

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

SPECIAL ESTABLISHMENT AND PROJECT REVIEW COMMITTEE

AGENDA

March 9, 2017

*Immediately following the Committee on Codes, Regulations and Legislation
(scheduled to begin at 9:15 a.m.)*

- *90 Church Street 4th Floor, Room 4A & 4B, New York City*
- *New York State Department of Health Offices at 584 Delaware Avenue, 2nd Floor Video Conference Room, Buffalo, NY 14202*
- *New York State Department of Health Offices at the Triangle Building, 335 East Main Street, 1st Floor Conference Room, Rochester, New York 14604*

I. COMMITTEE ON ESTABLISHMENT AND PROJECT REVIEW

Gary Kalkut, M.D., Vice Chair

A. Applications for Establishment and Construction of Health Care Facilities/Agencies

Ambulatory Surgery Centers– Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>
1. 162026 B	Manhattan RSC, LLC d/b/a Manhattan Reproductive Surgery Center (New York County)



Project # 162026-B
**Manhattan RSC, LLC d/b/a Manhattan Reproductive
Surgery Center**

Program: Diagnostic and Treatment Center **County:** New York
Purpose: Establishment and Construction **Acknowledged:** July 15, 2016

Executive Summary

Description

Manhattan RSC, LLC d/b/a Manhattan Reproductive Surgery Center (MRSC), a New York limited liability company, requests approval to establish and construct a single-specialty Article 28 freestanding ambulatory surgery center (FASC) specializing in gynecological services. The facility will be housed in approximately 10,467 square feet of leased space on the 21st floor of a building located at 65 Broadway, New York (New York County). The proposed FASC will include one Class "B" procedure room, two Class "C" operating rooms, pre-op and recovery areas with three pre-op bays and eight recovery bays, and the requisite support areas.

George D. Kofinas, M.D. is the sole member of MRSC and will serve as the facility's Medical Director. Dr. Kofinas is board-certified in Obstetrics and Gynecology (OB/GYN) and in Reproductive Endocrinology and Infertility. The Center will offer traditional gynecological services and reproductive endocrinology-infertility services, including in-vitro fertilization.

OPCHSM Recommendation

Contingent approval with an expiration of the operating certificate five years from the date of its issuance.

Need Summary

The applicant projects 838 procedures in Year One with Medicaid at 2% and charity care at 2%. The applicant indicated that, upon approval of this application, the physicians will bring the OBS practices into the regulatory environment of an Article 28 FASC, providing a measure of compliance with the latest standards of safe health care delivery.

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 of \$4,131,814 will be met through member's equity of \$651,459; \$680,355 in Landlord Allowances; and a bank loan for \$2,800,000 at 5.75% interest rate for a five-year term. JP Morgan Chase Bank, N.A has provided a letter of interest. The projected budget is as follows.

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$4,808,952	\$4,954,303
Expenses	<u>\$3,357,201</u>	<u>\$3,378,560</u>
Net Income/(Loss)	\$1,451,751	\$1,575,743

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, 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 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 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]
4. Submission of a signed agreement with an outside, independent entity, acceptable to the Department, to provide annual reports to DOH following the completion of each full year of operation. Reports will be due within 60 days of the conclusion of each year of operation as identified by the Effective Date on the Operating Certificate issued at project completion. Each report is for a full operational year and is not calendar year based. For example, if the Operating Certificate Effective Date is June 15, 2018, the first report is due to the Department no later than August 15, 2019. Reports must include:
 - a. Actual utilization including procedures;
 - b. Breakdown of visits by payor source;
 - c. Percentage of charity care provided by visits;
 - d. Number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - e. Number of emergency transfers to a hospital;
 - f. Number of nosocomial infections recorded;
 - g. A brief list of all efforts made to secure charity cases; and
 - h. A brief description of the progress of contract negotiations with Medicaid managed care plans.[RNR]
5. Submission of an executed loan commitment, acceptable to the Department of Health. [BFA]
6. Submission of an executed working capital loan commitment, acceptable to the Department of Health. [BFA]
7. Submission of a photocopy of the applicant's amended Administrative Services Agreement, acceptable to the Department. [CSL]
8. Submission of a photocopy of the applicant's amended Development Services Agreement, acceptable to the Department. [CSL]
9. Submission of a photocopy of the applicant's amended Billing Services Agreement, acceptable to the Department. [CSL]
10. Submission of a photocopy of the applicant's Anti-Kickback Statement signed by the applicant's attorney, acceptable to the Department. [CSL]

11. Submission of a photocopy of the applicant's amended and executed Operating Agreement, acceptable to the Department. [CSL]
12. Submission of a photocopy of the applicant's lease agreement, acceptable to the Department. [CSL]
13. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAEFP Drawing Submission Guidelines DSG-03 Outpatient Facilities. [AER]

Approval conditional upon:

1. The project must be completed within three years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before May 1, 2017 and construction must be completed by January 1, 2018, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]
4. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
5. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
6. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
7. The clinical space must be used exclusively for the approved purpose. [HSP]

Council Action Date

March 9, 2017

Need Analysis

Analysis

The service area consists of New York County. New York County has a total of 15 freestanding ambulatory surgery centers: eight multi-specialty ASCs and seven single-specialty ASCs. The table below shows the number of patient visits at ambulatory surgery centers in New York County for 2014 and 2015.

ASC Type	Facility Name	Total Patient Visits	
		2014	2015
Single	Carnegie Hill Endo, LLC	11,426	11,898
Multi	Center for Specialty Care Inc.	3,885	3,759
Multi	East Side Endoscopy	9,284	9,302
Multi	Fifth Avenue Surgery Center	1,544	751
Multi	Gramercy Park Digestive Disease Center	9,343	12,613
Multi	Gramercy Surgery Center, Inc.	2,667	3,030
Single	Kips Bay Endoscopy Center, LLC	9,084	9,561
Single	Manhattan Endoscopy Center, LLC	12,656	12,293
Multi	Manhattan Surgery Center	2,502	5,087
Single	Mid-Manhattan Surgi-Center	3,900	3,360
Multi	Midtown Surgery Center	3,161	2,598
Single	Retinal Ambulatory Surgery Center of New York Inc.	1,984	2,963
Multi	SurgiCare of Manhattan, LLC	3,734	4,439
Single	West Side GI	12,549	14,608
Single	Yorkville Endoscopy Center	10,685	8,596
Total		98,404	104,858

Source: SPARCS-2016

Patient visits to ASCs in New York County showed a 6.6% year-to-year increase from 2014 to 2015. The population of New York County in 2010 was 1,585,873 with 167,763 (10.6%) females between the ages of 35 and 49. This is the primary population group seeking treatment for infertility. Per Cornell Program on Applied Demographics (PAD) projection data, this population group is estimated to grow to 183,707 by 2025 and represent 11.4% of the projected population of 1,615,772.

The number of projected procedures is 838 in Year One and 863 in Year Three. These projections are based on the current practices of participating surgeons. The table below shows the projected payor source utilization for Years 1 and 3.

Projections-162026	Year One		Year Three	
	Volume	%	Volume	%
Commercial Ins - MC	662	79.0%	682	79.0%
Medicare - MC	17	2.0%	17	2.0%
Medicaid - MC	17	2.0%	17	2.0%
Private pay	125	15.0%	130	15.0%
Charity Care	17	2.0%	17	2.0%
Total	838	100.00%	863	100.00%

The Center initially plans to obtain contracts with the following Medicaid Managed care plans: Fidelis and Healthfirst. The applicant states that there are nine Federally Qualified Health Centers (FQHC) located within one mile of the proposed site. The center plans to reach out to the neighboring FQHCs to provide service to underinsured patients desiring in-vitro fertilization (IVF) services.

Conclusion

Approval of this project will bring gynecological and infertility surgery services into an Article 28 setting for the communities of New York County.

Recommendation

From a need perspective, contingent approval is recommended.

Program Analysis

Project Proposal

Proposed Operator	Manhattan RSC, LLC
Doing Business As	Manhattan Reproductive Surgery Center
Site Address	65 Broadway New York, NY (New York County)
Surgical Specialties	Single Specialty: Gynecological Services
Operating Rooms	2 (Class C)
Procedure Rooms	0
Hours of Operation	7 days a week, 6:00 am to 8:00 pm,
Staffing (1st / 3rd Year)	12.0 FTEs / 12.0 FTEs
Medical Director	George D. Kofinas, M.D., FACOG
Emergency, In-Patient & Backup Support Services Agreement and Distance	Will be provided by Mt Sinai Hospital West 5.6 miles / 29 minutes
On-call service	An answering service with access to the surgeon (or on-call physician) will be provided

Character and Competence

The sole member of Manhattan RSC, LLC is George D. Kofinas, M.D.

Dr. Kofinas is Board-certified in Obstetrics and Gynecology and holds sub-certification in Reproductive Endocrinology and Infertility. He has operated a private practice with a focus on reproductive medicine, surgery and in-vitro fertilization (IVF) for over 20 years and has over 30 years of experience in the field of Reproductive Endocrinology and Infertility. From 1987 to 2000, while at the Brooklyn Hospital Center, Dr. Kofinas served in several positions, to include: Chief of Reproductive Endocrinology and Infertility; Chairman of the Department of Obstetrics and Gynecology; and Director of the Residency Program. Since November 2000, he has served as New York Methodist Hospital's Chief of Reproductive Endocrinology and Infertility. Dr. Kofinas plans to perform procedures at the proposed Center as well as serve as the Center's 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.

Dr. Kofinas disclosed three open malpractices cases.

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 have a referral relationship with a local FQHC which, along with other neighboring diagnostic and treatment centers and outpatient clinics, will serve as primary care alternatives for those patients who do not have access to primary care services. The facility will also establish and maintain a list of nearby primary care physicians who are accepting new patients. The Center will serve all patients without regard to personal characteristics or source of payment. A sliding fee scale and charity care will be available for those patients who are uninsured or underinsured and desire general gynecological surgical and reproductive endocrinology/infertility ambulatory surgical services.

The Center intends on utilizing a state-of-the-art electronic medical record and will consider integrating into a Health Information Exchange. The Center also plans on exploring possible participation in an Accountable Care Organization.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Lease Rental Agreement

The applicant submitted an executed lease for the proposed site, summarized below:

Date:	September 22, 2016
Premises:	10,467 square feet on the 21 st floor of 65 Broadway New York
Landlord:	65 Broadway Owner LLC
Lessee:	Manhattan RSC, LLC
Term:	16 years with one five-year renewal option
Rental:	\$512,883 annually (\$42,740.25/month or \$49 per sq. ft.) with a 2.25% annual rate increase
Provisions:	Triple Net, lessee pays all fees associated with the leased asset

The applicant provided an affidavit stating that the lease is an arm's length arrangement. The applicant submitted letters from two NYS licensed realtors attesting to the rent being of fair market value.

Administrative Services Agreement

The applicant submitted an executed Administrative Services Agreement (ASA), as summarized below:

Date:	January 5, 2017
Facility/Operator:	Manhattan RSC, LLC
Administrator:	Frontier Healthcare Management Services, LLC
Service Provided:	Administrative services including: staffing/scheduling; accounting; purchasing; compliance with policies and procedures, and medical staff By-laws/rules; medical staff application and credentialing; accreditation; physical plant and materials management; nursing and administration.
Term:	Five years with two additional automatic two-year renewals
Fee/Compensation:	\$250,000 base fee per year, with a 1.5% cost of living increase per year; \$350,000 bonus compensation for every \$4 million operating profit the facility generates during any year of the contract.

While Frontier Healthcare Management Services, LLC will provide all of the above services, the Licensed Operator retains ultimate authority, responsibility and control for the operations.

Billing Services Agreement

The applicant submitted an executed Billing Services Agreement (BSA), as summarized below:

Date:	January 5, 2017
Facility/Operator:	Manhattan RSC, LLC
Contractor:	Frontier Healthcare Billing Services, LLC
Service Provided:	All Billing services including obtaining/entering pre-authorization patient information into the scheduling system, verifying patients eligibility and benefits, answering inquiries on claims on behalf of the facility, submitting bills, referring uncollectible bills to a collection agent and providing billing reports.
Term:	Five-years with two additional automatic two-year renewals
Billing Fee:	\$30 per technical and professional claim and a \$4,170 monthly fee per FTE required for benefit verification/authorization. A 3% per year cost of living increase shall be applied to the preceding years' fees at the beginning of each calendar year.

While Frontier Healthcare Billing Services, LLC. Will provide all of the above services, the Licensed Operator retains ultimate authority, responsibility and control for the operations.

Total Project Cost and Financing

Total project costs, estimated at \$4,131,814, are broken down as follows:

Renovation & Demolition	\$2,512,080
Design Contingency	\$251,208
Construction Contingency	\$251,208
Movable Equipment	\$986,328
Interim Interest Expense	106,400
CON Application Fee	\$2,000
CON Processing Fee	<u>22,590</u>
Total Project Cost	\$4,131,814

Project costs are based on a start date of May 1, 2017, with an eight-month construction period.

The applicant's financing plan appears as follows:

Cash	\$651,459
Landlord Improvement Allowance	\$680,355
Bank Loan (5.75% interest, 5-year term)	<u>\$2,800,000</u>
Total	\$4,131,814

JP Morgan Chase Bank, N.A. has provided a letter of interest for the loan at the stated terms.

Operating Budget

The applicant has submitted their first and third year operating budgets, in 2016 dollars, as summarized below:

	Year One		Year Three	
	Per Proc.	Total	Per Proc.	Total
<u>Revenues</u>				
Medicaid	\$903.88	\$15,366	\$931.24	\$15,831
Medicare	\$1,346.88	\$22,897	\$1,387.59	\$23,589
Commercial	\$6,056.51	\$4,009,409	\$6,056.59	\$4,130,593
Private Pay	\$6,090.24	<u>\$761,280</u>	\$6,033.00	<u>\$784,290</u>
Total Revenues		\$4,808,952		\$4,954,303
<u>Expenses</u>				
Operating	\$2,964.98	\$2,484,656	\$2,941.91	\$2,538,869
Capital	<u>\$1,041.22</u>	<u>\$872,545</u>	<u>\$972.99</u>	<u>\$839,691</u>
Total Expenses	\$4,006.21	\$3,357,201	\$3,914.90	\$3,378,560

Net Income or (Loss)	<u>\$1,451,751</u>	<u>\$1,575,743</u>
Utilization (procedures)	838	863

Utilization by payor source for the first and third years is anticipated as follows:

Medicaid	2.0%
Medicare	2.0%
Commercial	79.0%
Charity	2.0%
Private Pay	<u>15.0%</u>
Total	100.0%

The following is noted with respect to the submitted budget:

- Revenues are based on current and projected Federal and State government reimbursement rates, with commercial payor rates reflecting adjustments based on experience in the region.
- Expense assumptions are based upon staffing, operating and capital costs as determined based on the experience of the participating physicians, as well as the experience of other FASCs in New York State in providing similar service patient care.
- Utilization projections are based on the current caseloads of participating physicians. The doctors have submitted letters in support of their utilization projections
- Breakeven is approximately 83.65% of projected utilization or 701 procedures in Year One, and 81.46% of projected utilization or 703 procedures in Year Three.

The budgets are reasonable.

Capability and Feasibility

The total project cost of \$4,131,814 will be satisfied with \$651,459 equity from the proposed member; a \$680,355 landlord improvement allowance; and a bank loan for \$2,800,000 at the above stated terms. JP Morgan Chase Bank, N.A. has provided a letter of interest.

The working capital requirement is estimated at \$565,613 based on two months of third year expenses. The applicant will provide \$315,613 from personal resources and will finance \$250,000 for a five-year term at approximately 6% interest. JP Morgan Chase Bank, N.A. has provided a letter of interest. BFA Attachment A is the net worth statements of the applicant member, which indicates sufficient liquid resources to meet the equity and working capital requirements. BFA Attachment B is the pro-forma balance sheet that shows operations will start with \$1,370,328 in equity.

MSRC projects net income of \$1,451,751 and \$1,575,743 in the first and third years, respectively. Revenues for Medicare and Medicaid are based on current and projected Federal and State government reimbursement rates, with commercial payor rates reflecting adjustments based on experience in the region. The budgets are reasonable.

The applicant recognizes the need to address the eventual change over to Managed Care Organizations (MCOs). They are not yet in a position to execute and negotiate contracts or letters of intent with MCOs at this time, but plan on establishing contracts upon approval of this application.

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendation

From a financial perspective, contingent approval is recommended.

Supplemental Information

Surrounding Hospital Responses

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 in their service areas.

New York-Presbyterian/Lower Manhattan -- No Response

170 Williams Street
New York, New York 10038

Mount Sinai Beth Israel -- No Response

Fist Avenue at 16th Street
New York, New York 10003

NY Eye & Ear Infirmary of Mount Sinai -- No Response

310 East 14th Street
New York, New York 10003

NYU Hospital for Joint Diseases -- No Response

301 East 17th Street
New York, New York 10003

New York Methodist Hospital -- No Response

506 Sixth Street
Brooklyn, New York 11215

DOH Comment

In the absence of comments from hospitals in the area of the ASC, the Department finds no basis for reversal or modification of the recommendation for approval of this application based on public need, financial feasibility and owner/operator character and competence.

Attachments

BFA Attachment A	Personal Net Worth Statement of Proposed Member of Manhattan RSC, LLC d/b/a Manhattan Reproductive Surgery Center
BFA Attachment B	Pro Forma Balance Sheet of Manhattan RSC, LLC d/b/a Manhattan Reproductive Surgery Center
BHFP Attachment	Map

Pro Forma Balance Sheet of Manhattan RSC, LLC d/b/a Manhattan
Reproductive Surgery Center

ASSETS

Cash	
Leasehold Improvements	\$2,400,000
Movable Equipment	\$986,328
Organization Expenses	\$784,000
TOTAL ASSETS	\$4,170,328

Liabilities and Member Equity

LIABILITIES

Leasehold Improvement Loan	\$2,000,000
Equipment Loan	\$800,000

TOTAL LIABILITIES	\$2,800,000
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MEMBER EQUITY	\$1,370,328
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TOTAL LIABILITIES AND MEMBER EQUITY	\$4,170,328
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162026 Manhattan RSC

