healthcare staffing agency and as the vice president of Specialty Rx, Inc., a pharmaceutical company. Mr. Zupnick was previously the Chief Financial Officer for Pella Care, LLC, a licensed home care services agency. He discloses the following ownership interest:

Pella Care, LLC	1/2005 to present
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Character and Competence – Analysis:

Cheskel Berkowitz personally, and HHCNY, Inc. were fined \$536.89 pursuant to a Stipulation and Order issued by the New York State Department of Labor for a violation of Article 6 of the New York State Labor Law: Unpaid Wages. A civil penalty was also imposed in the amount of \$200. The terms of the stipulation have been satisfied and HHCNY, Inc. is considered to be back in compliance.

No negative information has been received concerning the character and competence for the remaining applicants identified as new members.

A review of operations for the Sunharbor Manor for the period identified above reveals the following:

- The facility was fined \$10,000 pursuant to a Stipulation and Order for surveillance findings on November 23, 2009. Deficiencies were found under 10 NYCRR 415.12 - Quality of Care.

A review of operations for the Sunharbor Manor for the period identified above, results in a conclusion of substantially consistent high level of care since there were no repeat enforcements.

A review of the Absolut Center for Nursing and Rehabilitation at Endicott for the period identified above reveals the following:

- The facility was fined \$16,000 pursuant to a Stipulation and Order for surveillance findings on December 5, 2007. Deficiencies were found under 10 NYCRR 415.12 – Quality of Care; 10 NYCRR 415.12(c) – Quality of Care: Pressure Sores; 10 NYCRR 415.12(h)(1)(2) – Quality of Care: Accidents; 10 NYCRR 415.15(a) Medical Services: Medical Director; and 10 NYCRR 415.27 – Quality Assessment and Assurance.
- The facility was fined \$2,000 pursuant to a Stipulation and Order for surveillance findings on July 22, 2009. Deficiencies were found under 10 NYCRR 415.12(j) – Quality of Care: Hydration.
- The facility was fined \$22,000 pursuant to a Stipulation and Order for surveillance findings on November 5, 2010. Deficiencies were found under 10 NYCRR 415.4(b) – Investigation/Report; 10 NYCRR 415.12(c) – Quality of Care: Pressure Sores; 10 NYCRR 415.12(f) – Mental/ Psychological Difficulties; 10 NYCRR 415.26(a) – Administrator; 10 NYCRR 415.26(b)(3)(4) – Governing Body; 10 NYCRR 415.15(a)(1) – Medical Director; 10 NYCRR 415.27(a)(a,b,c)(1,2,3,ii, iv) – Quality Assurance.

As it relates to the stipulation and order for surveillance findings on December 5, 2007, it has been determined that the facility operators did not have adequate time to resolve the preexisting conditions that led to the citation and that were prevalent in the nursing facility regarding the failure to prevent and promote pressure sores. The operators had only assumed the operational interests of the facility in May, 2007.

Under the previous ownership and according to the facility's previous recertification survey conducted on October 19, 2006, there were several deficiencies leading to the aforementioned citation for the failure to prevent and promote pressure sores. A January 7, 2009 survey, which was the first subsequent survey following the December 5, 2007 findings, demonstrated that the operators of this application had successfully addressed the citations, as there were no repeat findings.

The stipulation and order resulting from the surveillance findings on November 5, 2010 has been signed and paid in full by the operators.

Thus, a review of operations for the Absolut Center for Nursing and Rehabilitation at Endicott for the period identified above, results in a conclusion of substantially consistent high level of care since there were no other repeat enforcements.

A review of the Hamptons Center for Rehabilitation and Nursing for the period identified above reveals the following:

- The facility was fined \$8,000 pursuant to a Stipulation and Order for surveillance findings on April 21, 2008. Deficiencies were found under 10 NYCRR 415.4(b)(1)(ii) – Resident Behavior and Facility Practices: Staff Treatment of Residents; 10 NYCRR 415.12 – Quality of Care; 10 NYCRR 415.12(h)(2) – Quality of Care: Accidents; and 10 NYCRR 415.26 – Organization and Administration.
- The facility was fined \$4,000 pursuant to a Stipulation and Order for surveillance findings on September 16, 2009. Deficiencies were found under 10 NYCRR 415.12(h)(1)(2) – Quality of Care: Accidents and Supervision and 415.26 – Administration.
- The facility was fined \$10,000 pursuant to a Stipulation and Order for surveillance findings on July 30, 2010. Deficiencies were found under 10 NYCRR 415.12 – Provide Care/Services for Highest Well Being.

A review of operations for the Hamptons Center for Rehabilitation and Nursing for the period identified above, results in a conclusion of substantially consistent high level of care since there were no repeat enforcements.

A review of operations for the Absolut Center for Nursing and Rehabilitation at Allegany, Absolut Center for Nursing and Rehabilitation at Aurora Park, Absolut Center for Nursing and Rehabilitation at Dunkirk, Absolut Center for Nursing and Rehabilitation at Eden, Absolut Center for Nursing and Rehabilitation at Gasport, Absolut Center for Nursing and Rehabilitation at Houghton, Absolut Center for Nursing and Rehabilitation at Orchard Park, Absolut Center for Nursing and Rehabilitation at Salamanca, Absolut Center for Nursing and Rehabilitation at Three Rivers, Absolut Center for Nursing and Rehabilitation at Westfield, Elcor Nursing and Rehabilitation Center, Fort Tryon Center for Rehabilitation & Nursing, Franklin Center for Rehabilitation & Nursing, Niagara Rehabilitation and Nursing Center, North Westchester Restorative Therapy and Nursing Center, Park Avenue Extended Care Facility, Throgs Neck Extended Care Facility, and Townhouse Center for Rehabilitation and Nursing for the periods identified above, results in a conclusion of substantially consistent high level of care since there were no enforcements.

A review of Pella Care, LLC reveals that a substantially consistent high level of care has been provided since there were no enforcements.

- **PROJECT REVIEW:**

No changes in the program or physical environment are proposed in this application.

Recommendation

From a programmatic perspective, approval is recommended.

Financial Analysis

Asset Purchase Agreement

The change in ownership will be effectuated in accordance with an executed asset purchase agreement, the terms of which are summarized below:

<i>Date:</i>	July, 30, 2012
<i>Seller:</i>	The County of Suffolk
<i>Purchaser:</i>	SSS Operating, LLC
<i>Purchased Assets:</i>	All of the seller's right, title and interest in the business and operation of the facility, all leasehold improvements, furniture, fixtures and equipment owned or leased by seller, all inventory, supplies and other articles of personal property except for the excluded assets. All contracts, agreements, leases, undertakings, commitments and other arrangements except for excluded assets, all residents' funds held in trust. All security deposits and prepayments for future services. All financial books and records, policies and procedures manuals, resident/patient records relating to the facility, all employee and payroll records, goodwill and copies of all other books and records relating to the facility. To the extent transferrable all licenses and permits relating to the ownership or operation of the facility as well as the Medicare and Medicaid provider numbers and the provider agreements. All assets of seller existing on or after the date hereof, other than excluded assets.
<i>Excluded Assets:</i>	Real Estate, all accounts receivable regardless of when billed relating to services prior to the closing, cash on hand in banks, cash equivalents, other investments. All marketable securities and accrued interest and dividends prior to closing. All insurance policies prior to closing, all rebates, refunds or settlements related to the period prior to closing. Any retroactive adjustments for goods or services rendered prior to the closing date. All telephone and fax numbers
<i>Liabilities Assumed:</i>	All liabilities and obligations exclusively arising with respect to the operation of the facility and/or basic assets on and after the date hereof with respect to ownership and or operation of the facility, including but not limited to healthcare, Medicare and Medicaid overpayment and assessment liabilities and obligations exclusively relating to services rendered by the facility on and after the date hereof, the balance sheet liabilities limited to the specific liabilities and amounts therefore as set forth therein and all cobra obligations of seller relating to the termination of employment of any employee employed by seller. Except as expressly provided, buyer shall not be responsible for any other obligations or liabilities of seller or the facility. Buyer shall not assume, nor be responsible or otherwise liable, for anything relating to or arising out of any collective bargaining or other labor or union contracts or agreements relating to the facility.
<i>Purchase Price:</i>	\$5,000,000
<i>Payment of Purchase Price:</i>	Payable at closing from members' equity.

The applicant has Submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility.

The member of the realty entity, SSS Realty, LLC, is as follows:

<u>Proposed Members</u>	<u>Percentage Ownership</u>
Cheskel Berkowitz	11.30%
Joel Zupnick	11.30%
Zalmen Horowitz	16.58%
Israel Sherman	15.35%
Samuel Sherman	10.35%
Jeffrey Goldstein	5.00%
Magda Manela	8.81%
Howard Pomerantz	5.28%
Moshe Mendlowitz	5.28%
Theodore Pollak	1.98%
Muriel Klein	1.98%
Mordechai Blass	1.98%
Steven Lowenbraun	4.81%

Lease Agreement

Facility occupancy will continue to be subject to a lease agreement, the terms of which are summarized as follows:

- Premises:* 264-bed proprietary residential health care facility (RHCF) that includes a 12-bed AIDS unit and an adult day health care program with a capacity of 60 slots located at 14 Glover Drive, Yaphank, New York, (Suffolk County)
- Lessor:* SSS Realty, LLC
- Lessee:* SSS Operating, LLC
- Term:* 30 years commencing on the execution of the lease
- Rental:* \$1,200,032 per year (\$100,002.67 per month)
- Provisions:* Triple net

The lease arrangement is a non-arm’s length agreement. The applicant has submitted an affidavit attesting to the relationship between the landlord and operating entity.

Currently, Medicaid capital cost is reimbursed based on the interest and depreciation reimbursement methodology. After the change in the ownership, capital reimbursement will be based on the return of and return on equity methodology. Based on depreciable asset value, the estimated remaining real property’s life is approximately 17 years.

Operating Budget

Following is a summary of the submitted operating budget, presented in 2012 dollars, for the first year subsequent to change in ownership:

Inpatient

	<u>Per Diem</u>	<u>Total</u>
Revenues:		
Medicaid	264.15	17,716,276
Medicare	572.80	5,295,521
Private Pay	305.55	2,529,343
Medicaid AIDS	364.16	951,914
Medicare AIDS	1,299.60	348,293
Assessment Revenue	16.53	<u>1,288,650</u>
Total		\$28,129,997
Expenses:		
Operating		\$26,727,859

Capital	1,133,437
Total	27,861,296
Net Income	\$ 268,701
Utilization: (patient days)	87,474
Occupancy	<u>90.78%</u>

The following is noted with respect to the submitted operating budget:

- Overall utilization is projected at 90.78%, while utilization by payor source is expected as follows:

Medicaid	76.67%
Medicare	10.57%
Private Pay	9.46%
Medicaid AIDS	2.99%
Medicare AIDS	0.31%

- Breakeven utilization is projected at 89.87%.

Outpatient ADHCP

	<u>Per Diem</u>	<u>Total</u>
Revenues:		
Medicaid	149.44	\$1,028,147
Other	125.50	<u>24,222</u>
Total		\$1,052,369
Expenses:		
Operating		<u>\$725,548</u>
Total		\$725,548
Net Income		\$ 326,821

Capability and Feasibility

The purchase price and initiation of operations, as a financially viable entity, will be funded through the member's equity. Please see BFA Attachment A for the member's net worth statements, which show that the applicant's do not have sufficient available liquid assets to cover all aspects of the application. However, the applicants have provided a Letter of Interest from Cornell Realty Management, LLC for a personal loan of \$6,000,000 at an 8% interest rate with a 10 year term and another Personal Loan from Nachum Sherman for \$1,500,000 with an interest rate of 6% for 10 years. With these personal loans, the applicants have sufficient assets to finance the acquisition of the operations.

Working capital requirements are estimated at \$4,764,474, based on two months' of first year expenses. \$2,382,237 of which, will be satisfied from the proposed member's equity with the balance of \$2,382,237, satisfied through a loan from Greystone at 5.6% over 5 years. Presented as BFA Attachment A, is the net worth of proposed members, which shows with the aforementioned personal loans, adequate resources are available to finance working capital. The submitted budget indicates that a net income of \$595,522 would be maintained during the first year following the change in ownership. The budget appears reasonable.

Presented as BFA Attachment B, is the pro-forma balance sheet of SSS Operating, LLC, which indicates positive members' equity of \$7,382,242 as of the first day of operations.

It is noted that assets include \$4,706,502 in goodwill, which is not an available liquid resource, nor is it recognized for Medicaid reimbursement purposes. Thus, for Medicaid purposes the net asset position would be a positive member's equity position of \$2,675,740.

Presented as BFA Attachment C, is a financial summary of John J. Foley from 2009 through 2011. As shown on Attachment C, the facility had an average negative working capital position and an average negative net asset position. Also, the facility achieved an average net loss of \$8,967,691 from the period 2009 through 2011. The loss was caused by various county allocations that make up the current operating budget of the facility and are the primary reason for the substantial operating loss. One of the largest reasons for the losses is the county's obligation to meet the fringe benefits that the county has provided to its employees, which was over 120% of the salaries. The new operator has reduced this amount to 42.95% of salaries. The applicant also intends to increase permanent nursing staff but at the same time, they are also reducing overall nursing costs with the reduction of the temporary nursing staff that is currently serving the patients. These changes will have an overall positive impact on the facility's net revenue.

The facility is also eliminating transportation costs related to its ADHCP of approximately \$500,000. Because the facility's ADHCP Medicaid rate does not include transportation, this service will be billed by the individual ambulette company. Also with this new operator, it is estimated that the utilization will return to the facility's historical occupancy levels of approximately 92.8%, which the facility had achieved up until the announcement of the sale back in 2011. The new operator is also not restricted as the county facility was to admit predominantly Medicaid patients due to the restrictions placed on public homes. They are now able to admit more Medicare and Private pay patients, which is shown in the year 1 and 3 utilization projections. This revised payor mix, while higher than what the county was admitting to the facility, is still lower than the payer utilization percentages of other homes in the region and appears to represent a reasonable projection of the payer mix for the facility in the initial years of the new operation.

Presented as BFA Attachment D, is a financial summary of Sunharbor Manor from 2009 through 2011. As shown on Attachment D, the facility had an average positive working capital position and an average positive net asset position. Also, the facility achieved an average net income of \$1,684,090 from the period 2009 through 2011.

Presented as BFA Attachment E, is the financial summary of Absolut Center for Nursing & Rehab @ Alleghany from 2009 through 2011.

As shown on Attachment E, the facility had an average positive working capital position and an average positive net asset position. The facility has achieved an average net income of \$103,552 from 2009 through 2011.

Presented as BFA Attachment F, is the financial summary of Absolut Center for Nursing & Rehab @Aurora Park from 2009 through 2011. As shown on Attachment F, the facility had an average positive working capital position and average positive net asset position. Also, the facility achieved an average net income of \$904,224 from 2009 through 2011.

Presented as BFA Attachment G, is the financial summary of Absolut Center for Nursing & Rehab @ Dunkirk from 2009 through 2011. As shown on Attachment G, the facility had an average positive working capital position and an average positive net asset position. Also, the facility achieved an average net income of \$54,213 from 2009 through 2011.

Presented as BFA Attachment H, is the financial summary of Absolut Center for Nursing & Rehab @ Eden from 2009 through 2011. As shown on Attachment H, the facility had an average negative working capital position and an average negative net asset position. The facility incurred an average net loss of \$157,175 during the period 2009 through 2011. The applicant has indicated that the reason for the historical losses is the result of a 40-bed facility being highly susceptible to changes in volume and case mix due to its size. The facility has reduced operating expenses based on a budgeted system that reduces expenses. Along with improvements in payer mix and case mix, these changes have resulted in improvements in financial performance that have been noted in 2011, with the drop in the loss by over \$230,000 from 2010.

Presented as BFA Attachment I is the financial summary of Absolut Center for Nursing & Rehab @ Endicott from 2009 through 2011. As shown on Attachment I, the facility had an average positive working capital position and an average negative net asset position. Also, the facility incurred an average net loss of \$10,093 during the period 2009 through 2011. The applicant has indicated that the facility has had environmental deficiencies that required the facility to make substantial capital improvements and change management in order to correct the deficiencies. A new quality assurance nurse has been hired to monitor the corrective plans and the facility's volume and CMI are improving. This initiative appears to have worked for the facility, as can be seen with the significant positive turnaround in net income for 2011.

Presented as BFA Attachment J, is the financial summary of Absolut Center for Nursing & Rehab @ Gasport from 2009 through 2011. As shown on Attachment J, the facility had an average negative working capital position and an average negative net asset position. Also, the facility incurred an average net profit of \$100,997 during the period 2009 through 2011.

Presented as BFA Attachment K, is the financial summary of Absolut Center for Nursing & Rehab @ Houghton from 2009 through 2011.

As shown on Attachment K, the facility had an average negative working capital position and an average negative net asset position. Also, the facility incurred an average net loss of \$171,312 during the period 2009 through 2011.

The applicant has indicated that the facility is located in an economically distressed rural area of New York State and the facility's payer mix has a significant impact on its financial status. The facility hired a new administrator to improve the referral network from area hospitals and improve the financial performance of the facility by increasing admissions of Medicare and commercial residents.

Presented as BFA Attachment L, is the financial summary of Absolut Center for Nursing & Rehab @ Orchard Park from 2009 through 2011. As shown on Attachment L, the facility had an average positive working capital position and an average negative net asset position. Also, the facility incurred an average net loss of \$714,656 during the period 2009 through 2011. The applicant has indicated that the loss in 2010 was the result of occupancy and case mix issues and prior revenue adjustments in 2010. The facility improved operations by initiating a budgeted system that reduces expenses when volume and CMI decrease or increase. These budget changes along with improvements in payer mix and case mix have resulted in improvements in financial performance that were noted in 2011 prior to the decrease in revenues due to prior years third party settlements of \$2,620,253 that was booked in 2011. Without this one-time event the facility would have had a net income of \$528,233 for the year.

Presented as BFA Attachment M, is the financial summary of Absolut Center for Nursing & Rehab @ Salamanca from 2009 through 2011. As shown on Attachment M, the facility had an average positive working capital position and an average positive net asset position. Also, the facility achieved an average net income of \$59,342 during the period 2009 through 2011. The 2011 loss is due to an increase in bad debt reserves from 2010 to 2011 of \$181,901 and expenses increased by \$408,256 due to prior period adjustments. Without these two factors the facility would have had a small net income for the year of approximately \$17,567.

Presented as BFA Attachment N, is the financial summary of Absolut Center for Nursing & Rehab @ Three Rivers from 2009 through 2011. As shown on Attachment N, the facility had an average positive working capital position and an average positive net asset position during the period 2009 through 2011. Also, the applicant achieved an average net loss of \$200,771 during the period 2009 through 2011. The loss was caused by a decrease in revenues from 2010 to 2011 and an increase in operating expenses from 2010 to 2011 due to an increase in patient care mix. This also resulted in higher revenue for 2011, but this was negated by prior years' third party settlement amounts of \$1,381,976, which was booked in 2011. Without this settlement, the facility would have had a net income of \$590,423 in 2011.

Presented as BFA Attachment O, is the financial summary of Absolut Center of Nursing & Rehab @ Westfield from 2009 through 2011. As shown on Attachment O, the facility had an average positive working capital position and an average positive net asset position. The applicant achieved an average net income of \$681,394 during the period 2009 through 2011.

Presented as BFA Attachment P is the financial summary of The Hamptons Center for Rehab & Nursing from 2009-2011. As shown on attachment P, the facility had an average negative working capital and net asset positions, and generated an average net loss of \$1,424,545 during the period 2008 through 2011. The loss was caused by the facility just opening in July 2006, and being under the initial budget based rate. In 2009, the facility was able to reduce their losses by almost one million dollars from 2008. This was accomplished through a reduction in costs and a favorable working capital loan refinancing, as well as the facility receiving a rebased rate based on the 2008 cost report submission. Also, the facility reduced expenses by using more staff and reducing the use of outside agencies. By the end of 2010, the facility achieved its first profitable year of operations with a net income of \$3,911,918 and in 2011 it achieved its second profitable year with a net income of \$866,956. During the first few years that the facility was in operation, the losses were funded by a credit line from the bank and from member's funds, which were sufficient to cover historical and projected losses.

Based on the preceding, and subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Net Worth of Proposed Members
BFA Attachment B	Pro-forma Balance sheet SSS Operating, LLC, d/b/a Atlantic Harbor Center for Rehabilitation and Nursing
BFA Attachment C	Financial Summary John J Foley Skilled Nursing Facility
BFA Attachment D	Financial Summary, Sunharbor Manor
BFA Attachment E	Financial Summary Absolut Center for Nursing & Rehab @ Alleghany
BFA Attachment F	Financial Summary Absolut Center for Nursing & Rehab @Aurora Park
BFA Attachment G	Financial Summary Absolut Center for Nursing & Rehab @ Dunkirk
BFA Attachment H	Financial Summary Absolut Center for Nursing & Rehab @ Eden
BFA Attachment I	Financial Summary Absolut Center for Nursing & Rehab @ Endicott
BFA Attachment J	Financial Summary Absolut Center for Nursing & Rehab @ Gasport
BFA Attachment K	Financial Summary Absolut Center for Nursing & Rehab @ Houghton
BFA Attachment L	Financial Summary Absolut Center for Nursing & Rehab @ Orchard Park
BFA Attachment M	Financial Summary Absolut Center for Nursing & Rehab @ Salamanca,
BFA Attachment N	Financial Summary Absolut Center for Nursing & Rehab @ Three Rivers
BFA Attachment O	Financial Summary Absolut Center of Nursing & Rehab @ Westfield
BFA Attachment P	Financial Summary The Hamptons Center for Rehab & Nursing

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 7th day of February, 2013, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish SSS Operating, LLC d/b/a Atlantic Harbor Center for Rehabilitation and Nursing as the new operator of John J. Foley Skilled Nursing Facility, an existing 264-bed County residential health care facility (RHCF), and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

122194 E

FACILITY/APPLICANT:

SSS Operating, LLC d/b/a Atlantic Harbor
Center for Rehabilitation and Nursing

APPROVAL CONTINGENT UPON:

1. The submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
2. Submission of an executed Loan commitment for working capital that is acceptable to the Department of Health. [BFA]
3. Submission of an executed Personal Loan commitment for the purchase of the operations of the facility that is acceptable to the Department. [BFA]
4. Submission of a photocopy of an executed facility lease agreement, which is acceptable to the Department. [CSL]
5. Submission of a photocopy of the applicant's executed proposed articles of organization, which is acceptable to the Department. [CSL]
6. Submission of a photocopy of the applicant's executed proposed operating agreement, which is acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

N/A

Documentation submitted to satisfy the above-referenced contingencies (4 copies) should be submitted within sixty (60) days to:

Mr. Keith McCarthy
Acting Director
Bureau of Project Management
NYS Department of Health
Empire State Plaza
Corning Tower, Room 1842
Albany, New York 12237