

**STATE OF NEW YORK**  
**PUBLIC HEALTH AND HEALTH PLANNING COUNCIL**

**ANNUAL MEETING**

**AGENDA**

*June 3, 2021*

*Immediately following the Committee on Codes, Regulations and Legislation meeting  
(Codes scheduled to begin at 9:30 a.m.)*

*Via Live Webcast*

**I. INTRODUCTION OF OBSERVERS**

Jeffrey Kraut, Chair

**II. ELECTION OF OFFICERS**

**A. Election of Vice Chairperson**

**B. Announce Committee Chairpersons and Vice Chairpersons**

- 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. ADOPTION OF 2022 PHHPC MEETING DATES**

2022 Public Health and Health Planning Council Meeting Dates

**IV. APPROVAL OF MINUTES**

April 8, 2021 Meeting Minutes

**V. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES**

**Report of the Department of Health**

Howard A. Zucker, M.D., J.D., Commissioner of Health

**VI. REGULATION**

**Report of the Committee on Codes, Regulations and Legislation**

Angel Gutiérrez, M.D., Chair of the Committee on Codes, Regulations and Legislation

**For Discussion**

- 20-22 Amendment of Section 405.11 of Title 10 NYCRR  
(Hospital Personal Protective Equipment (PPE) Requirements)
- 20-23 Amendment of Section 415.19 of Title 10 NYCRR  
(Nursing Home Personal Protective Equipment (PPE) Requirements)
- 20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR;  
Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and  
Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health  
Coordination System)
- 20-27 Amendment of Section 405.11 and Addition of New Sections 77.13, 77.14  
and 415.33 to Title 10 NYCRR (COVID-19 Confirmatory Testing)
- 20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to  
Title 10 NYCRR (Investigation of Communicable Disease; Isolation and Quarantine)
- 21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing  
Home and Adult Care Facility Residents and Personnel)

**VII. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS**

**Report of the Committee on Establishment and Project Review**

Peter Robinson, 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**

**Hospice Services - Construction**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>          | <b><u>E.P.R.C. Recommendation</u></b> |
|----|----------------------|---|---------------------------------------|
| 1. | 211032 C             | Niagara Hospice, Inc.<br>(Niagara 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

**NO APPLICATIONS**

**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

**CON Applications**

**Certified Home Health Agencies - Construction**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>      | <b><u>E.P.R.C. Recommendation</u></b> |
|----|----------------------|---------------------------------------|---------------------------------------|
| 1. | 211039 C             | Guthrie Home Health<br>(Tioga County) | 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**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>           | <b><u>E.P.R.C. Recommendation</u></b> |
|----|----------------------|--|---------------------------------------|
| 1. | 211035 E             | Griffiss Surgery Center<br>(Oneida County) | 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 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 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**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>   | <b><u>E.P.R.C. Recommendation</u></b> |
|----|----------------------|--|---------------------------------------|
| 1. | 202273 B             | 147 Wellness LLC t/b/k/a<br>Midtown Endoscopy & Surgical<br>Center, LLC<br>(New York County)<br>Mr. Kraut - Interest | Contingent Approval                   |

**Certified Home Health Agencies – Establish/Construct**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>                                      | <b><u>E.P.R.C. Recommendation</u></b> |
|----|----------------------|---|---------------------------------------|
| 1. | 202250 E             | Assured Care Home Health, LLC<br>(Nassau County)<br>Mr. Kraut Recusal | Contingent Approval                   |

**CATEGORY 6:** Applications for Individual Consideration/Discussion

**NO APPLICATIONS**

**VIII. ADMINISTRATIVE LAW JUDGE’S REPORT AND RECOMMENDATION**

|    | <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>   |
|----|----------------------|--|
| 1. | 171041 E             | Shining Star Home Health Care<br>(Kings County)<br>Ms. Carver-Cheney - Recusal |

**IX. NEXT MEETING**

July 15, 2021

July 29, 2021

**X. ADJOURNMENT**

## Public Health and Health Planning Council 2022 Timeline

| <b>PHHPC<br/>Mailing #1<br/>(Committee Day<br/>Mailing)</b> | <b>PHHPC<br/>Committee Meeting</b> | <b>PHHPC<br/>Mailing #2<br/>(Full Council Mailing)</b> | <b>PHHPC<br/>Full Council<br/>Meeting</b> | <b>PHHPC<br/>Meeting<br/>Location</b> |
|---|------------------------------------|--|---|---------------------------------------|
| <b>01/20/22</b>   | <b>01/27/22</b>                    | <b>02/03/22</b>  | <b>02/10/22</b>                           | <b>NYC</b>                            |
| <b>03/17/22</b>   | <b>03/24/22</b>                    | <b>03/31/22</b>  | <b>04/07/22</b>                           | <b>Albany</b>                         |
| <b>05/12/22</b>   | <b>05/19/22</b>                    | <b>05/26/22</b>  | <b>06/02/22</b>                           | <b>NYC</b>                            |
| <b>07/07/22</b>   | <b>07/14/22</b>                    | <b>07/21/22</b>  | <b>07/28/22</b>                           | <b>Albany</b>                         |
| <b>09/08/22</b>   | <b>09/15/22</b>                    | <b>09/29/22</b>  | <b>10/06/22</b>                           | <b>NYC</b>                            |
| <b>11/10/22</b>   | <b>11/17/22</b>                    | <b>12/01/22</b>  | <b>12/08/22</b>                           | <b>Albany</b>                         |

*PHHPC meetings begin @ 10:00 a.m. (Time subject to change)*

*Albany Location – Empire State Plaza, Concourse Level, Meeting Room 6*

*NYC Location - 90 Church Street, Meeting Rooms A/B, 4<sup>th</sup> Floor, New York, NY*

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

**Minutes**  
**April 8, 2021**

The meeting of the Public Health and Health Planning Council was held on Thursday, April 8, 2021 via Zoom and live webcast. Chairman Jeffrey Kraut presided.

**COUNCIL MEMBERS PRESENT**

|                      |                         |
|----------------------|-------------------------|
| Dr. John Bennett     | Dr. Ms. Ann Monroe      |
| Dr. Howard Berliner  | Ms. Ellen Rautenberg    |
| Dr. Jo Ivey Boufford | Mr. Peter Robinson      |
| Dr. Lawrence Brown   | Dr. John Ruge           |
| Ms. Carvery-Cheney   | Ms. Nilda Soto          |
| Dr. Angel Gutiérrez  | Dr. Theodore Strange    |
| Dr. Gary Kalkut      | Mr. Hugh Thomas         |
| Mr. Jeffrey Kraut    | Dr. Kevin Watkins       |
| Mr. Scott La Rue     | Dr. Patsy Yang          |
| Mr. Harvey Lawrence  | Dr. Zucker (ex-officio) |
| Dr. Glenn Martin     |                         |

**DEPARTMENT OF HEALTH STAFF PRESENT**

|                         |                    |
|-------------------------|--------------------|
| Mr. Udo Ammon           | Mr. George Macko   |
| Dr Richard Becker       | Ms. Karen Madden   |
| Mr. Jason Corvino       | Ms. Kathy Marks    |
| Ms. Valarie Deetz       | Ms. Shaymaa Mousa  |
| Ms. Barbara DelCogliano | Ms. Marthe Ngwashi |
| Mr. Mark Furnish        | Mr. Mark Noe       |
| Mr. Brian Gallagher     | Ms. Tracy Raleigh  |
| Ms. Shelly Glock        | Ms. Carol Rodat    |
| Mr. Michael Heeran      | Ms. Kerri Tily     |
| Mr. Adam Herbst         | Ms. Lisa Thomson   |
| Dr. Eugene Heslin       |                    |
| Ms. Colleen Leonard     |                    |

**INTRODUCTION**

Mr. Kraut called the meeting to order and welcomed Council members, Commissioner Zucker, meeting participants and observers.

## **APPROVAL OF THE MEETING MINUTES OF DECEMBER 9, 2020**

Mr. Kraut asked for a motion to approve the December 9, 2020 Minutes of the Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval. Mr. LaRue seconded the motion. The minutes were unanimously adopted. Please refer to page 2 of the attached transcript.

## **REPORT OF DEPARTMENT OF HEALTH ACTIVITIES**

### **Department of Health Activities**

Mr. Kraut introduced Dr. Zucker to give a report on the Department of Health report.

### **COVID-19**

Dr. Zucker began his report by stating that the past month marked the one year anniversary of much of the worst of New York State's experience of epic early surge of COVID-19, when life as we all know it's switched to a halt. This surge came at a time when little was known about the virus, the it spread, who it affected, who was most severely affected. The Department did not know in March of 2020 is that COVID SARS-COV-2 was airborne and easily spread from person to person, which who are not showing symptoms at the time. By the time New York had first identified our first case on March 1st, the virus had already spread much further than we had thought it could have and was here long before we even knew. The decisions made by New York State throughout March, April to manage hospitalizations and contain viral spread among the 19 million residents that we have in the New York prevented at least a hundred thousand infections projected by the early epidemiological models. The hard work brought New York State from the epicenter of the outbreak to the lowest infection rates in the country in a matter of weeks. However, the surge that we saw beginning this past November, and lasted through early 2021 was a tragic reminder that the virus does not take vacations. The past experience with COVID is that hospitalizations tend to follow new infections by about three weeks. The Department expected patient hospitalizations and ICU hospitals in particular to peak on January 19, so this was roughly three weeks after the height of the holiday season. During that peak we had that 9,273 patients that were hospitalized with COVID statewide. We had 1,621 in the ICU. As the post holiday decline and cases slowed and began to reverse nationally, there was a growing concern about an additional uptick of COVID-19 across the country. The number of daily new hospital sorry, the number of new cases per one hundred thousand New York residents has been approximately 40 based on a seven day rolling average. The Department continues to closely monitor the regional trends in the cases, as well as data on the health systems capacity. Currently, there are 4,422 patients hospitalized with COVID statewide and 947 of those patients in the ICU and then around 600 who are incubated.



Dr. Zucker advised that there are of SARS-COV-2 with mutations that evidence shows may increase the viral load and the ease with which the illness spreads threatens to undue the progress we've made in lowering our infection rates. The Department's lab as well as the other labs around the state and around the country are rapidly sequencing to track the spread of variance and to pinpoint areas where additional precautions may be necessary to prevent infections and deaths. They are sequencing about 90 specimens per day, and it's revealing sequences and working with the additional labs to obtain a clearer picture of the spread of variance throughout the State. More than 8,812 strains have been sequenced at last to date. There are variants of interest, there are different classifications, there are two. There is the variance of interest and the variance concern. The first is of interest, which have genetic markers that we think might affect transmission diagnostics or even the immune response to vaccines or a previous infection. Variance of interest may be predicted to have an increased risk of transmissibility or severity of disease. Variance of concern are more worrisome classification because of the variance to which we have evidence of increased transmissibility or more severe disease or demonstrated decrease in the neutralization to antibody. The variance of concern may require some additional public health measures in order to monitor and control for their spread, including increased testing and sequencing. These variants may also require altering the existing vaccines or treatments to account for lost of effectiveness.

Dr. Zucker stated that just recently, NIH began testing a new version of a vaccine which is designed to protect against the B 1 3 5 1 variant. The FDA has indicated that it will expedite the process for updated vaccines target with these variants, which is an encouraging sign. There are roughly about 4,900 confirmed cases of 4 different variants of concern in New York State. The most notable one is the B 1 1 7 variant as well as the lineage associated with the New York B 1 5 2 6 variant. We have the most evidence for these variants Downstate. However, there is sequencing biases Downstate seems to be where the majority of sequencing is occurring. A study published in April's Nature Early found that variants, especially the B 1 3 5 1 variant and those with the E 4 8 4 K mutation may have the potential to reduce the effectiveness of vaccines and other treatments. So, basically what it says is that you have this variant, this mutation E 4 8 4 K, and if you have that then the potential for the effect of this vaccine maybe compromise. This mutations thought to result in lower antibody titers against the virus and therefore potentially a weakened response. We do know that half of the newer variants have that mutation, E 4 8 4 mutation. So, we're looking at the clinical picture. The Department is working closely with some hospitals and together have been speaking with CDC to stay on top of this matter.

Dr. Zucker advised that this is truly a battle of vaccine versus variants. New York State is well positioned to win this war. New York is at the center of our vaccination campaign is keeping New Yorkers Safe. We make the vaccine is safe, it's administered safely are the top priorities as initial supplies were severely limited. Initially, we need to be sure that the doses we had went to the New Yorkers who need it most and those who are at highest risk of severe COVID-19 and the New Yorkers who are most likely to contract the virus, so we did that early on. Now, as of today, all New Yorkers aged 16 and above are eligible for vaccinations. The Governor mentioned this on April 6<sup>th</sup>. As supplies grow, New York has opened up dozens of state operated vaccination sites. The Department has helped community pop ups and take other

actions to make sure all New Yorkers can book appointments, get vaccinated no matter where they live. We are not facing this challenge alone. The State has built a robust vaccination infrastructure. It involves local health departments, it involves hospitals, FQHC's, involves community health centers, pharmacies, long term care facilities, it involves both state and federal operated vaccination sites all across the state of New York.

Dr. Zucker announced that on December 14, 2020, New York's own critical care nurse, Sandra Lindsay, became the first person of the United States to receive the COVID-19 vaccine. Four months later now in New York, you have 10.8 million doses that have been administered in New York State. So, one in two hundred six thousand doses were administered just yesterday alone. 35 percent of the state's population has received at least one dose and 22 percent are now fully vaccinated, so we're making tremendous progress.

Dr. Zucker spoke of how he went over to the University at Albany to look at the vax site. He stated that was probably one of the best things I've done in the last couple and the most uplifting things I've done in the last couple weeks, because the enthusiasm that everyone has there, the people working there. One of the staff members there actually said the government service for decades and this is one of the best things he's ever done, probably the best things he's ever done, just getting people vaccinated, seeing the impact that they are making, improving the lives of New Yorkers. I spent a fair amount of time talking to the people who had just been vaccinated. They said how quickly they went through the system, how efficient it was, how thrilled they were to get their vaccines, how happy they were with the state and the system that's been put into place. And it was really good to hear and this was from those who have been at home, elderly, living by themselves to young people, to people who are now back at work, essential worker. It was just really a great experience. And then talking to all the people working there, providing the vaccines and helping out, it was sort of the best example of a community effort.

Dr. Zucker mentioned that April is National Donate Life Month and National Donate Life Month always comes during this time. I always have my pin, which is right there. April 16th is National Light Blue and Green Day. Wear those colors promote the importance of urgency as an organ and or tissue donor. If you're not already registered as a donor, I encourage you to sign up today on New York state's registry. This is as important as anything else. We've worked really hard and this year has been so focused on the vaccine, but there are so many other things that the department does and so many other things that we do as a community, health community and donating one's organs at the appropriate time is an important thing, as the Donate Life Registry is one of our big achievements in the state.

Dr. Zucker concluded his report. To read the complete report and questions from the Members, please see pages 2 through 11 of the attached transcript.

## **REGULATION**

Mr. Kraut introduced Dr. Gutiérrez to give his Report of the Committee on Codes, Regulations and Legislation.

### **Report of the Committee on Codes, Regulation and Legislation**

#### **For Adoption**

20-33 Amendment of Parts 11, 46 and 85 of Title 10 NYCRR (Name Change for the Physically Handicapped Children's Program)

Dr. Gutiérrez began his report by briefly describing Amendment of Parts 11, 46 and 85 of Title 10 NYCRR (Name Change for the Physically Handicapped Children's Program) and motioned for adoption. Dr. Watkins seconded the motion. The motion to adopt passed with one member opposing. Please see pages 11 and 12 of the transcript.

Dr. Gutiérrez concluded his report.

## **PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS**

Mr. Kraut introduced Mr. Robinson to give the Report of the Committee on Establishment and Project Review.

### **Report of the Committee on Establishment and Project Review**

Peter Robinson, Chair, 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**

##### **Acute Care Services - Construction**

| <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>                               | <b><u>Council Action</u></b> |
|----------------------|--|------------------------------|
| 202244 C             | University Hospital SUNY Health Science Center (Oneida County) | Contingent Approval          |

**Diagnostic and Treatment Centers - Construction**

| <u>Number</u> | <u>Applicant/Facility</u>                                   | <u>Council Action</u> |
|---------------|---|-----------------------|
| 211005 C      | Syracuse Community Health Center, Inc.<br>(Onondaga County) | 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**

**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**

| <u>Number</u> | <u>Applicant/Facility</u>   | <u>Council Action</u> |
|---------------|---|-----------------------|
| 201113 B      | Syosset SASC, LLC t/b/k/a Syosset Ambulatory Surgery Center, LLC<br>(Nassau County) | Contingent Approval   |

|          |  |                     |
|----------|--|---------------------|
| 202090 B | Intrepid Lane ASC, LLC d/b/a<br>Intrepid Lane Endoscopy and<br>Surgery Center<br>(Onondaga County) | Contingent Approval |
| 202257 E | Heritage One Day Surgery<br>(Onondaga County)  | Contingent Approval |

Mr. Robinson calls applications 202244, 211005, 201113, 202090, and 202257 and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 12 through 15 of the transcript.

**Diagnostic and Treatment Centers – Establish/Construct**

| <u>Number</u> | <u>Applicant/Facility</u>                               | <u>Council Action</u> |
|---------------|---|-----------------------|
| 202191 E      | New York Preventive Health<br>Center<br>(Queens County) | Contingent Approval   |

**Dialysis Services – Establish/Construct**

| <u>Number</u> | <u>Applicant/Facility</u>                | <u>Council Action</u> |
|---------------|--|-----------------------|
| 202102 B      | Novo Dialysis Jamaica<br>(Queens County) | Contingent Approval   |

**Certificates**

**Certificate of Dissolution**

| <u>Applicant</u>   | <u>Council Action</u> |
|--|-----------------------|
| Morningside House Nursing Home Company, Inc.                     | Approval              |
| Fragile X Association of New York, Inc.                          | Approval              |
| Adirondack Tri-County Nursing and Rehabilitation<br>Center, Inc. | Approval              |

Mr. Robinson calls applications 202191, 202102, Morningside House Nursing Home Company, Inc., Fragile X Association of New York, Inc. and Adirondack Tri-County Nursing and Rehabilitation Center, Inc. and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 15 and 16 of the transcript.

**Certificate of Amendment of the Certificate of Incorporation**

**Applicant**

Albany Medical Center

**Council Action**

Approval

Mr. Robinson calls Albany Medical Center and notes for the record that Dr. Bennett has declared an interest but was not present at the meeting. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see page 16 of the transcript.

**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 2:** Applications Recommended for Approval with the Following:

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

**Restated Certificate of Incorporation**

**Applicant**

Canton-Potsdam Hospital Foundation, Inc.  
Mr. Thomas- Interest/Abstaining

**Council Action**

Approval

Mr. Robinson calls Canton-Potsdam Hospital Foundation, Inc. and notes for the record that Mr. Thomas has declared an interest and will be abstaining. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. Thomas' noted abstention. Please see pages 16 and 17 of the transcript.

**CATEGORY 6:** Applications for Individual Consideration/Discussion

**CON Applications**

**Certified Home Health Agencies – Establish/Construct**

| <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>                 | <b><u>Council Action</u></b> |
|----------------------|--|------------------------------|
| 201038 E             | St. Joseph's Health at Home<br>(Onondaga County) | Contingent Approval          |

Mr. Robinson calls application 201038 and motions for approval. Mr. Thomas seconds the motion. The motion to approve. Please see page 17 of the transcript.

**Acute Care Services – Establish/Construct**

| <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>   | <b><u>Council Action</u></b> |
|----------------------|--|------------------------------|
| 211023 E             | The New York Community<br>Hospital of Brooklyn, Inc.<br>(Kings County)<br>Mr. Kraut – Recusal<br>Dr. Strange - Recusal | Contingent Approval          |

Mr. Robinson calls application 211023 and notes for the record that Mr. Kraut and Dr. Strange declared conflict and have exited the Zoom meeting. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. Kraut and Dr. Strange's recusals. Please see pages 17 and 18 of the transcript.

**Ambulatory Surgery Centers – Establish/Construct**

| <b><u>Number</u></b> | <b><u>Applicant/Facility</u></b>  | <b><u>Council Action</u></b> |
|----------------------|---|------------------------------|
| 202093 C             | Richmond Pain Management ASC<br>(Richmond County)<br>Mr. Kraut – Recusal<br>Dr. Strange – Recusal | Contingent Approval          |

Mr. Robinson calls application 202093 and notes for the record that Mr. Kraut and Dr. Strange declared conflict and remain outside the Zoom meeting. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. Kraut and Dr. Strange's recusals and they return to the Zoom session. Please see page 18 of the transcript.

Mr. Robinson concluded his report.

**ADJOURNMENT:**

Mr. Kraut announced the upcoming PHHPC meetings and adjourned the public portion of the meeting and was calling into order Executive Session to consider a Health Personnel and Interprofessional Relations matter.



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

**April 8, 2021**  
**Full Council Transcript**

**Jeffrey Kraut** Good morning.

**Jeffrey Kraut** I'm Jeff Kraut and I have privilege to call to order the virtual meeting of the Public Health and Health Planning Council. I'd like to welcome the members, Commissioner Zucker, participants and observers. We're going to be viewing the public meeting via the webcast. There's a forum that we've asked you to fill out that records your attendance at this meeting that's required by the Joint Commission on Public Ethics, and you will find the forum posted on the department's website at [www.NYHealth.gov](http://www.NYHealth.gov) under the Certificate of Need tab. You should also email the completed forms to [Colleen.Leonard@Health.NY.gov](mailto:Colleen.Leonard@Health.NY.gov) and we appreciate you filling that out so we can comply with the Executive Order. We also remind council members, staff and audience that we're subject to the open meeting law, we broadcast over the internet. You have to keep yourself on mute when not speaking. I ask that you avoid the rustling of papers when you do speak, we'll pick up any of those conversations anything on the microphones will pick up the chatter. Because we have synchronized captioning, obviously, we can't have two people speaking at the same time. When you first speak, state your name and identify yourself as a council member or DOH staff. This will be of assistance to record the meeting. We just, please don't use the chat function to communicate. That is open to the public. Everybody can see it. None of the chats are private, as are none of your side conversations. I'd ask that all the members of the council have their cameras turned on. When anybody is speaking to the council, they are to have their camera turned on so we can see and record them as they participate. Today's meeting is we're going to hear a report from Dr. Zucker, followed by a committee on regulation and then the project review recommendations and establishment actions. And I'd ask, we've batched the applications, so you should know that we've organized the agenda based on topics and categories to patch the CON's and we ask the members to take a look at the batching that we've prepared in the agenda to see if there's any category, any project that needs to be moved to an alternative category and to please let Colleen know as well. When we conclude that meeting, we will go into an executive session to deal with a matter responsive to public health law on personnel matters.

**Jeffrey Kraut** I want to welcome the Department of Health's New General Counsel, Kathy Marks, who I believe is on. I'm looking at the screen.

**Kathy Marks** Good morning.

**Jeffrey Kraut** Good morning, Kathy and welcome.

**Kathy Marks** Thank you.

**Jeffrey Kraut** That's Kathy there, at least on my screen, third row.

**Jeffrey Kraut** And Kathy has quite an impressive background if any of you have seen her resume. She is very significant in public service, having served as an Assistant US attorney in the, I believe, the Southern District for nearly 16 years as a counsel to the New

York, and then as, and then for nearly 16 years and as a counsel to the New York state Attorney General's Office, the Medicaid Fraud Control Unit, for the past three years. Most recently and prior to arrival at DOH, she was a partner at Yanqui LLP in White Plains and she handled federal and state litigation on a wide variety of areas. Kathy, we hope not to keep you too busy, but we're glad with that background. We welcome you as an advisor to us and look forward to your participation.

**Jeffrey Kraut** This is also a good time to acknowledge that we've received a table of organization based on a previous request that you've received from the department, so we have an idea of who the individuals are in charge of the major operating units. It's, if you saw the full DO down to all the operating divisions project offices, it's quite an extensive operation. But as you know, these individuals and their deputies are the ones we primarily deal with on the matters that come before the council.

**Jeffrey Kraut** In order to start the meeting, I'd like to adopt the meeting of the minutes. Have a motion for the adoption of the December 9th, 2020 meeting minutes.

**Jeffrey Kraut** May I have a motion?

**Jeffrey Kraut** I have a motion, Dr. Berliner.

**Jeffrey Kraut** I have a second, Mr. La Rue.

**Jeffrey Kraut** All those in favor?

All Aye.

**Jeffrey Kraut** Thank you.

**Jeffrey Kraut** And motion carries.

**Jeffrey Kraut** It's now my pleasure. We've had a tumultuous couple a year, unprecedented in so many fashions, and we're very pleased Dr. Zucker is able to join us and to provide us an update about the department's activities.

**Jeffrey Kraut** Dr. Zucker, we are limited in time today, but go ahead, I'm sure there's a lot of activities, I'm sure.

**Dr. Zucker** Thank you, thank you very much and thank you all for being on the call. And at some point, we'll get back to our meeting in person. It's nice to see everybody through Zoom. I look forward to a day, like I said, when we can get our meetings back safely in person.

**Dr. Zucker** This past month marks the one year anniversary of much of the worst of New York State's experience of epic early surge of COVID-19, when life as we all know it's switched to a halt. This surge came at a time when little was known about the virus, the it spread, who it affected, who was most severely affected. That we now find ourselves in the midst of a vaccination campaign against the virus is a testament to the scientific progress and the collaboration like nothing we have ever seen before as we work to hold the line against new variants of the virus, I'll speak about that in a little bit and vaccinate New York, as quickly and effectively as possible. There's still much we can learn from one another and there's still much more that we need to do. I've said that it's a battle of the

vaccine versus variants in a war of the nation versus nurture, versus nature. It really is very much what our nation does and what nature does.

**Dr. Zucker** Today, I want to discuss New York State's experience fighting COVID-19 over the past year, how we navigate this harrowing challenge and how we are keeping New York safe in the weeks and months ahead. New York's early surge last year was unlike anything seen around the world. Our cases, as I've mentioned before, doubled on March 5th and 6th. And during that 72 hour peak between April 11th and 13th, which is coming up here next week, it was eighteen thousand eight hundred twenty five patients in the hospital, hospitals statewide, fifty two hundred twenty five people in the ICU and forty four hundred ninety four people intubated at that point. So, we're approaching that one year anniversary of some very difficult days.

**Dr. Zucker** What we didn't know in March of 2020 is that COVID SARS-COV-2 was airborne and easily spread from person to person, which who are not showing symptoms at the time. By the time we had first identified our first case on March 1st, the virus had already spent much further than we had thought it could have and was here long before we even knew. The decisions made by New York State throughout March, April to manage hospitalizations and contain viral spread among the 19 million residents that we have in the state prevented at least a hundred thousand infections projected by the early epidemiological models. Gashes in New York took in those early days helped us to decrease our test positivity to below of nearly one percent for nearly two months. And last Summer we were really down to twenty seven point eight percent. We brought New York State from the epicenter of the outbreak to the lowest infection rates in the country in a matter of weeks. However, the surge that we saw beginning this past November, and lasted through early 2021 was a tragic reminder that the virus do not take vacations. Our past experience with COVID is that hospitalizations tend to follow new infections by about three weeks. And as we expect patient hospitalizations and ICU hospitals in particular peaked on January 19, so this was roughly three weeks after the height of the holiday season. And during that peak we had that ninety two hundred seventy three patients that were hospitalized with COVID statewide. We had sixteen hundred and twenty one in the ICU. As the post holiday decline and cases slowed and actually begun to reverse nationally, there was a growing concern about an additional uptick of COVID-19 across the country. We read about this in the articles and we've obviously spoken to those on the national front looking at this for areas outside New York. We're seeing similar patterns in New York. The number of daily new hospital sorry, the number of new cases per one hundred thousand New York residents has been approximately 40 based on a seven day rolling average. The department continues to closely monitor the regional trends in the cases, as well as data on the health systems capacity. Currently, there are forty four hundred twenty two patients hospitalized with COVID statewide and nine hundred forty seven of those patients in the ICU and then around 600 who are incubated. With regards to the various, I think this is the big issue. There are new variants of SARS-COV-2 with mutations that evidence shows may increase the viral load and the ease with which the illness spreads threatens to undue the progress we've made in lowering our infection rates. So, our --- central lab, as well as the other labs around the state and around the country, for that matter, are rapidly sequencing to track the spread of variance and to pinpoint areas where additional precautions may be necessary to prevent infections and deaths. So, --- is sequencing about 90 specimens per day, and it's revealing sequences and working with the additional labs to obtain a clearer picture of the spread of variance throughout the state. More than eight thousand eight hundred twelve strains have been sequenced at last to date. There are variants of interest. There are different classifications, there are two. There is the variance of interest, the variance concern. The first is of

interest, which have genetic markers that we think might affect transmission diagnostics or even the immune response to vaccines or a previous infection. Variance of interest may be predicted to have an increased risk of transmissibility or severity of disease. Variance of concern are more worrisome classification because of the variance to which we have evidence of increased transmissibility or more severe disease or demonstrated decrease in the neutralization to antibody. The variance of concern may require some additional public health measures in order to monitor and control for their spread, including increased testing and sequencing. These variants may also require altering the existing vaccines or treatments to account for lost of effectiveness. Just recently, NIH began testing a new version of a vaccine which is designed to protect against the B 1 3 5 1 variant. The FDA has indicated that it will expedite the process for updated vaccines target with these variants, which is an encouraging sign.

**Dr. Zucker** So, what's the status of the variance of concern in New York, I think is important to go through. Through our screening activities so far, we know there's roughly about forty nine hundred confirmed cases of four different variants of concern in New York State. The most notable one is the B 1 1 7 variant, which was known as the -- variants, as well as the lineage associated with the New York B 1 5 2 6 variant. We have the most, we have the most evidence for these variants Downstate. However, there is sequencing biases Downstate seems to be where the majority of sequencing is occurring. A study published in Nature Early this month found that variants, especially the B 1 3 5 1 variant and those with the E 4 8 4 K mutation may have the potential to reduce the effectiveness of vaccines and other treatments. So, basically what it says is that you have this variant, this mutation E 4 8 4 K, and if you have that then the potential for the effect of this vaccine maybe compromise. This mutations thought to result in lower antibody titers against the virus and therefore potentially a weakened response. We do know that half of the newer variants have that mutation, E 4 8 4 mutation. So, we're looking at the clinical picture. We're working with some of the hospitals. I was on the phone with one of the President's of the hospitals in New York yesterday about this. They, speaking with CDC. I spoke with CDC a couple of weeks ago about this and we're going to try to track this to get more information. So, we'll watch this. I can promise you that the department is on top of this very closely.

**Dr. Zucker** With regards to vaccines, as I mentioned earlier, this is truly a battle of vaccine versus variants. New York State is well positioned to win this war. At the center of our vaccination campaign is keeping New Yorkers safe. We make the vaccine is safe, it's administered safely are the top priorities as initial supplies were severely limited. Initially, we need to be sure that the doses we had went to the New Yorkers who need it most and those who are at highest risk of severe COVID-19 and the New Yorkers who are most likely to contract the virus, so we did that early on. Now, as of today, all New Yorkers aged 16 and above are eligible for vaccinations. The Governor mentioned this on April 6th, just the other day. As supplies grow, we've opened up dozens of state operated vaccination sites. We've helped community pop ups and take other actions to make sure all New Yorkers can book appointments, get vaccinated no matter where they live. We're on that. We are not facing this challenge alone. We've built a robust vaccination infrastructure. It involves local health departments, it involves hospitals, FQHC's, involves community health centers, pharmacies, long term care facilities, it involves both state and federal operated vaccination sites all across the state of New York. On December 14, 2020, New York's own critical care nurse, Sandra Lindsay, became the first person of the United States to receive the COVID-19 vaccine. I think about that a lot because with the millions and millions of people, the vaccine, I sort of think of that. I remember that day when she got that shot in her arm. And just four months later now in New York, you have ten point

eight million doses that have been administered in New York State. So, one in two hundred six thousand doses were administered just yesterday alone. 35 percent of the state's population has received at least one dose and 22 percent are now fully vaccinated, so we're making tremendous progress. The other day I was, I went over to university at Albany to look at the vax site. That was probably one of the best things I've done in the last couple and the most uplifting things I've done in the last couple weeks, because the enthusiasm that everyone has there, the people working there. One of the staff members there actually said the government service for decades and this is one of the best things he's ever done, probably the best things he's ever done, just getting people vaccinated, seeing the impact that they are making, improving the lives of New Yorkers. I spent a fair amount of time talking to the people who had just been vaccinated. They said how quickly they went through the system, how efficient it was, how thrilled they were to get their vaccines, how happy they were with the state and the system that's been put into place. And it was really good to hear and this was from those who have been at home, elderly, living by themselves to young people, to people who are now back at work, essential worker. It was just really a great experience. And then talking to all the people working there, providing the vaccines and helping out, it was sort of the best example of a community effort.

**Dr. Zucker** So in conclusion, as we step away from our pandemic response for just a moment, I will mention again that April is National Donate Life Month. And National Donate Life Month always comes during this time. I always have my pin, which is right there. Next Friday, April 16th is National Light Blue and Green Day. Wear those colors promote the importance of urgency as an organ and or tissue donor. If you're not already registered as a donor, I encourage you to sign up today on New York state's registry. This is as important as anything else. We've worked really hard and this year has been so focused on the vaccine, but there are so many other things that the department does and so many other things that we do as a community, health community and donating one's organs at the appropriate time is an important thing, as the Donate Life Registry is one of our big achievements in the state.

**Dr. Zucker** So, I want to thank you. I'm happy to answer any questions that you may have. I know that this has been a tough a tough year for so many of us in many ways.

**Dr. Zucker** So, I'm glad to take questions that may come up.

**Jeffrey Kraut** Thank you, Dr. Zucker.

**Jeffrey Kraut** I'm going to call on members who have indicated, just ,I want to share just, you know, relative to what you said, like one special day, Sandra Lindsey, who worked for us or received the vaccine. Two weeks ago, we had a ceremony with the Smithsonian who came in and took the vial, the needle, her ID badge, the scrubs and her vaccine card and it is going to be the terminal display of a history of medicine in the United States, so at the Smithsonian. So, it's, we have another opportunity to celebrate that day over and over again with millions of visitors to the Smithsonian. So, we're looking forward to that.

**Jeffrey Kraut** I'll open it up for questioning.

**Jeffrey Kraut** Dr. Berliner, then, Mr. La Rue.

**Jeffrey Kraut** And then Mr. Brown, Dr. Brown.

**Dr. Berliner** Commissioner, thank you. Thank you for your talk.

**Dr. Berliner** Reasonably early into the epidemic, who knows when it was anymore, the Governor announced that we would be working in concert with New Jersey and Connecticut. I mean, kind of a regionalization of of the approach to to dealing with COVID, haven't heard anything about that since and it seems like the three states are going in in separate directions. I'm wondering if you could just say a little bit about is that still an active effort and what's happening.

**Dr. Zucker** It is an incredibly active effort and I will tell you that every week, although yesterday we didn't get on the phone. Every week on Tuesday morning, two days ago, the health commissioner in Connecticut and the health commissioner in New Jersey on the phone for a half an hour to an hour discussing exactly what was going on in their state. This has been going on since the beginning. Later this afternoon, the entire Northeast region has --- one to two from Massachusetts, actually from Maine all the way down to New Jersey. We sometimes bring in --- as well to discuss exactly how to address these issues. And Deirdre and Judith to the commisssoners in our neighboring states and I talked regularly about exactly what's happening. Any time there's an uptick. The other day we were talking about the upticks and what they're seeing in their states, how they're approaching things, what their government is doing. So, it's, it's always have, I will promise you that.

**Dr. Berliner** Great to hear.

**Dr. Berliner** Thank you so much.

**Scott La Rue** Good morning, Commissioner.

**Scott La Rue** Scott La Rue, member of the council.

**Scott La Rue** I'd just like to take a moment and recognize and thank you and all the staff of the department for what I think is an incredible job that your team has done during this pandemic. You were supporting our health system 24 hours a day, 365 days. It is never let up. I've taken calls from your staff in the middle of the night working on issues. I may not have always liked the answer or the resources weren't always available, but it wasn't from a lack of effort by the team at the department. And I think they should be commended for the commitment they had to the people we serve. It's unfortunate that the nursing homes are no longer a discussion in reality, and it's nothing more than a political conversation. And I hope that this council or there will be some vehicle when the politics have settled down, that we can have an honest conversation about long term care in New York and how to properly respond to what we've learned from this unprecedented pandemic.

**Dr. Zucker** So, number 1, I want to thank you for those companies and on behalf of the entire department, I appreciate that. And I will tell you, the public will say the department has worked fearlessly and ferociously, I should say, on addressing this pandemic and moving forward and many people in the department, all the people, but the amount of work and how long the hours they worked on this, it's just a real testament to the professionalism.

**Dr. Zucker** On the issue of long term care, I hear you. We have not, I know there's a lot going on. All the noise and then is also what needs to get done. And the Governor mentioned that he wanted to ensure that this is a high priority. It was addressed and I

mentioned my budget hearing and also the Governor's mentioned as part of the budget as general to ensure that as one of the things that is a priority. I will tell you that we are looking at this and it's hard because we are juggling so many things at one time. We are looking at what we need to do to make sure that long term care is addressed and looking at me in a very new way as we move forward on things. And it's not just an issue of disease, but it's also issue all the other aspects of long term care, whether it's issues of behavioral health and nutrition. Transportation is, a lot of things that we have seen and I've always said, as I said, this is one of the reasons that this whole pandemic is sort of with a lot of the challenges that we see in the health care system and long term care one part of that. And we really saw a lot of the challenges with long term care, so I promise you that is something that we will continue to address and make sure it's better going forward.

**Jeffrey Kraut** Thank you.

**Jeffrey Kraut** I'm going to go to Dr. Brown, Dr. Kalkut, then Mr. Lawrence.

**Dr. Brown** Dr. Zucker, but first, this is Lawrence Brown, a member of the council.

**Dr. Brown** Dr. Zucker, I can't wait like you, that opportunity where we can see each other in the Brownsville Recreation Center again. That was a fantastic surprise and it's good to see you then in a different type of setting. I would like to share with you the rationale for the question that I'm going to raise. And I do so because the fact that I am on this council, largely not only being a citizen of the state of New York, but also for two important communities. One is communities of color and the other with respect for communities that in fact continue to suffer from substance use disorders. I raise these two because those two are then, as you know, disproportionately impacted by this pandemic. And I do, and I salute and I must echo the comments of my colleague Scott with respect to the great work by the department. I would love if it would be possible for the department to share information about how it is responding to the health equity issues, particularly given the fact that it has been challenging to get access to vaccine, has been challenging to be able to provide vaccines in the arms of communities that have been disproportionately affected. Part of this has to do with long standing concerns and issues, as you are well aware of. But the other part of it has to do with the access to the resources. I should tell you that my own program where we have 2,900 patients, that it has been a challenge to get access to vaccine, even though we were approved as a vaccine site. So, I just want to share with you that there are still some impediments that is not because there's not intention and not motivation. It still has the effect of having populations that are still to support disproportionate effect.

**Dr. Brown** Thank you so much.

**Dr. Zucker** Thank you for that information.

**Dr. Zucker** I will say that the Governor has made a strong effort and we been out there and I've been out there within about discussing some of the issues of these people, just the disparities in the percentage of those who get vaccinated, who are either all communities of color, whether it's Black or Hispanic. And we saw it and I looked at the numbers again, I was just looking at this. And I was thinking about what you just said, it's about trust issues. But we are also making sure the vaccine gets out to the communities and is working with great faith based communities to have these pop ups in different aspects of different areas of the state to address the issues that you raised. But I will look at figuring out how we can get some of the information about sharing what we are finding

now gathered just as information is coming in. And when this is all done, we will end up providing all this information the way this is what we track down. But as Governor mentioned the other day, we still have a strong effort that we are still making sure that these disparities that we have on this.

**Dr. Zucker** So, I hear you.

**Jeffrey Kraut** Dr. Kalkut, then Mr. Lawrence.

**Dr. Kalkut** Yeah, thank you and thank you, Howard, for the report.

**Dr. Kalkut** I want to comment on an uptick in the RSV cases in the Downstate and I think in the state. And I've noticed for the past 6 weeks, same reported, interestingly, from Australia, that in their Spring and I wanted to compliment the department and particularly OHIP in responding by making available a prophylactic drug that usually is used only in the Winter and extended now to use currently. And if the epidemic or the rise continues, we'll continue to prevent hospitalizations and ICU admissions. So, the agility and responsiveness of the department or an RSV surge has been really traumatic.

**Dr. Kalkut** And thank you for that and gratitude from all of us on the work on COVID over the past year.

**Dr. Zucker** Thank you.

**Dr. Zucker** We do track all the other illnesses I was showing the Governor the other day, the flunumbers and how we how flat we are this year on flu, constant to the previous curves in years where the numbers are just dramatically, much higher.

**Dr. Kalkut** Thank you.

**Jeffrey Kraut** Mr. Lawrence.

**Mr. Lawrence** Good morning, Dr. Zuker.

**Mr. Lawrence** Thank you.

**Mr. Lawrence** I would like to echo the comments of my colleagues in expressing our appreciation for your work, which you've done, and the department's work around the vaccine and around COVID. We are, one of the things that we have sensing and experiencing out in our community is that people are going through something, again, similar to post-traumatic stress syndrome. In many cases, they've been we have one of the largest concentrations of public housing and probably in the state. And people have been sheltering in place, they've been going through a very tough time, as we all have been over the past year. And so what we're seeing is an increase in excuse me, in domestic violence. Just this past Monday, there was a murder suicide involving I guess a father and two or three other adults. And in conversation with the local precinct commander and with the commissioner here in the city, it is it was made very clear that what they are seeing is an incredible increase in domestic violence and also additional mental health challenges. So, my question is, you know, I know you're battling the getting the vaccines out and you're battling the virus, but there's another battle that is happening and that has implications as we move through and conquer, hopefully conquer the virus. And people are attempting to return to some normal sense of life. What else can we do to really begin



to address the mental health issues and also some of the domestic violence that's occurring as a result of people really enduring a most stressful year.

**Dr. Zucker** So, it's interesting to bring this up because this morning when I was coming into the building in Albany, I was about 10 minutes talking to one of my colleagues, members of our legal team and she and I were talking literally about this issue, about Behavioral health and some of the challenges that that those with behavioral health issues are facing in general and also as a result of this and I have spoken with Dan Sullivan, who's the commission for the Office of Mental Health. We need to address this more, not just a short term. It's a long term effect because there are implications that this stress that and sort of some of the challenges that younger population, older population, all ages are faced with itself. So, we're working on that and we need to work on the more, I will tell you that we need to address more. This is one of those long term challenges, domestic violence issue as well. I think all this ties together. Society, I feel like society is very status, very integrated in people like to work with other people when you put people, isolate them from month after month or you put them in an area just in home and they don't have a chance to relate to other people, it becomes a real stress on your mental health in general. And I think that, I think two things. One is we have to address the challenges there, but also the faster we get people back to society that sort of works together and it is back to a normal routine and the quicker some of these other challenges may not continue to exacerbate. And on that point, I feel it's important to recognize and this is something I've been speaking to many people about, we have close to 11 million shots in arms right now. We have millions of people who have had both vaccines and obviously some just need to get one shot with the vaccine. We have millions of people who have had the illness itself. We have five million children in the state. I keep looking at these numbers of how do we get enough people with enough immunity so that we can get ourselves back to where we need to be. And I do feel very strongly that this month and it's next month, because come the Summertime, you know, as you said, people have been sort of getting tired. And I think that they're going to go out they're going to end up going out. It's going to warm weather and I'd like to be sure that we have as much out there and low lowest positive as possible so that come the. Because I think a lot of these schools get kids into the school and do other things and get and that will take away some of the challenges, some health challenges at home. That being said, we still need to address the underlying issues there and also in domestic violence issue, which and I've heard that also and that in the last couple of months, I've heard a lot about the domestic violence issues. And maybe, maybe it's just more that I'm reading more about or maybe as this goes on into a year into something some of its challenges.

**Jeffrey Kraut** Thank you, Commissioner.

**Jeffrey Kraut** Are there any other questions for the commissioner?

**Jeffrey Kraut** Dr. Martin.

**Dr. Martin** Good morning, Commissioner.

**Dr. Martin** Of course, I echo all the comments that have been made thanking the department for the massive amount of effective work that you guys have done over the last year.

**Dr. Martin** I just wanted to make a comment, though, about the mental health that came up like Dr. Brown, I said, on the Behavioral Health Services Advisory Committee, clearly,

it's come up there. And as you know, DOH has had helplines and a variety of different things. -- has got medical society has got its own outreach to health care providers and the like. The one thing I just wanted to emphasize, though, is that I think to a large extent this response should remain open primary care and on the medical side and not on the mental health psychiatric side. A lot of what people are experiencing are stress related symptoms that human beings experience as part of stress. Most humans are actually resilient. Most people do not get PTSD. Most people do not suffer chronic mental illness after really annoying and violent and horrible things. It's usually twenty five percent plus or minus. And so I just want to make sure that we don't overreact and psychiatric size the whole population for what's going through a rather normal reaction. And that they do need some support, they do need some education, we do need some help. But that we should be careful to make sure that it's seen as part of the large extent of normal human response and that the physician and medical community should be able to be supportive of that without having to turn it into a psychiatric issue for those who really don't have that. And that's the only caveat I do that is to report to have a combined response and not pigeonhole it psychiatrically.

**Dr. Martin** So, thank you.

**Dr. Zuccker** I hear you. I hear you on that. But I do feel that, the sooner we get back to normal, the better it will be for everyone. That's a very peaceful environment you have in your backdrop.

**Dr. Martin** It's very quiet.

**Jeffrey Kraut** Any other questions for the commissioner?

**Jeffrey Kraut** Well, Commissioner, again, you know, I want to thank you. What you know, what's embedded in these questions is, I guess, a hunger and a desire for the council to turn its attention and to be supportive in the role of shaping health policy in the future. This this last year, we've had so many learnings of what we can do with flexibility, with what can we do when we're focused, what we can we do when when really competitors join together to work on a problem. And we also learned a lot about those problems and the nature of them and how deep seeded some of them and how they manifest themselves under extreme pressure. So, I think you're going to find a willing partner of the group here and we're going to be talking about that throughout the year to turn our attention maybe on more value added activities that would contribute positively to those discussions. And so we don't just forget all the learnings of the past year and what we've realized and and we take that to shape a new future for the health of New Yorkers.

**Jeffrey Kraut** And lastly, just can't repeat what everybody has said, behalf of the council on behalf of residents of New York, we owe a debt of gratitude to all the individuals who work day and night, stay away from their families to help serve us and get us through this this challenging, unprecedented year and thank you for your leadership and that of your staff, we know how challenging it was, but each and every day.

**Dr. Zucker** So, two quick ones. I agree, I'm going to be checking back to the team to address some of these things as far as the vaccine, so as the vaccine gets out and things, such a quiet back down, back to normal and spoken a lot about primary care and some of the challenges that we face in primary care. This is a good example of how critical primary care is, particularly as we move forward and address some of the issues that we get, are disparities in health care.

**Dr. Zucker** And then lastly, I just want to say that this is really it is a team effort. And even though I serve as the Commissioner, the department is still unbelievably dedicated individuals. And I think a little bit that rover, that that Mars rover image popped into my head since I remember with Apollo 13 one time ago, go the other three guys up there. And there's a guy at Mission Control Center that was talking about him behind the scenes. They were incredible number of scientists, thousands of people working to get those guys in their spacecraft got to see trouble up there. And I sort of feel that there is an incredible amount of analysis of people in this department and working day and night at locations and I really, I thank them for what they're doing.

**Jeffrey Kraut** Well, thank you, Dr. Zucker.

**Jeffrey Kraut** You, the phrase we use sometimes is for leaders as you bask in the reflected glory of the people who work for you. So, we thank you.

**Dr. Zucker** Thanks a lot.

**Jeffrey Kraut** Thank you very much for joining us, too.

**Jeffrey Kraut** I am now going to turn to Dr. Gutierrez, and ask him to give the report on the Codes, Regulations and Legislation Committee.

**Jeffrey Kraut** Dr. Gutierrez.

**Dr. Gutierrez** Thank you very much.

**Dr. Gutierrez** And this morning, we, the Codes Regulation and Legislation Committee met to deal with the adoption of an amendment to part 11 46 85 of Title 10, NYCRR to change the name of the Physically Handicapped Children Program to the Children and Youth with Special Health Care Needs Support Service. We were advised on the subject by Ms. Jackie Sheltry of the department who is available still for further questions from the council. The proposal was passed by the committee and I so move with this proposal.

**Jeffrey Kraut** I have a motion by Dr. Gutierrez.

**Jeffrey Kraut** I have a second by Dr. Watkins.

**Jeffrey Kraut** Are there any questions on this matter?

**Jeffrey Kraut** Hearing none, I'll call for a vote, all those in favor aye.

**All Aye.**

**Jeffrey Kraut** Opposed?

**Dr. Martin** Nay.

**Jeffrey Kraut** One opposition, Dr. Martin.

**Jeffrey Kraut** Abstention?

**Jeffrey Kraut** The motion carries.

**Jeffrey Kraut** Any other matter, Dr. Gutierrez?

**Dr. Gutierrez** That concludes my report, thank you.

**Jeffrey Kraut** Thank you,.

**Jeffrey Kraut** I'll now turn to Mr. Robinson to provide the report of the Project Review and Establishment Committee.

**Mr. Robinson** Thank you.

**Mr. Robinson** As members will recall, we do batch the applications as we present them to the full council, given that they've all had a thorough vetting at the committee level, however, please feel free to identify any particular project that you would like to call out and have addressed separately and be happy to make that modification.

**Mr. Robinson** Okay, and we are calling into Category one. These are applications recommended for approval with no issues, recusals, abstentions and interests under construction. And I am calling the following applications 2 0 2 2 4 4 C, University Hospital, SUNY Health Sciences Center Stratifying and Extension Clinic doing businesses Upstate Cancer Center Barona to be located at 5448 State Route 31 in Barona to include therapeutic radiology services and the addition of a linear accelerator. The department recommended approval with conditions and contingencies, as did the committee.

**Mr. Robinson** Application 2 1 1 0 5 C, Syracuse Community Health Center Inc. Onondaga County, relocating the main site from 819 South Solino Street, Syracuse to 930 Salena Street, Syracuse and identification is a safety net. The department is recommending approval with conditions and contingencies, as did the committee.

**Mr. Robinson** And I'm going to continue on with ambulatory surgery, 2 0 1 1 1 3 B, Syosset, SASC L.L.C. doing, so the Syosset Ambulatory Surgery Center L.L.C. in Nassau County. This is to establish and construct a multi specialty ambulatory surgery center to provide orthopedics, pain management and neurosurgery to be located 115 Eilene Way in Syosset. The department recommends approval with conditions and contingencies with an expiration of the operating certificate 5 years from the date of issuance and the committee makes a similar recommendation.

**Mr. Robinson** Application 2 0 2 0 9 B, Intrepid Lahn ACLC doing businesses Intrepid Lane Endoscopy and Surgery Center in --- County to establish and construct a multi specialty ambulatory surgery center to provide urology, colorectal and endoscopy surgery with four operating rooms located at 190 Intrepid Lane in Syracuse. The department recommends approval with conditions and contingencies with an expiration of the operating certificate 5 years from the date of issuance, as does the committee.

**Mr. Robinson** And application 2 0 2 2 5 7, Heritage 1 Day surgery in Onondaga County to transfer fifteen point six six percent interest to 1 new member from 5 existing members. Here, the department recommends approval with a condition and a contingency, as does the committee.

**Mr. Robinson** I make those motions, Mr. Kraut.

**Jeffrey Kraut** Thank you.

**Jeffrey Kraut** May I have a second?

**Jeffrey Kraut** I have a second by Dr. Gutierrez, both verbally and visually.

**Jeffrey Kraut** And this is there anybody have any question or the department needs to comment on any aspect of any one of these applications.

**Jeffrey Kraut** Dr. Berliner, please.

**Dr. Berliner** Yeah, I have a question for the department about the letters we received, so, you know, the implicit in the letters was the fact that they didn't know that this application was coming or they would have participated in the in the committee meeting, is this is this a mistake on their part, which is their problem, or is this something that, is this is our problem, I guess I'm asking

**Tracy Raleigh** I can take that.

**Tracy Raleigh** You know, this is Tracy Raleigh from the department.

**Tracy Raleigh** The letter, as I read it, just expresses regret for late communications on the matter. So typically, we would have received this or they would have been presented at the Establishment Review Committee. But, you know, so they did, everyone is aware of the agenda when it's posted. So, certainly, you know, it would have been available for public as well as -- to come and participate. We did provide the letter that we received from --- Health to the members. It does express opposition to the project to SUNY. Just to remind and just for the record, we also received a another letter, not in time to time in consideration of our correspondence policy to to provide to the members, but from Oneida Health also in opposition. These you know, just to remind the members, this project really is certifying what was a private practice of SUNY that was located in Oneida as an Article 28 and relocating it in Verona, which is in the nation's territory. It did have support from the nations and it was in conjunction with the planning that this center was put forward.

**Dr. Strange** ----

**Jeffrey Kraut** Dr. Strange?

**Jeffrey Kraut** Thank you.

**Tracy Raleigh** And we also did, thank you.

**Tracy Raleigh** And we also did receive a response from SUNY reiterating that SUNY has served there the region for oncology services and in its existing practice in Oneida. And this is really in response to wanting to take the next step and enhance those services and the physical plan of the facilities where it exists now. From the department's perspective, it is in alignment with our need methodology. We do have the sufficient need for the linear accelerator. It is already providing a linear accelerator service in the current practice. We view this as offering the community choice and consumer choice in oncology services.

**Tracy Raleigh** And so I offer those comments in response.

**Jeffrey Kraut** Yeah, Howard just wanted to make.

**Dr. Berliner** Yeah, Tracy, I'm not I'm not disputing the department's position or the vote of of the committee. I'm just wondering about the process issue of well, now, there were two organizations that have have come out against this. You know, why didn't either of them show up at the meeting or send the stuff earlier? And the question is, really, is this on them and if it's on them, you know, too too bad or is is this a problem of ours that the information didn't get out to the appropriate?

**Jeffrey Kraut** Tracy, let me just respond. I would say when it comes to other Article 28 applicants and they are concerned about competitive impacts, I would say this is absolutely on them. You have the hospital associations, the regional ones, print the CON logs out. And if an entity is really, you know, when you regulated by the Department of Health and we know CON, there is no excuse other than they should look inwards to their management structure, that they do not have processes in place that monitors their market and brings these to awareness. So, I have very little sympathy for people who say I didn't know and your relicensed Article 28 health provider. I get more concerned when the public is not aware and I think by putting this on Nischan making it available, you know, it's not restricted. You just you go in once a week, once a month. You see what's been filed. This application has appeared from the day it was filed, not when the date got on the calendar. So, I'm being a little strident here. And I would ask those entities to, you know, if this is your problem, they should solve it. But I think we should talk about how to do a better job of making people aware. Having said that, you know, when we get applications, we could do a listserv and send out we receive such and such an application. It's in your region, you know, are there. It's so easy now to make more people aware and I think we should do that anyway, Howard and that's one of the things I want to talk about as we move forward about our processes on making both the public and the and the provider world available. I think because I think there's there's room for improvement no matter what. But in this situation, I would say it's not our issue.

**Jeffrey Kraut** Ann.

**Dr. Berliner** Thanks, Jeff.

**Ann Monroe** I hate to continue this, but I have understood since I've been on the council that Tracy would say things like we have notified the other providers in the region and there is no objection. So, I would like to just understand what your process is.

**Jeffrey Kraut** The only time we notify another provider, only in one instance, it's only for freestanding ambulatory surgery centers that are not hospital based. That is the only process that we affirmatively will notify for region because we solicit comments.

**Ann Monroe** So, that was that was a situation.

**Tracy Raleigh** That's right. This is a diagnostic and treatment center of medication, and that is correct. And that's based on that policy that was set by the council.

**Jeffrey Kraut** Dr. Martin.

**Dr. Martin** Thank you.

**Dr. Martin** Tracy, as I understood the letters that we did receive, that the major argument from the room system was that didn't even mention the ---. It was all the radiology and other services that they thought were going to cut into their profit that helps to support the not profitable but important services they provide. And then I think the response was basically, what are you talking about? We don't offer it. We don't plan on offering it. Nothing changes. So, I just wanted to confirm, is that, in fact, the case that this, whatever action we take today wouldn't change their ability to provide those services that --- is concerned about?

**Tracy Raleigh** Correct, the response from SUNY Upstate clarified that the application is not for radiology services, so it is relocating and will have urology and oncology services, not radiology, radiology services and that was noted in the application.

**Dr. Martin** Thank you.

**Jeffrey Kraut** So, if there's no other comments, I'd like to call for a vote.

**Jeffrey Kraut** All those in favor, aye.

**All Aye.**

**Jeffrey Kraut** Opposed?

**Jeffrey Kraut** Abstention?

**Jeffrey Kraut** The motion carries.

**Jeffrey Kraut** Thank you.

**Jeffrey Kraut** Continuing on with the batching application 2 0 2 1 9 1 E, New York Preventive Health Center in Queens County, transferring 100 percent ownership interest to Ojai 28, LLC, doing business as New York Preventive Health Center to three new members. The department and the committee recommended approval with a condition and a contingency.

**Jeffrey Kraut** Dialysis, 2 0 2 1 0 2 B, Dialysis, Jamaica in Queens County establish a constructed 36 station chronic renal dialysis center, including hemodialysis training and support, to be located at 214 seventy Jamaica Avenue in Queens. Approval with conditions and contingencies by both the department and the committee.

**Jeffrey Kraut** And then Certificate of dissolution for Morningside House Nursing Home Co. Inc, Fragile X Association of New York Inc and adirondack Tri County Nursing and Rehabilitation Center Inc.

**Jeffrey Kraut** With the department and the committee recommending approval.

**Jeffrey Kraut** And I so move.

**Jeffrey Kraut** I have a motion.

**Jeffrey Kraut** I have a second by Dr. Gutierrez.

**Jeffrey Kraut** Any comments from the department or any questions from the council member on these applications?

**Jeffrey Kraut** Hearing none, a call for a vote, all those in favor, aye.

**All Aye.**

**Jeffrey Kraut** Opposed?

**Jeffrey Kraut** Abstentions.

**Jeffrey Kraut** The motion carries.

**Jeffrey Kraut** Okay, so these won't be broken up a little bit because of abstentions and interests being declared. So, what we have to take these individually certificate of Amendment of the Certificate of Incorporation for Albany Medical Center. This is has an interest and an abstention by Dr. Bennett, who I believe has left the call. The department recommends approval, as does the committee and I so move.

**Jeffrey Kraut** I have a motion.

**Jeffrey Kraut** I have a second. Dr. Gutierrez.

**Jeffrey Kraut** Any questions on this matter?

**Jeffrey Kraut** All those in favor, aye.

**All Aye.**

**Jeffrey Kraut** Opposed?

**Jeffrey Kraut** Abstention?

**Jeffrey Kraut** The motion carries

**Jeffrey Kraut** On this application, Mr. Thomas is declaring an interest and abstaining.

**Jeffrey Kraut** This is a restated certificate of incorporation, Kant in Potsdam Hospital Foundation, Inc. Amend the corporate purposes and effectuate a corporate name change department and committee recommend approval and I so move.

**Jeffrey Kraut** I have a motion.

**Jeffrey Kraut** A second, Dr. Gutierrez.

**Jeffrey Kraut** Any questions on this?

**Jeffrey Kraut** All those in favor, aye.

**All Aye.**

**Jeffrey Kraut** Opposed?



**Jeffrey Kraut** Abstention?

**Jeffrey Kraut** The motion carries.

**Jeffrey Kraut** Okay, so now we are turning to the applications that were recently acted upon in the special committee meeting that was held earlier this morning. I'm going to take these individually.

**Jeffrey Kraut** Application 201038 E, St. Joseph's Health at Home in Onondaga County. Establish St. Joseph's Health at Home as the new operator of the certified home health agency currently operated in St. Joseph's Hospital Health Center with Trinity Home Health Services as the parent and Trinity Health as the grandparent. The department and the committee recommend approval with a condition and a contingency and I so move.

**Jeffrey Kraut** I have a motion.

**Jeffrey Kraut** I have a second, Mr. Thomas.

**Jeffrey Kraut** Any questions?

**Jeffrey Kraut** All those in favor, aye.

All Aye.

**Jeffrey Kraut** Opposed?

**Jeffrey Kraut** Abstention?

**Jeffrey Kraut** The motion carries

**Jeffrey Kraut** Next to applications call for recusal and conflict both by Mr. Kraut and Dr. Strange. So, if you will remove yourselves from the meeting and you will hear from either Lisa or Colleen immediately after that to come back to the meeting.

**Dr. Strange** Yep, I'm here. I'm going to just get off the meeting.

**Jeffrey Kraut** Yeah, leave the meeting and then you'll get a text to come back in.

**Jeffrey Kraut** Okay, Dr. Boufford, you ready for this?

**Jeffrey Kraut** Okay application 211023 E, the New York Community Hospital of Brooklyn Inc and Kings County again noting the conflict and recusal by both Mr. Kraut and Dr. Strange to establish Maimonides Medical Center, located at 4802 10th Avenue and Brooklyn Kings County is the active parent and co-operator of the New York Community Hospital, Brooklyn Inc, located at 2525 Kings Highway in Brooklyn in Kings County. The department is recommending approval with a condition and a contingency, as did the committee and I so move.

**Dr. Boufford** I, thank you and Dr. Gutierrez has seconded.

**Dr. Boufford** Any questions or comments from council members?

**Dr. Boufford** Hearing none, all in favor, say aye or wave aye.

**Dr. Boufford** Opposed?

**Dr. Boufford** Any abstentions?

**Dr. Boufford** Motion passes.

**Mr. Robinson** Okay, and then application 202093C, Richmond Pain Management, AFSC in Richmond County, again, a conflict and recusal by Mr. Kraut and Dr. Strange. This is to certify an existing single specialty pain management ambulatory surgery center as a multi specialty ambulatory surgery center to provide orthopedic spine and pediatric surgical services and perform renovations to add a decontamination sterilization suite. So, the department has recommended approval with conditions and contingencies and maintaining an operating certificate expiration date of August 14th, 2021. The committee's recommendation was approval with conditions and contingencies, but extending the operating certificate expiration date to August 14th, 2023 to give the applicant time to demonstrate their commitment to serving the Medicaid and underserved populations. I am making the committee motion to the full council.

**Dr. Boufford** Thank you.

**Dr. Boufford** Dr. Gutierrez has seconded.

**Dr. Boufford** Any discussion comment by council members?

**Dr. Boufford** Gary, you have your mute off.

**Dr. Boufford** You're going to say anything, I'm sorry, I'm just looking at the screen I have

**Gary** No.

**Dr. Boufford** Okay.

**Dr. Boufford** So, we'll go with the with the committee recommendation, which is different from the original.

**Dr. Boufford** Any other comments.

**Dr. Boufford** Hearing none, all in favor, aye.

**All** Aye.

**Dr. Boufford** Opposed?

**Dr. Boufford** Any abstentions?

**Dr. Boufford** Motion passes.

**Mr. Robinson** Thank you.

**Mr. Robinson** So can we get Mr. Kraut and Dr. Strange back?

**Mr. Robinson** And this concludes the report of the Establishment of Project Review Committee.

**Mr. Robinson** Thank you.

**Mr. Robinson** Back to you, Jeff.

**Jeffrey Kraut** Thank you so much.

**Jeffrey Kraut** So, that concludes the public portion of the meeting of the Public Health and Health Planning Council. In a moment, we're going to go into session to consider a case arising under public health law Section 2801 B. The next full committee day is going to be on May 13th, and the full council will convene again on June 3rd. I thank all the members of the Department of Health, the council members and the public for participating today.

**Jeffrey Kraut** And we will now go into executive session.

20-22 Amendment of Section 405.11 of Title 10 NYCRR  
(Hospital Personal Protective Equipment (PPE) Requirements)

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending section 405.11, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 405.11 is amended by adding a new subdivision (g) as follows:

(g) (i) The hospital shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control guidance, for at least 60 days by August 31, 2020, and at least 90 days by September 30, 2020, at rate of usage equal the average daily rate that PPE was used between April 13, 2020 and April 27, 2020; provided, however, that upon request the Department may grant an extension of the deadline to October 30, 2020, at its sole and exclusive discretion for having at least a 90 day supply of PPE where the hospital demonstrates, to the Commissioner's satisfaction, that:

(A) the hospital's inability to meet this deadline is solely attributable to supply chain issues that are beyond the hospital's control and purchasing PPE at market rates would facilitate price gouging by PPE vendors; or

(B) the seven-day rolling average of new COVID-19 infections in New York State remains below one and a half percent (1.5%) of the total seven-day rolling average of COVID-19 tests performed over the same period; and there are ten or less states in the United States that have a seven-day rolling average of new COVID-19 infections exceeding five thousand cases.

(ii) Failure to possess and maintain such a supply of PPE may result in the revocation or suspension of the hospital's license; provided, however, that no such revocation or suspension shall be ordered unless the Department has provided the hospital with a fourteen day grace period, solely for a hospital's first violation of this section, to achieve compliance with the requirement set forth herein.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities.

### **Legislative Objectives:**

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

### **Needs and Benefits:**

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the

identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Subsequently, on March 13, 2020, former President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors.

In order for hospital staff to safely provide care for COVID-19 positive patients who require hospitalization, while ensuring that they themselves do not become infected with COVID-19, or any other communicable disease, it is critically important that personal protective equipment (PPE), including masks, gloves, respirators, face shields and gowns, is readily available and are used. As a result of global PPE shortages at the outset of the State of Emergency, New York State provided general hospitals and other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all general hospitals maintain a 90-day supply of PPE, at a usage rate



equal to the highest average rate of usage during the COVID-19 emergency, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.

## **COSTS:**

### **Costs to Regulated Parties:**

The purpose of this regulation is to require general hospitals to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, this regulation imposes no long-term additional costs to regulated parties.

### **Costs to Local and State Governments:**

This regulation will not impact local or State governments unless they operate a general hospital, in which case costs will be the same as costs for private entities.

### **Costs to the Department of Health:**

This regulation will not result in any additional operational costs to the Department of Health.

### **Paperwork:**

This regulation imposes no addition paperwork.

**Local Government Mandates:**

General hospitals operated by local governments will be affected and will be subject to the same requirements as any other general hospital licensed under PHL Article 28.

**Duplication:**

These regulations do not duplicate any State or Federal rules.

**Alternatives:**

The Department believes that promulgation of this regulation is the most effective means of ensuring that general hospitals have adequate stockpiles of PPE necessary to protect hospital staff from communicable diseases, compared to any alternate course of action.

**Federal Standards:**

Part 1910 of Title 29 of the Code of Federal Regulations requires general hospitals to provide adequate PPE to hospital staff. However, no federal standards apply to stockpiling of such equipment.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. These regulations are expected to be proposed for permanent adoption at the next meeting of the Public Health and Health Planning Council following the termination of the COVID-19 emergency.

**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

This regulation will not impact local governments or small businesses unless they operate a general hospital. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses.

### **Compliance Requirements:**

These regulations require all general hospitals to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

### **Professional Services:**

It is not expected that any professional services will be needed to comply with this rule.

### **Compliance Costs:**

The purpose of this regulation is to require general hospitals to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, this regulation imposes no long-term additional costs to regulated parties.

### **Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As these regulations require general hospitals to maintain stockpiles of PPE, which they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

|                    |                    |                     |
|--------------------|--------------------|---------------------|
| Allegany County    | Greene County      | Schoharie County    |
| Cattaraugus County | Hamilton County    | Schuyler County     |
| Cayuga County      | Herkimer County    | Seneca County       |
| Chautauqua County  | Jefferson County   | St. Lawrence County |
| Chemung County     | Lewis County       | Steuben County      |
| Chenango County    | Livingston County  | Sullivan County     |
| Clinton County     | Madison County     | Tioga County        |
| Columbia County    | Montgomery County  | Tompkins County     |
| Cortland County    | Ontario County     | Ulster County       |
| Delaware County    | Orleans County     | Warren County       |
| Essex County       | Oswego County      | Washington County   |
| Franklin County    | Otsego County      | Wayne County        |
| Fulton County      | Putnam County      | Wyoming County      |
| Genesee County     | Rensselaer County  | Yates County        |
|                    | Schenectady County |                     |

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States

Census estimated county populations for 2010:

|                 |                 |                 |
|-----------------|-----------------|-----------------|
| Albany County   | Monroe County   | Orange County   |
| Broome County   | Niagara County  | Saratoga County |
| Dutchess County | Oneida County   | Suffolk County  |
| Erie County     | Onondaga County |                 |

There are 47 general hospitals located in rural areas.

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

These regulations require all general hospitals, including those in rural areas, to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

**Compliance Costs:**

The purpose of this regulation is to require general hospitals to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, this regulation imposes no long-term additional costs to regulated parties.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As these regulations simply require general hospitals to maintain stockpiles of PPE, that they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted.



## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

20-23 Amendment of Section 415.19 of Title 10 NYCRR  
(Nursing Home Personal Protective Equipment (PPE) Requirements)

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending section 415.19, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 415.19 is amended by adding a new subdivision (f) as follows:

(f) (i) The facility shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect facility personnel, consistent with federal Centers for Disease Control guidance, for at least 30 days at rate of usage equal to the average daily rate that PPE was used between April 19, 2020 and April 27, 2020 by August 31, 2020, and for at least 60 days at a rate of usage equal to the average daily rate that PPE was used between April 19, 2020 and April 27, 2020 by September 30, 2020; provided, however, that upon request the Department may grant an extension of the deadline to have such sixty day supply to October 30, 2020, at its sole and exclusive discretion, to meet this requirement where the facility demonstrates, to the Commissioner's satisfaction, that:

(A) the facility's inability to meet this deadline is solely attributable to supply chain issues that are beyond the facility's control and purchasing PPE at market rates would facilitate price gouging by PPE vendors; or

(B) the seven-day rolling average of new COVID-19 infections in New York State remains below one and a half percent (1.5%) of the total seven-day rolling average of COVID-19 tests performed over the same period; and there are ten or less states in the United States that have a seven-day rolling average of new COVID-19 infections exceeding five thousand cases.

(ii) Failure to possess and maintain such a supply of PPE may result in the revocation or suspension of the facility's license; provided, however, that no such revocation or suspension shall be ordered unless the Department has provided the facility with a fourteen day grace period, solely for a facility's first violation of this section, to achieve compliance with the requirement set forth herein.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities.

### **Legislative Objectives:**

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

### **Needs and Benefits:**

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the

identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Subsequently, on March 13, 2020, former President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors.

In order for a nursing home's staff to safely provide care for residents, while ensuring that they themselves do not become infected with COVID-19, or any other communicable disease, it is critically important that personal protective equipment (PPE), including masks, gloves, respirators, face shields and gowns, is readily available and are used. As a result of global PPE shortages at the outset of the State of Emergency, New York State provided nursing homes and other health care facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all nursing homes maintain a 60-day supply of PPE, at rate of usage

equal the average daily rate that PPE was used between April 19, 2020 and April 27, 2020, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.

## **COSTS:**

### **Costs to Regulated Parties:**

The purpose of this regulation is to require nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). Therefore, this regulation imposes no long-term additional costs to regulated parties.

### **Costs to Local and State Governments:**

This regulation will not impact local or State governments unless they operate a nursing home, in which case costs will be the same as costs for private entities.

### **Costs to the Department of Health:**

This regulation will not result in any additional operational costs to the Department of Health.

**Paperwork:**

This regulation imposes no addition paperwork.

**Local Government Mandates:**

Nursing homes operated by local governments will be affected and will be subject to the same requirements as any other nursing home licensed under PHL Article 28.

**Duplication:**

These regulations do not duplicate any State or Federal rules.

**Alternatives:**

The Department believes that promulgation of this regulation is the most effective means of ensuring that nursing homes have adequate stockpiles of PPE necessary to protect nursing home staff from communicable diseases, compared to any alternate course of action.

**Federal Standards:**

No federal standards apply to stockpiling of such equipment at nursing homes.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. These regulations are expected to be proposed for permanent adoption at the next meeting of the Public Health and Health Planning Council following the termination of the COVID-19 emergency.



**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

This regulation will not impact local governments or small businesses unless they operate a nursing home. To date, 79 nursing homes in New York qualify as small businesses given that they employ less than 100 staff.

### **Compliance Requirements:**

These regulations require all nursing homes to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

### **Professional Services:**

It is not expected that any professional services will be needed to comply with this rule.

### **Compliance Costs:**

The purpose of this regulation is to require nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). Therefore, this regulation imposes no long-term additional costs to regulated parties.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As these regulations require nursing homes to maintain stockpiles of PPE, consistent with the directive in Public Health Law section 2803(12) for nursing homes to maintain or contract to have at least a two-month supply of PPE, as well as OSHA regulations and recommendations regarding the payment for and provision of PPE, any adverse impacts are expected to be minimal.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

|                    |                    |                     |
|--------------------|--------------------|---------------------|
| Allegany County    | Greene County      | Schoharie County    |
| Cattaraugus County | Hamilton County    | Schuyler County     |
| Cayuga County      | Herkimer County    | Seneca County       |
| Chautauqua County  | Jefferson County   | St. Lawrence County |
| Chemung County     | Lewis County       | Steuben County      |
| Chenango County    | Livingston County  | Sullivan County     |
| Clinton County     | Madison County     | Tioga County        |
| Columbia County    | Montgomery County  | Tompkins County     |
| Cortland County    | Ontario County     | Ulster County       |
| Delaware County    | Orleans County     | Warren County       |
| Essex County       | Oswego County      | Washington County   |
| Franklin County    | Otsego County      | Wayne County        |
| Fulton County      | Putnam County      | Wyoming County      |
| Genesee County     | Rensselaer County  | Yates County        |
|                    | Schenectady County |                     |

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States

Census estimated county populations for 2010:

|                 |                 |                 |
|-----------------|-----------------|-----------------|
| Albany County   | Monroe County   | Orange County   |
| Broome County   | Niagara County  | Saratoga County |
| Dutchess County | Oneida County   | Suffolk County  |
| Erie County     | Onondaga County |                 |

Licensed nursing homes are located in these identified rural areas.

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

These regulations require all nursing homes, including those in rural areas, to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

**Compliance Costs:**

The purpose of this regulation is to require nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). Therefore, this regulation imposes no long-term additional costs to regulated parties.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As these regulations simply require nursing homes to maintain stockpiles of PPE, which is consistent with the directive in Public Health Law section 2803(12) for nursing homes to maintain or contract to have at least a two-month supply of PPE, as well as OSHA regulations and recommendations regarding the payment for and provision of PPE any adverse impacts are expected to be minimal.

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR;  
Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and  
Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination  
System)



## **SUMMARY OF EXPRESS TERMS**

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 90-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) 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:

A new Part 360 is added to Title 10, to read as follows:

Part 360 Surge and Flex Health Coordination System Activation During a State Disaster

Emergency Declaration

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

As of July 2020, there are 213 hospitals - public, private, and independent - across New York State, each operating as essentially a private entity in a highly competitive environment. Prior to the COVID-19 pandemic, these individual institutions and hospital networks rarely worked together or coordinated as a unified healthcare system. But a pandemic on the scale of the COVID-19 crisis demonstrated that our health care facilities could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility.

No one situation best encapsulates this lack of coordination than what transpired at Elmhurst Hospital, a facility in the New York City-operated Health & Hospitals (H&H) system, during the third week of March. Elmhurst Hospital was overwhelmed with patients at a time when there were just 4,000 total COVID-19 hospitalizations statewide, nearly 900 available beds across the eleven hospitals in the H&H system, and more than 3,500 open beds across all public and private hospitals in New York City. In other words, the problem the Elmhurst situation exposed was not one of hospital capacity, but one of patient load management across all hospitals and hospital systems.

As the Elmhurst situation demonstrated, the COVID-19 crisis demanded a new coordinated approach to ensure no one hospital was overwhelmed by COVID-19 patients or needed more ventilators, while a hospital nearby had capacity for more patients and excess equipment. There was an immediate realization that if peak projections actually materialized in New York, it was imperative for government to coordinate and organize all hospitals under the umbrella of one unified system, and efficiently use all the resources available in the state to attempt to meet the significant demands of the crisis.

This approach was operationalized in late March when Governor Andrew M. Cuomo directed the New York State Department of Health (NYSDOH) to create a new and innovative “Surge and Flex” system, designed to create for the first time one singular coordinated statewide public healthcare system to prevent the virus from overwhelming any one hospital in the state. The approach was literally a life-saver—it helped New York at our peak of hospitalizations in April to facilitate the transfer of thousands of patients. The purpose of this NYSDOH regulation is to institutionalize the Surge and Flex operation to both allow the state to quickly activate Surge

and Flex in the event of a resurgence of coronavirus, while also giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex.

The Surge and Flex system operation launched in March 2020 included four key elements which this regulation will institutionalize, as detailed below.

**First, the State quickly built unprecedented hospital capacity.**

Health experts modeled that New York State could potentially need as many as 140,000 COVID-only hospital beds when there were only 53,000 hospital beds total in the entire state. As a result, New York State had to quickly build unprecedented bed capacity including requiring all hospitals to delay non-life-threatening elective procedures and increase their number of beds by at least 50 percent (by turning single rooms into doubles and freeing meeting rooms and other areas for patient care among other measures) and preferably 100 percent. In addition, the State worked with local and federal government partners to deploy and stand up temporary hospitals and create contingency plans with large-scale venue operators, hotels, and college dormitory operators, to ensure we were prepared for a worst-case scenario - a projected need for as many as 140,000 COVID patients hospitalized at one time. In total, this approach enabled New York State in a matter of weeks to expand hospital capacity from 53,000 total beds to more than 90,000.

**Second, more beds require more staff.**

Staffing was a major issue. In many cases, health care staff were becoming sick with COVID and unable to work. This put tremendous strain on the system. To address staffing shortages, New York State established a web portal to recruit and connect health care professionals from across the nation willing to serve, an effort that enlisted the support of nearly 100,000 health care workers. New York State connected these healthcare heroes with housing as

needed and provided support to hospital human resource offices to expedite the onboarding process. Further, New York State facilitated transfers of healthcare staff from upstate hospitals that had few COVID-19 patients to hospitals in New York City in need of staffing support. In the case of another wave of COVID-19 or another infectious disease it is critical that extra staffing capacity be available to meet the emergency.

**Third, more beds require more supplies and equipment.**

Access to life-saving supplies and materials was a scramble for every state in the nation because our country is reliant on an international supply chain. There was a dire need for ventilators and there was a literal hunger games scenario among states and nations to purchase enough to meet the demand under the crisis. But purchasing alone wasn't enough. There simply weren't enough supplies. To address any potential supply and equipment shortages, New York State used data and a daily reporting system to build a statewide inventory of personal protective equipment (PPE), ventilators, medications and other critical items. Using a reporting system, New York State could take limited resources and distribute them to the hospitals and other institutions that needed them the most. For example, a hospital in New York City may have had only a few ventilators while other facilities nearby had more than 100. The Surge and Flex system allowed for the overburdened hospital to get unused ventilators from a nearby facility. New York State distributed more than 13,000,000 pieces of PPE and other equipment, including thousands of ventilators. To ensure no hospital lacked supplies and equipment while others had excess, the state built an operational system that could quickly transport supplies and equipment from a hospital with excess to a hospital in need.

**Fourth, the State had to coordinate all aspects of the Surge and Flex operation.**

For this operational undertaking, the State convened a Hospital Capacity Coordination Committee (HCCC), an around the clock command center with representatives from each of the State's hospital systems to serve as the central hub for operations related to patient transfers, supply and equipment deployment, and staffing support. Guided by online data dashboards that tracked hospital capacity, equipment use, and supply stockpiles by institution in real time, and provided a 24/7 hotline accessible to every hospital in the state, the HCCC had a dedicated desk and assigned leader for every aspect of the operation: patient management, supply & equipment deployment, staffing deployment, and for each supporting function including transportation, legal, and intergovernmental relations.

Taken together, the "Surge and Flex" strategy enabled New York during our apex in late March and through the month of April to save lives and avoid the type of catastrophic failure of the healthcare system that Italy and other nations experienced. This regulation provides the Department of Health with the necessary tools to enact each of these four critical parts of NYS Surge and Flex operation during a second wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital and healthcare system prepare for this contingency in order to ensure a straightforward transition from standard operating procedures to "Surge and Flex."

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's health care delivery systems and mitigating the threat to the health of the people of New York. Further, this Part

establishes certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

To the extent that any provision of this Part conflicts with any other regulation of the Department, this Part shall take precedence. All authorities granted to the Commissioner shall be subject to any conditions and limitations that the Commissioner may deem appropriate. The Commissioner may delegate activation of the authorities provided by this Part to appropriate executive staff within the Department. In the event that there are inconsistent statutes, which would preclude effectiveness of such regulation, such regulation shall be effective upon the suspension of such inconsistent statute by the Governor pursuant to authority in Article 2-B of the Executive Law, and such regulation shall immediately be effective.

#### Section 360.2. Surge and Flex Health Care Coordination System Requirements.

(a) In the event of a declared State disaster emergency, the Commissioner shall have all necessary authority to activate the Surge and Flex Health Care Coordination System (hereinafter “Surge and Flex System”), including the following:

(1) Increase Bed Capacity. At the Commissioner’s direction, health care facilities shall increase by at least 50% and up to 100% the number of acute care beds and/or change the service categories of beds certified or otherwise approved in any entity regulated by the Department. At the Commissioner’s direction, health care facilities shall postpone all non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall approve temporary changes at regulated health care facilities to physical plants, to facilitate the increased capacity and shall expedite review of construction

applications related to temporary locations, provided that schematics are filed with the Department and patient safety is maintained.

(2) Enhanced Staffing Capacity. Health care facilities shall establish plans to meet enhanced staffing levels sufficient to ensure that the increased bed capacity has adequate staffing. The Commissioner may further expand or modify criteria for staffing. Health care facilities shall have access to a State-run portal for staffing needs identifying both volunteers and available staff; whether licensed or registered in New York State, or authorized or licensed to practice in any other state or Canada.

(3) Availability of Supplies and PPE. Health care facilities shall maintain and actively manage a supply of personal protective equipment (PPE) appropriate for use during a declared health emergency that could last at least 90-days pursuant to Sections 360.2 and 405.11(g) of this Title. The Commissioner shall have all necessary authority to re-distribute the resources of a regulated entity if there is a determination that such resources are limited and in order to preserve the health and safety of New Yorkers, including:

- (i) Requiring that any medical or other equipment that is held in inventory by any entity in the State, or otherwise located in the State, be reported to the Department, in a form and with such frequency as the Commissioner may determine, but at minimum every 24 hours.
- (ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine, but at minimum every 24 hours.
- (iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and four times per day if such testing results are



negative via the electronic clinical laboratory reporting system, or any other form and frequency as the Commissioner may determine.

(iv) Suspending or restricting visitation, in accordance with the need to conserve PPE, and subject to such conditions or limitations as the Commissioner may determine.

(4) Statewide Coordination.

(i) Discharging, transfer, and receiving of patients. Health care facilities regulated by the Department shall, if directed to do so by the Commissioner, rapidly discharge, transfer, or receive patients, while protecting the health and safety of such patients and residents, and consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA). The Department shall coordinate with health care facilities to balance individual facility patient load, and may promulgate further directives to specify the method and manner of transfer or discharge.

(ii) Designating Health Care Facilities as Trauma Centers. The Department is authorized to designate an entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; or modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility or other determination about patient care as appropriate, including restricting admission or treatment to patients with a particular diagnosis.

(iii) Maintaining a Statewide Health Care Data Management System. Health care facilities or systems shall report as directed by the Department any information necessary to implement the Surge and Flex System (e.g. available hospital beds, equipment available and in use) and the Department shall use that data in order to monitor, coordinate, and manage during the emergency.

Section 360.3. Hospital emergency Surge and Flex Response Plans.

(a) Every general hospital (hereinafter, “hospital”) shall adopt a detailed emergency Surge and Flex Response Plan (hereinafter, “plan”) that, at a minimum, includes the following elements:

- (1) Bed surge plan. The plan shall explain how the hospital will increase the number of current staffed acute care operational beds to a number set by the Commissioner, which shall be up to a 50% increase of such beds within seven days from the date of the declaration of the state disaster emergency, and up to a 100% increase within 30 days. For the purposes of this Part, an “acute care operational bed” means a bed that is staffed and equipped with appropriate infrastructure such that it can be used to deliver health care services to a patient. The Commissioner may further define the type of acute care operational beds for a given state disaster emergency, which may include isolation beds, intensive care (ICU) beds, pediatric and/or acute care beds.
- (2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 90-day supply of PPE within 30 days, based on a usage rate determined by the Commissioner, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain agreements executed by the hospital. Such plan shall further include, as appropriate, how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions.

(3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.

(4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.

(5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

(b) The Chief Executive Officer (CEO) of the hospital, or system, if authorized by the Commissioner to report on a system-wide basis, shall certify to the review and approval of the plan and including an attestation that it can be implemented and achieved in the event of a declared disaster emergency. The CEO shall be responsible for ensuring that the plan is reviewed and updated, as necessary, every six months and shall re-certify that it is able to be implemented and achieved upon each review.

(c) The Department may require the hospital to submit its disaster emergency response plan and history of semi-annual certifications for review, and may require the hospital to make such amendments to the plan as the Commissioner deems appropriate, to ensure that the plan will achieve the requirements established in subdivision (a) of this section, including increases in bed capacity.

(d) In the event of a declared state disaster emergency, any or all hospitals shall execute their plans immediately upon the direction of the Commissioner.

(e) Additional preparedness requirements.

(1) PPE. Every hospital shall, at all times, continue to maintain the required 90-day supply of PPE appropriate for use in a disaster emergency including a pandemic, based on a usage rate and determined by the Commissioner, and pursuant to section 405.11(g) of this Title.

(2) Information technology. Every hospital shall ensure that non-essential staff who are capable of working remotely in the event of an emergency are equipped and trained to do so, and that infrastructure is in place to allow for the repurposing of existing workspaces as needed when activating the Surge and Flex System.

(f) Reporting requirements during the activation of the Surge and Flex System.

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2. Such data may include, but shall not be limited to:

(i) Bed availability, both in total and by designated service.

(ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.

(iii) Patient demographics.

(iv) Other health statistics, including deaths.

(v) PPE and other supplies, in stock and ordered.

(vi) PPE and other supply usage rates.

(2) Such reports shall be submitted every 24 hours, except and unless otherwise directed by the Department.

#### Section 360.4 Clinical laboratory testing

(a) In the event of a declared state disaster emergency, the Commissioner shall have all necessary authority to:

(1) Authorize clinical laboratories to operate temporary collecting stations to collect specimens from individuals.

(b) In addition, and to the extent consistent with any Executive Order issued by the Governor, the Commissioner shall have all necessary authority to:

(1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test specimens from New York State, provided that such laboratories must meet any federal requirements.

(2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.

- (3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.
  - (4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.
  - (5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.
  - (6) Permit licensed pharmacists to order and administer clinical tests.
- (c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.
- (d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

Subdivision (g) of section 405.24 is amended to read as follows:

Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in

the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster. This shall be in addition to the Surge and Flex Plan that is required pursuant to Part 360 of the Title.

Section 400.1 of 10 NYCRR is amended to read as follows:

(a) This Subchapter shall be known and may be cited as "Medical Facilities--Minimum Standards," and shall apply to medical facilities defined as hospitals within article 28 of the Public Health Law. The standards within a particular article shall constitute the minimum standards for the identified medical facility in addition to those standards that may apply to such facilities as set forth in Articles 1 and 3 of this Subchapter as applicable.

(b) During the period of a state disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive

Law, which suspends or otherwise modifies state statutes pursuant to his authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 700.5 of 10 NYCRR is added to read as follow:

700.5 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.



A new paragraph (8) is added to subdivision (e) of section 1001.6 of 10 NYCRR, to read as follows:

(8) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 1.2 of 10 NYCRR is added to read as follows.

#### 1.2 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Chapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action

necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (4) subdivision (g) of section 487.3 of 18 NYCRR is added to read as follows:

(4) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any

provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (6) subdivision (f) of section 488.3 of 18 NYCRR is added to read as follows:

(6) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (5) subdivision (g) of section 490.3 of 18 NYCRR is added to read as follows:

(5) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any

provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

## REGULATORY IMPACT STATEMENT

### **Statutory Authority:**

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: “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 2801 defines the term “hospital” as also including residential health care facilities (nursing homes) and diagnostic and treatment centers (D&TCs). 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 such health care facilities.

PHL section 4662 authorizes the Commissioner to issue regulations governing assisted living residences. Social Services Law (SSL) section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. PHL section 576 authorizes the Commissioner to regulate clinical laboratories.

PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the Commissioner to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

**Legislative Objectives:**

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. Similarly, PHL Articles 36 and 40 ensure that the Department has the tools needed to achieve these goals in the home care and hospice spaces, and PHL section 4662 and SSL section 461 likewise ensure that the Department has appropriate regulatory authority with respect to assisted living residences and adult care facilities. PHL section 576 ensures that the Commissioner has appropriate regulatory authority over clinical laboratories. Finally, PHL section 225 ensures that the State Sanitary Code includes appropriate regulations in the areas of communicable disease control and environmental health, among others.

Each of these areas has been impacted by COVID-19. By permitting the Commissioner to temporarily suspend or modify regulatory provisions in each these areas, where not required by state statute or federal law, or where the Commissioner is authorized by a gubernatorial Executive Order, these amendments provide crucial flexibility for this and future emergency response efforts.

## **Needs and Benefits:**

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, “temporarily suspend any statute, local law, ordinance, orders, rules, or regulations, or parts thereof, of any agency . . . if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the state disaster emergency.” To that end, on March 7, 2020 and in response to the COVID-19 pandemic, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency, thereby enabling additional State action that aided in addressing the threat COVID-19 presents to the health and welfare of New York State residents and visitors.

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 90-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

During a state disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as is the case with COVID-19, this authority will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

**Costs:**

**Costs to Regulated Parties:**

As a significant portion of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties.

To the extent that additional requirements are imposed on regulated parties by these proposed regulatory amendments, most requirements would be in effect only for the duration of a declared state disaster emergency, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.



**Costs to Local Governments:**

As a significant portion of these regulatory amendments would give the Commissioner authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties, including facilities operated by local governments.

To the extent additional requirements are imposed on local governments that operate facilities regulated by the Department, most requirements would be in effect only for the duration of a declared state disaster emergency, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.

**Cost to State Government:**

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

**Paperwork:**

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although these proposed amendments require additional reporting, these reports can be submitted electronically using the current platforms that facilities are already using. Moreover, such reporting requirements would only be activated during a declared state disaster emergency, thereby limiting the burden.

**Local Government Mandates:**

Facilities operated by local governments will be subject to the same requirements as any other regulated facility, as described above.

**Duplication:**

These proposed regulatory amendments do not duplicate state or federal rules.

**Alternatives:**

The alternative would be to not promulgate the regulation. However, this alternative was rejected, as the Department believes that these regulatory amendments are necessary to facilitate response to a state disaster emergency.

**Federal Standards:**

42 CFR 482.15 establishes emergency preparedness minimum standards in four core areas including emergency planning, development of applicable policies and procedures, communications plan, and training and testing. These proposed amendments would complement the federal regulation and further strengthen hospitals' emergency preparedness and response programs.

**Compliance Schedule:**

These regulatory amendments will become effective upon publication of a Notice of Adoption in the New York State Register.

**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

The proposed regulatory amendments would primarily affect health care professionals, licensed health care facilities, permitted clinical laboratories, emergency medical service personnel, providers, and agencies, and pharmacies.

### **Compliance Requirements:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, as well as hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, which would apply regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans.

### **Professional Services:**

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

**Compliance Costs:**

As a significant portion of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to small businesses and local governments.

To the extent additional requirements are imposed on small businesses and local governments by these proposed regulatory amendments, most requirements would only be in effect for the duration of a declared state disaster emergency, thereby limiting costs. Ongoing costs requiring hospitals to maintain a minimum PPE supply and ensure work from home capabilities should have been addressed throughout the ongoing COVID-19 pandemic, thereby limiting costs of continued implementation. Ongoing costs related to hospital development of disaster emergency response plan will complement and build upon existing planning documents that hospitals are already required to have, which also limits costs.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the proposed regulatory amendments.

**Minimizing Adverse Impact:**

Although the proposed regulatory amendments impose some additional requirements on regulated parties, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would impose ongoing requirements would only apply

to hospitals, and as noted above, will largely be a continuation of the efforts already being employed by these entities.

**Small Business and Local Government Participation:**

Due to the emergency nature of COVID-19, small businesses and local governments were not consulted.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Number of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.” The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

|                    |                   |                     |
|--------------------|-------------------|---------------------|
| Allegany County    | Greene County     | Schoharie County    |
| Cattaraugus County | Hamilton County   | Schuyler County     |
| Cayuga County      | Herkimer County   | Seneca County       |
| Chautauqua County  | Jefferson County  | St. Lawrence County |
| Chemung County     | Lewis County      | Steuben County      |
| Chenango County    | Livingston County | Sullivan County     |
| Clinton County     | Madison County    | Tioga County        |
| Columbia County    | Montgomery County | Tompkins County     |
| Cortland County    | Ontario County    | Ulster County       |
| Delaware County    | Orleans County    | Warren County       |
| Essex County       | Oswego County     | Washington County   |
| Franklin County    | Otsego County     | Wayne County        |
| Fulton County      | Putnam County     | Wyoming County      |

Genesee County

Rensselaer County

Yates County

Schenectady County

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County

Monroe County

Orange County

Broome County

Niagara County

Saratoga County

Dutchess County

Oneida County

Suffolk County

Erie County

Onondaga County

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans.

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.



### **Compliance Costs:**

As a large part of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to public and private entities in rural areas.

To the extent additional requirements are imposed on public and private entities in rural areas by these proposed regulatory amendments, such requirements would only be in effect for the duration of a declared state disaster emergency.

Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

### **Economic and Technological Feasibility**

There are no economic or technological impediments to the rule changes.

### **Minimizing Adverse Impact**

Although the proposed regulatory amendments impose additional requirements on regulated parties, including those in rural areas, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would require disaster emergency preparedness planning on the part of regulated parties will complement and build upon existing state and federal planning requirements.

### **Rural Area Participation**

Due to the emergency nature of COVID-19, parties representing rural areas were not

consulted in the initial draft. However, parties representing rural may submit comments during the notice and comment period for the proposed regulations.

## **JOB IMPACT STATEMENT**

The Department of Health has determined that these regulatory changes will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

20-27 Amendment of Section 405.11 and Addition of New Sections 77.13, 77.14 and 415.33 to Title 10 NYCRR (COVID-19 Confirmatory Testing)

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, and in the Commissioner of Health by Sections 3401 and 4143 of the Public Health Law, 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:

Section 405.11 of 10 NYCRR is amended by adding a new subdivision (h) to read as follows:

(h) *COVID-19 Confirmatory Testing.*

(1) Any patient with symptoms of COVID-19 or who has been exposed to COVID-19 shall be tested for the COVID-19 virus, along with any other clinically appropriate testing.

(2) Whenever a person expires while in the hospital, or while enroute to the hospital, and in the professional judgment of the attending clinician there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed in the 14 days before death, the hospital shall administer a COVID-19 test within 48 hours after death, along with any other clinically appropriate testing. Such COVID-19 test shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of such test results through the Health Emergency Response Data System (HERDS). Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the hospital lack the ability to perform such testing expeditiously, the hospital should request assistance from the State Department of Health.

A new section 415.33 of 10 NYCRR is added to read as follows:

#### 415.33 COVID-19 Confirmatory Testing

(1) Any resident with symptoms of COVID-19 or who has been exposed to COVID-19 shall be tested for the COVID-19 virus, along with any other clinically appropriate testing.

(2) Whenever a person expires while in a nursing home, where in the professional judgment of the nursing home clinician there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed in the 14 days before death, the nursing home shall administer a COVID-19 test within 48 hours after death, along with any other clinically appropriate testing.

Such COVID-19 test shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of such test results through the Health Emergency Response Data System (HERDS).

Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the nursing home lack the ability to perform such testing expeditiously, the nursing home should request assistance from the State Department of Health.

A new section 77.13 of 10 NYCRR is added to read as follows:

#### 77.13 COVID-19 Confirmatory Testing – Funeral Directors.

Whenever the funeral director has been advised by an attending health care practitioner (whether the death was in hospice, an adult care facility, or any another setting where a positive diagnosis was not made) and there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed within 14 days prior to death in a nursing home or hospital, or by the hospice

agency, coroner, or medical examiner, the funeral director shall administer a COVID-19 test within 48 hours after death, whenever the body is received within 48 hours after death. Such test shall be performed using rapid testing methodologies to the extent available. The funeral director shall report the death to the Department immediately after and only upon receipt of such test results, through a means determined by the Department. Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the funeral director lack the ability to perform such testing expeditiously, the funeral director should request assistance from the State Department of Health.

A new section 77.14 of 10 NYCRR is added to read as follows:

**77.14 COVID-19 Confirmatory Testing – Coroners and Medical Examiners.**

Whenever a coroner or medical examiner has a reasonable suspicion that COVID-19 was a cause of death, but no such test was performed within 14 days prior to death in a nursing home or hospital, or by the hospice agency, the coroner or medical examiner shall administer a COVID-19 test within 48 hours after death, whenever the body is received within 48 hours after death.

Such test shall be performed using rapid testing methodologies to the extent available. The coroner or medical examiner shall report the death to the Department immediately after and only upon receipt of such test results, through a means determined by the Department.

Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the coroner or medical examiner lack the ability to perform such testing expeditiously, the coroner or medical examiner may request assistance from the State Department of Health.

## REGULATORY IMPACT STATEMENT

### **Statutory Authority:**

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: “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 2801 defines the term “hospital” as also including residential health care facilities, which are commonly referred to as nursing homes. 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 such health care facilities. PHL section 3401 authorizes the Commissioner to issue regulations pertaining to the business of funeral directing, and section 4143 authorized the Commissioner to collect information from coroners and medical examiners related to cause of death.



**Legislative Objectives:**

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. The objective of PHL Section 3401 is to authorize the Commissioner to regulate the business of funeral directing, and the objective of section 4143 is to authorize the Commissioner to collect such information related to cause of death from coroners and medical examiners as the Commissioner may require.

**Needs and Benefits:**

Contact tracing is particularly important for cases of COVID-19 as the State continues its highly effective containment and mitigation strategies to ensure that the spread of COVID-19 remains at a level that the hospital system can accommodate. In order for New York State to more fully assess the number of COVID-19 cases and conduct contact tracing, testing of hospital patients and nursing home residents must be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Patients or residents without symptoms, but who have had an exposure to COVID-19 must also be tested for COVID-19, and any other clinically appropriate testing. Further, in the event of an unattended death, in those instances where such testing was not already performed, the coroner, medical examiner, or funeral director must perform the test, depending on who first receives the deceased.

Consistent with CDC guidance and the end of the influenza season, the Department is removing the general requirement that hospitals and nursing homes test patients and residents for influenza, and the general requirement that funeral directors, coroners and medical examiners to test deceased persons for influenza.

**Costs:****Costs to Regulated Parties:**

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID-19 testing technologies have been advertised at as low as \$5 per test.

**Costs to Local Governments:**

For those local governments that operate a general hospital or nursing home, the costs will be the same as those described above.

**Cost to State Government:**

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

**Paperwork:**

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although this regulation will require hospitals and nursing homes to test persons for COVID-19, the Department does not anticipate that such additional tests will be burdensome given that these facilities are already testing patients and residents for these diseases in many instances.

**Local Government Mandates:**

Facilities operated by local governments will be subject to the same requirements as any other regulated facility, as described above.

**Duplication:**

These proposed regulatory amendments do not duplicate state or federal rules.

**Alternatives:**

The alternative would be to not promulgate the regulation, and to allow deaths to be reported as “presumed” deaths of COVID-19. However, this alternative was rejected on two grounds. First, a lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing, which would allow COVID-19 to spread indefinitely. Second, the regulations would encourage hospitals, nursing homes and hospices to test patients early for COVID-19, which will increase safety of patients and residents.

**Federal Standards:**

No federal standards apply.

**Compliance Schedule:**

These regulatory amendments will become effective upon publication of a Notice of Adoption in the New York State Register.

**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

For those local governments or small businesses that operate a general hospital or nursing home, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

### **Compliance Requirements:**

As discussed above, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

### **Professional Services:**

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used when available.

**Compliance Costs:**

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as \$5 per test.

**Economic and Technological Feasibility:**

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

**Minimizing Adverse Impact:**

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.88. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these regulatory requirements, thus helping to minimize any adverse impacts.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted. However, parties representing local governments and small businesses may submit comments during the notice and comment period in the event the Department promulgates proposed regulations.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Number of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.” The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

|                    |                   |                     |
|--------------------|-------------------|---------------------|
| Allegany County    | Greene County     | Schoharie County    |
| Cattaraugus County | Hamilton County   | Schuyler County     |
| Cayuga County      | Herkimer County   | Seneca County       |
| Chautauqua County  | Jefferson County  | St. Lawrence County |
| Chemung County     | Lewis County      | Steuben County      |
| Chenango County    | Livingston County | Sullivan County     |
| Clinton County     | Madison County    | Tioga County        |
| Columbia County    | Montgomery County | Tompkins County     |
| Cortland County    | Ontario County    | Ulster County       |
| Delaware County    | Orleans County    | Warren County       |
| Essex County       | Oswego County     | Washington County   |
| Franklin County    | Otsego County     | Wayne County        |



|                |                    |                |
|----------------|--------------------|----------------|
| Fulton County  | Putnam County      | Wyoming County |
| Genesee County | Rensselaer County  | Yates County   |
|                | Schenectady County |                |

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

|                 |                 |                 |
|-----------------|-----------------|-----------------|
| Albany County   | Monroe County   | Orange County   |
| Broome County   | Niagara County  | Saratoga County |
| Dutchess County | Oneida County   | Suffolk County  |
| Erie County     | Onondaga County |                 |

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used.

**Compliance Costs:**

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected, but not known, to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing

methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as \$5 per test. Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

**Economic and Technological Feasibility:**

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

**Minimizing Adverse Impact:**

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.88. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these regulatory requirements, thus helping to minimize any adverse impacts.

**Rural Area Participation**

Due to the emergency nature of COVID-19, parties representing rural areas were not

consulted in the initial draft. However, parties representing rural may submit comments during the notice and comment period in the event the Department promulgates proposed regulations.

## **JOB IMPACT STATEMENT**

The Department of Health has determined that these regulatory changes will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to  
Title 10 NYCRR (Investigation of Communicable Disease; Isolation and Quarantine)

## **SUMMARY OF EXPRESS TERMS**

These regulations clarify the authority and duty of the New York State Department of Health (“Department”) and local health departments to protect the public in the event of an outbreak of communicable disease, through appropriate public health orders issued to persons diagnosed with or exposed to a communicable disease. These regulations also require hospitals to report syndromic surveillance data to the Department upon direction from the Commissioner and clarify reporting requirements for clinical laboratories with respect to communicable diseases.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 576, and 2803 of the Public Health Law, Section 2.2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, Section 2.6 is repealed and a new Section 2.6 is added, a new Section 2.13 is added, Sections 2.25 through 2.30 are repealed, a new Section 58-1.14 is added, and Section 405.3 is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (b) and (c) of Section 2.2 are amended, and new subdivisions (h) through (q) are added, to read as follows:

(b) [A *case* is defined as] Case shall mean a person who has been diagnosed [as likely to have] as having a particular disease or condition. The diagnosis may be based [solely] on clinical judgment, signs and symptoms combined with known exposure based on the best available evidence of transmissibility to a case or suspected case, [solely] and/or on laboratory evidence, [or on both criteria] as applicable.

(c) [A *suspected case* is defined as] Suspected case shall mean a person who has been [diagnosed] determined as [likely to have] possibly having a particular disease or condition. [The suspected diagnosis] A suspected case may be based [solely] on signs and symptoms, signs and symptoms combined with known exposure based on the best available evidence of transmissibility to a case or suspected case, [or solely] and/or on laboratory evidence, [or on both criteria] as applicable. The term “suspected case” shall include persons under

investigation, consistent with any guidance that the Commissioner of Health may issue with respect to a particular disease.

\* \* \*

- (h) Contact shall mean any person known to have been sufficiently associated with a case or suspected case that, based on the best available evidence of transmissibility, such person has had the opportunity to contract a particular disease or condition.
  
- (i) Isolation shall mean the physical separation and confinement of an individual or group of individuals who are infected or reasonably determined by the State Commissioner of Health or local health authority to be infected with a highly contagious disease or organism, for such time as will prevent or limit the transmission of the reportable disease or organism to non-isolated individuals, in the clinical judgment of the State Commissioner of Health, or of the local health authority and consistent with any direction that the State Commissioner of Health may issue.
  
- (j) Quarantine shall mean the physical separation and confinement of an individual or groups of individuals who are reasonably determined by the State Commissioner of Health or local health authority to have been exposed to a highly contagious communicable disease, but who do not show signs or symptoms of such disease, for such time as will prevent transmission of the disease, in the clinical judgment of the State Commissioner of Health, or of the local



health authority and consistent with any direction that the State Commissioner of Health may issue.

- (k) Home quarantine or home isolation shall mean quarantine or isolation in a person's home, consistent with this Part and any direction that the State Commissioner of Health may issue;
- (l) Congregate quarantine shall mean quarantine at a location operated or contracted by the State or local health authority, consistent with this Part and any direction that the State Commissioner of Health may issue, where multiple persons are quarantined;
- (m) Highly contagious communicable disease shall mean a communicable disease or unusual disease that the State Commissioner of Health determines may present a serious risk of harm to the public health, for which isolation or quarantine may be required to prevent its spread.
- (n) Monitor shall mean contacting a person who is the subject of an isolation or quarantine order by the State Department of Health or local health authority, to ensure compliance with the order and to determine whether such person requires a higher level of medical care, consistent with any direction that the State Commissioner of Health may issue.
- (o) Mandatory quarantine shall mean quarantine pursuant to a legal order consistent with this Part.
- (p) Voluntary quarantine shall mean quarantine pursuant to a voluntary agreement with a public health authority.
- (q) Confinement shall mean enforcement of an isolation or quarantine order through the use or possible use of law enforcement personnel.

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

(a) Except where other procedures are specifically provided in law, every local health authority, either personally or through a qualified representative, shall immediately upon receiving a report of a case, suspected case, outbreak, or unusual disease, investigate the circumstances of such report at any and all public and private places in which the local health authority has reason to believe, based on epidemiological or other relevant information available, that such places are associated with such disease. The local health authority shall implement public health response activities and issue public health orders as necessary to control disease spread. Such investigations, response activities, and orders shall be, consistent with any direction that the State Commissioner of Health may issue and subject to any State approvals that may be required. As applicable, such actions shall include:

- (1) Verifying the existence of a disease or condition;
- (2) Ascertaining the source of the disease-causing agent or condition;
- (3) Identifying unreported cases;
- (4) Locating and evaluating contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collecting and submitting, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;

- (6) Examining the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;
- (7) Instructing a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Taking any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

(b) When a case or suspected case of a disease, condition, outbreak, or unusual disease occurs in any business, organization, institution, or private home, the person in charge of the business, organization, institution or the home owner, as well as any individuals or entities required to report pursuant to sections 2.10 and 2.12 of this Part, shall cooperate with the State Department of Health and local health authorities in the investigation of such disease, condition, outbreak, or unusual disease.

(c) Investigation Updates and Reports.

- (1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health.
- (2) The local health authority shall complete investigation reports of outbreaks within 30 days of the conclusion of the investigation in a manner prescribed by the State

Commissioner of Health, unless the State Commissioner of Health prescribes a different time period.

(d) Commissioner authority to lead investigation activities.

(1) The State Commissioner of Health may elect to lead investigation activities where:

- (i) Residents of multiple jurisdictions within the State are affected by an outbreak of a reportable disease, condition, or unusual disease; or
- (ii) Residents in a jurisdiction or jurisdictions within the State and in other state are affected by an outbreak of a reportable disease, condition, or unusual disease; or
- (iii) An outbreak of an unusual disease or a reportable disease or condition involves a single jurisdiction with the high potential for statewide impact.

(2) Where the State Commissioner of Health elects to lead investigation activities pursuant to paragraph (1) of this subdivision, the State Commissioner of Health shall lead such investigation, but local health authorities shall take all reasonable steps to assist in such investigation, including supply of personnel, equipment or information. Provided further that the local health authority shall take any such action as the State Commissioner of Health deems appropriate and that is within the jurisdiction of the local health authority. Any continued investigation by the local health authority shall be solely pursuant to the direction of the State Commissioner of Health, and the State Commissioner of Health shall have access to any investigative materials which were heretofore created by the local health authority.

- (e) Any person who violates a public health order issued pursuant to this section shall be subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that the order is violated shall constitute a separate violation of this Part.

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

- (a) Duty to issue isolation and quarantine orders

- (1) Whenever appropriate to control the spread of a highly contagious communicable disease, the State Commissioner of Health may issue and/or may direct the local health authority to issue isolation and/or quarantine orders, consistent with due process of law, to all such persons as the State Commissioner of Health shall determine appropriate.
- (2) Paragraph (1) of this subdivision shall not be construed as relieving the authority and duty of local health authorities to issue isolation and quarantine orders to control the spread of a highly contagious communicable disease, consistent with due process of law, in the absence of such direction from the State Commissioner of Health.
- (3) For the purposes of isolation orders, isolation locations may include home isolation or such other residential or temporary housing location that the public health authority issuing the order determines appropriate, where symptoms or conditions indicate that medical care in a general hospital is not expected to be required, and consistent with any direction that the State Commissioner of Health may issue. Where symptoms or conditions indicate that medical care in a general hospital is expected to be required, the isolation location shall be a general hospital.

(4) For the purposes of quarantine orders, quarantine locations may include home quarantine, other residential or temporary housing quarantine, or quarantine at such other locations as the public health authority issuing the order deems appropriate, consistent with any direction that the State Commissioner of Health may issue.

(b) Any isolation or quarantine order shall specify:

(1) The basis for the order;

(2) The location where the person shall remain in isolation or quarantine, unless travel is authorized by the State or local health authority, such as for medical care;

(3) The duration of the order;

(4) Instructions for traveling to the isolation or quarantine location, if appropriate;

(5) Instructions for maintaining appropriate distance and taking such other actions as to prevent transmission to other persons living or working at the isolation or quarantine location, consistent with any direction that the State Commissioner of Health may issue;

(6) If the location of isolation or quarantine is not in a general hospital, instructions for contacting the State and/or local health authority to report the subject person's health condition, consistent with any direction that the State Commissioner of Health may issue;

(7) If the location of isolation or quarantine is a multiple dwelling structure, that the person shall remain in their specific dwelling and in no instance come within 6 feet of any other person, and consistent with any direction that the State Commissioner of Health may issue;

- (8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;
- (9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;
- (10) Notification of the right to request that the public health authority issuing the order inform a reasonable number of persons of the conditions of the isolation or quarantine order;
- (11) A statement that the person has the right to seek judicial review of the order;
- (12) A statement that the person has the right to legal counsel, and that if the person is unable to afford legal counsel, counsel will be appointed upon request.

(c) Whenever a person is subject to an isolation or quarantine order, the State Department of Health or local health authority, or the local health authority at the State Department of Health's direction shall, consistent with any direction issued by the State Commissioner of Health:

- (1) monitor such person to ensure compliance with the order and determine whether such person requires a higher level of medical care;
- (2) whenever appropriate, coordinate with local law enforcement to ensure that such person comply with the order; and

- (3) the extent such items and services are not available to such person, provide or arrange for the provision of appropriate supports, supplies and services, including, but not limited to: food, laundry, medical care, and medications.
- (d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the local health authority, and consistent with any direction that the State Commissioner of Health may issue.
- (e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.
- (f) Any person who violates a public health order issued pursuant to this section shall be subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that the order is violated shall constitute a separate violation of this Part.
- (g) Duty of attending physician
- (1) Every attending physician shall immediately, upon discovering a case or suspected case of a highly contagious reportable communicable disease, cause the patient to be



appropriately isolated and contact the State Department of Health and the local health authority where the patient is isolated and, if different, the local health authority where the patient resides.

(2) Such physician shall advise other members of the household regarding precautions to be taken to prevent further spread of the disease, consistent with any direction that the State Commissioner of Health may issue.

(3) Such physician shall furnish the patient, or caregiver of such patient where applicable, with detailed instructions regarding the disinfection and disposal of any contaminated articles, consistent with any direction that the State Commissioner of Health may issue.

Sections 2.25, 2.26, 2.27, 2.28, 2.29, and 2.30 are repealed.

Paragraph (11) of subdivision (d) of section 405.3 is amended, paragraph (12) is renumbered paragraph (13), and a new paragraph (12) is added, to read as follows:

(11) written minutes of each committee's proceedings. These minutes shall include at least the following:

- (i) attendance;
- (ii) date and duration of the meeting;
- (iii) synopsis of issues discussed and actions or recommendations made; [and]

(12) whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, such syndromic surveillance data as the commissioner deems appropriate, which the hospital shall submit in the manner and form determined by the commissioner; and

(13) any record required to be kept by the provisions of this Part.

\* \* \*

Section 58-1.14 Reporting of certain communicable diseases

(a) The commissioner shall designate those communicable diseases, as defined by section 2.1 of the Sanitary Code, that require prompt action, and shall make available on the Department's website a list of such communicable diseases.

(b) Laboratories performing tests for screening, diagnosis or monitoring of communicable diseases requiring prompt action pursuant to subdivision (a) of this section, for New York State residents and/or New York State health care providers, shall:

(i) immediately report to the commissioner all positive results for such communicable diseases in a manner and format as prescribed by the commissioner; and

(ii) report all results, including positive, negative and indeterminate results, to the commissioner in a time and manner consistent with Public Health Law § 576-c.

\* \* \*

Section 405.3 is amended by adding a new subdivision (g) as follows:

(g) Whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, the commissioner may direct general hospitals, as defined in Article 28 of the public health law, and consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA), to accept patients pursuant to such procedures and conditions as the commissioner may determine appropriate.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is Section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York. Additionally, Section 2103 of the PHL requires all local health officers to report cases of communicable disease to the New York State Department of Health (Department).

The statutory authority for the proposed new section 58-1.14 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 576 of the PHL, which authorizes the Department to adopt regulations prescribing the requirements for the proper operation of a clinical laboratory, including the methods and the manner in which testing or analyses of samples shall be performed and reports submitted.

The statutory authority for the proposed amendments to section 405.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 2803 of the PHL, which 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.

**Legislative Objectives:**

The legislative objective of PHL § 225 is, in part, to protect the public health by authorizing PPHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

The legislative objective of PHL § 576 is, in part, to promote public health by establishing minimum standards for clinical laboratory testing and reporting of test results, including to the Department for purposes of taking prompt action to address outbreaks of disease.

The legislative objective of PHL § 2803 includes among other objectives authorizing PPHPC, with the approval of the Commissioner, to adopt regulations concerning the operation of facilities licensed pursuant to Article 28 of the PHL, including general hospitals.

**Needs and Benefits:**

The 2019 Coronavirus (COVID-19) is a disease that has caused mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and can be fatal.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. A short time later, on January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On January 31, 2020, the Secretary of Health and Human Services determined that as a result of confirmed cases of COVID-19 in the United States, a public health emergency exists and has existed since January 27, 2020, nationwide.

Thereafter, the United States quickly progressed from identifying travel-associated cases and person-to-person transmission of COVID-19 among close contacts of travel-associated cases, to the identification of community spread of the disease throughout the country.

The Department proposes to adopt these regulations, originally proposed as emergency regulations, that update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

The following is a summary of the amendments to the Department's regulations:

*Part 2 Amendments:*

- Relocate and update definitions, and add new definitions
- Repeal and replace current section 2.6, related to investigations, to make existing clarify local health department authority.
  - Sets forth specific actions that local health departments must take to investigate a case, suspect case, outbreak, or unusual disease.
  - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
  - Clarifies authority for the Commissioner to lead investigation activities.
  - Codifies in regulation the requirement that local health departments send reports the Department during an outbreak.
- New section 2.13 added to clarify isolation and quarantine procedures.
  - Clarify that the State Department of Health has the authority to issue isolation and quarantine orders, as do local departments of health.

- Clarifies locations where isolation or quarantine may be appropriate.
- Sets forth requirements for the content of isolation and quarantine orders.
- Specifies other procedures that apply when a person is isolated or quarantined.
- Explicitly states that violation of an order constitutes grounds for civil and/or criminal penalties
- Relocates and updates existing regulatory requirements that require the attending physician to report cases and suspected cases to the local health authority, and to requires physicians to provide instructions concerning how to protect others.

*Part 58 Amendments*

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases
  - Requires the Commissioner to designate those communicable disease that require prompt action, and to make available a list of such disease on the State Department of Health website.
  - Requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the Commissioner.
  - Requires clinical laboratories to report all test result, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

*Part 405 Amendments*

- Mandates hospitals to report syndromic surveillance data during an outbreak of a highly contagious communicable disease.
- Permits the Commissioner to direct hospitals to take patients during an outbreak of a highly contagious communicable disease, which is consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA).

## **COSTS:**

### **Costs to Regulated Parties:**

The requirement that hospital submit syndromic surveillance reports when request during an outbreak is not expected to result in any substantial costs. Hospitals are already regularly and voluntarily submitting data to the Department, and nearly all of them submit such reports electronically. With regard to the Commissioner directing general hospitals to accept patients during an outbreak of a highly contagious communicable disease, hospitals are already required to adhere to the federal Emergency Medical Treatment and Labor Act (EMTALA). Accordingly, both of these proposed amendments will not impose any substantial additional cost to hospitals.

Clinical laboratories must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to imposes any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of



local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

**Costs to Local and State Governments:**

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations. Further, making explicit the Department’s authority to lead investigation activities will result in increased coordination of resources, likely resulting in a cost-savings for State and local governments.

Any clinical laboratories operated by a local government must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

To the extent that the State Department of Health and local health departments issue isolation and quarantine orders in response to COVID-19, such actions will impose costs upon the state. As the scope of any outbreak is difficult to predict, the cost to the State of issuing such orders cannot be predicted at this time.

**Paperwork:**

Some hospitals may be required to make additional syndromic surveillance reports that they are not already making. Otherwise, these regulations do not require any additional paperwork.

**Local Government Mandates:**

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

**Duplication:**

There is no duplication in existing State or federal law.

**Alternatives:**

The alternative would be to leave in place the current regulations on disease investigation and isolation and quarantine. However, many of these regulatory provisions have not been updated in fifty years and should be modernized to ensure appropriate response to a disease outbreak, such as COVID-19.

**Federal Standards:**

States and local governments have primary authority for controlling disease within their respective jurisdictions. Accordingly, there are no federal statutes or regulations that apply to disease control within NYS.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

### **Compliance Requirements:**

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties. With respect to mandating syndromic surveillance reporting during an outbreak of a highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

### **Professional Services:**

It is not expected that any professional services will be needed to comply with this rule.

**Compliance Costs:**

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

Further, making explicit the Department's authority to lead investigation activities will result in increased coordination of resources, likely resulting in a cost-savings for State and local governments.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with regulated entities to ensure they are aware of the new regulations and have the information necessary to comply.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity provided comments during the notice and comment period.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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| Delaware County    | Orleans County     | Warren County       |
| Essex County       | Oswego County      | Washington County   |
| Franklin County    | Otsego County      | Wayne County        |
| Fulton County      | Putnam County      | Wyoming County      |
| Genesee County     | Rensselaer County  | Yates County        |
|                    | Schenectady County |                     |

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States

Census estimated county populations for 2010:

Albany County  
Broome County  
Dutchess County  
Erie County

Monroe County  
Niagara County  
Oneida County  
Onondaga County

Orange County  
Saratoga County  
Suffolk County

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during an outbreak is historically a practice that already occurs. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102.

**Compliance Costs:**

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, no initial or annual capital costs of compliance are expected above and beyond the cost of compliance for the requirements currently in Parts 2, 58 and 405.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with local health departments to ensure they are aware of the new regulations and have the information necessary to comply.

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity provided comments during the notice and comment period.



## **JOB IMPACT STATEMENT**

The Department of Health has determined that this regulatory change will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)

Pursuant to the authority vested in the Commissioner of Health by sections 201, 206 and 2803 of the Public Health Law, sections 461 and 461-e of the Social Services Law, and Executive Orders 202, 202.86 and 202.88, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended by adding a new Subpart 66-4, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 66-4, titled COVID-19 Nursing Home and Adult Care Facility Vaccination Program, is added to read as follows:

#### 66-4.1. Duration and Applicability

The provisions of this Subpart shall apply to all nursing homes and adult care facilities. To the extent any provision of this Subpart becomes inconsistent with any Executive Order, the remainder of the provisions in the Subpart shall remain in effect and shall be interpreted to the maximum extent possible as consistent with such Executive Orders.

#### 66-4.2 Requirements for Nursing Homes

(a) Within fourteen days of the effective date of this regulation, every nursing home regulated pursuant to Part 415 of this Title shall offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any required next dose of the COVID-19 vaccine.

(b) The operator and administrator of every nursing home regulated pursuant to Part 415 of this Title must ensure that all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility has an opportunity to receive the first or any

required next dose of the COVID-19 vaccine within fourteen days of having been hired by or admitted or readmitted to such facility, as applicable.

(c) The requirement to ensure that all new and current personnel and residents have an opportunity to receive the COVID-19 vaccination, as set forth in subdivisions (a) and (b) of this section, shall include, but not be limited to:

(1) Posting conspicuous signage throughout the facility, including at points of entry and exit and each residential hallway, reminding personnel and residents that the facility offers COVID-19 vaccination;

(2) Providing all personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for a COVID-19 vaccination but declined. Such affirmation must state that the signatory is aware that, if they later decide to be vaccinated for COVID-19, it is their responsibility to request vaccination from the facility. The facility shall maintain signed affirmations on file at the facility and make such forms available at the request of the Department; and

(3) Certifying to the Department, on a weekly basis, that the facility has proactively offered all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within fourteen days of being hired, admitted, or readmitted.

#### 66-4.3. Requirements for Adult Care Facilities

(a) Within seven days of the effective date of this regulation, the operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title shall make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment, and shall document

attempts to schedule and methods used to schedule the vaccine in the individual's personnel file or case management notes, as applicable.

(b) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title must arrange for the COVID-19 vaccination, including the first or any required next dose, of all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility. The requirement to arrange for COVID-19 vaccination of such personnel and residents shall include, but not be limited to:

(1) For residents:

(i) during the pre-admission screening process, and in no event after the first day of admission or readmission, the adult care facility shall screen the prospective or newly-admitted or readmitted resident for COVID-19 vaccine eligibility, including whether any first doses of the vaccine were previously administered, and whether the resident is interested in obtaining the COVID-19 vaccine. Such information shall be documented with the resident's pre-admission screening information and, if admitted, retained in the resident's case management records; and

(ii) within seven days of admission or readmission, the facility shall make diligent efforts to schedule all consenting and eligible new or readmitted residents for the COVID-19 vaccination. The facility must document attempts to schedule and methods used to schedule the vaccine appointment in the resident's case management notes.

(2) For personnel:

(i) during the pre-employment screening process, the facility shall solicit information from the prospective personnel regarding their vaccination status, including whether any

first doses of the vaccine were previously administered, and whether the prospective personnel is interested in obtaining the COVID-19 vaccine. Such information must be documented with the personnel's pre-employment screening information and, if hired, retained in the personnel file; provided, however, that nothing in this paragraph shall be construed to require an adult care facility to make any hiring determination based upon the prospective personnel's COVID-19 vaccination status, history, or interest in COVID-19 vaccination; and

(ii) within seven days of hiring new personnel, the facility shall make diligent efforts to schedule all consenting and eligible new personnel for the COVID-19 vaccination. The facility must document attempts to schedule and methods used to schedule the vaccine appointment in the individual's personnel file; and

(3) Certifying to the Department, on a weekly basis, that the facility has proactively arranged for all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within seven days of being hired, admitted, or readmitted.

(c) The facility shall further provide all current and new personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for the facility to arrange for a COVID-19 vaccination, but declined. Such affirmation must state that the signatory is aware that, if they later decide to be vaccinated for COVID-19, it is their responsibility to request the facility arrange for their vaccination. The facility shall maintain signed affirmations on file at the facility and make such forms available at the request of the Department.

66-4.4. Penalties.

(a) A violation of any provision of this Subpart is subject to all civil and criminal penalties provided for by law. To the extent any Executive Order is inconsistent with the penalties prescribed herein, the penalties in the Executive Order shall apply.

(b) All other violations of this Subpart shall be subject to penalties in accordance with sections 12 and 12-b of the Public Health Law.

(c) For adult care facilities, failure to arrange for the vaccination of every facility resident and personnel as set forth in section 66-4.3 of this Part constitutes a “failure in systemic practices and procedures” under Social Services Law 460-d(7)(b)(2)(iii) and pursuant to 18 NYCRR 486.5(a)(4)(v).

(d) In addition to any monetary penalties or referral for criminal investigation to appropriate entities, the Department shall be empowered to immediately take custody and control of such vaccine at a nursing home and re-allocate in accordance with the State’s Vaccination Plan.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The statutory authority is provided under sections 201, 206, and 2803 of the Public Health Law (PHL), and sections 461 and 461-e of the Social Services Law (SSL).

PHL § 201 authorizes the New York State Department of Health (Department) to control and promote the control of communicable diseases to reduce their spread. Likewise, PHL § 206 authorizes the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases.

PHL § 2803 authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities.

SSL § 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities. SSL § 461-e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facility's residents and the operation of the facility.

### **Legislative Objectives:**

The legislative objectives of PHL §§ 201 and 206 are to protect the health and life of the people of the State of New York, including by controlling the spread of communicable diseases. The legislative objectives of PHL Article 28, including PHL § 2803, include the efficient provision and proper utilization of health services of the highest quality. The legislative objective of SSL § 461 is to promote the health and well-being of residents of adult care



facilities. Collectively, the legislative purpose of these statutes is to protect the residents of New York's long-term care facilities by providing safe, efficient, and adequate care.

**Needs and Benefits:**

These regulations are necessary to prevent the spread of COVID-19 in nursing homes and adult care facilities and to help ensure the health and life of residents of nursing homes and ACFs by requiring such congregate care facilities to offer or arrange for consenting residents and personnel to receive the COVID-19 vaccine. This requirement will help ensure residents are less likely to suffer a COVID-related death or severe illness and that fewer staff test positive for COVID-19.

COVID-19 is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

New York State first identified cases on March 1, 2020 and thereafter become the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. With over 2 million confirmed

cases and almost 42,000 deaths as of May 25, 2021, New York State has been immensely affected by COVID-19.

Given the disproportionate adverse health impacts of COVID-19 for older adults and those with comorbidities, many of whom reside in New York's nursing homes and ACFs, it is imperative that nursing homes and ACFs facilitate the prompt vaccination of its residents. Moreover, in order to ensure that nursing home and ACF personnel can safely provide resident care, it is critically important that nursing homes offer continued COVID-19 vaccinations on-site for their current and new personnel and that ACFs arrange for their current and new personnel to receive the COVID-19 vaccine at an off-site location, such as a State-operated vaccination site or a pharmacy.

Based on the foregoing, the Department has made the determination that this regulation is necessary to best protect the residents of New York's nursing homes and ACFs.

## **COSTS:**

### **Costs to Regulated Parties:**

The purpose of this regulation is to require nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing homes cover administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), "starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series."

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation, particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

**Costs to Local and State Governments:**

This regulation will not impact local or State governments unless they operate a nursing home or ACF, in which case costs will be the same as costs for private entities. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two adult care facilities operated by county governments.

**Costs to the Department of Health:**

This regulation will not result in any additional operational costs to the Department of Health.

**Paperwork:**

This regulation imposes no additional paperwork. Although the regulation requires recordkeeping by facilities, including documentation in personnel files and resident clinical or case management records, these records must already be maintained by facilities.

**Local Government Mandates:**

Nursing homes and ACFs operated by local governments will be affected and will be subject to the same requirements as any other nursing home licensed under PHL Article 28 or ACF licensed under SSL Article 7, Title 2.

**Duplication:**

These regulations do not duplicate any State or federal rules.

**Alternatives:**

The Department believes that promulgation of this regulation is the most effective means of ensuring that nursing homes and ACFs adequately ensure their residents and personnel are vaccinated against COVID-19. Accordingly, the alternative of not issuing these regulations was rejected.

**Federal Standards:**

No federal standards apply.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

**Contact Person:** Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

This regulation will not impact local governments or small businesses unless they operate a nursing home or ACF. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two ACFs operated by county governments (Chenango and Warren Counties).

Additionally, to date, 79 nursing homes in New York qualify as small businesses given that they have 100 or fewer employees. There are also 483 ACFs that have 100 or fewer employees and therefore qualify as small businesses.

### **Compliance Requirements:**

This regulation primarily requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. Additionally, nursing homes and ACFs will be required to certify to the Department that the facility has proactively arranged for or offered, as applicable, all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within the prescribed period of time. The regulation also requires facilities to provide all current and new personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for the facility to arrange for or offer, as

applicable, a COVID-19 vaccination, but they declined. Further, nursing homes are required to post conspicuous signage throughout the facility reminding personnel and residents that the facility offers COVID-19 vaccinations.

**Professional Services:**

No professional services are required by this regulation. However, nursing homes may choose to partner with a pharmacy to offer COVID-19 vaccinations for personnel and residents of the facility, rather than receiving and administering the vaccine directly.

**Compliance Costs:**

This regulation requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing homes cover administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), “starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series.”

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local

pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

This regulation is consistent with the existing responsibilities nursing homes and ACFs have to maintain the health and safety of residents, ensure sufficient staffing levels, and ensure staff are free from communicable diseases. Therefore, any adverse impacts are expected to be minimal and are outweighed by the regulation's health and safety benefits to residents and staff.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not directly consulted.

**Cure Period:**

This regulation does not include a cure period given the emergent nature of COVID-19 and the serious threat the virus causes to all New Yorkers, particularly those residing in nursing homes and adult care facilities, considering such residents' age and comorbidities. As detailed more fully within the regulations, nursing homes and adult care facilities will have 14 and 7 days, respectively, to offer vaccinations to residents and staff. The Department finds these 14-



and 7-day periods to comply with the regulatory requirements are sufficient to ensure facilities can establish or revise their vaccination policies and procedures, while balancing the emergent nature of COVID-19 and the urgent need to protect facility residents and personnel from this dangerous disease.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

|                    |                    |                     |
|--------------------|--------------------|---------------------|
| Allegany County    | Greene County      | Schoharie County    |
| Cattaraugus County | Hamilton County    | Schuyler County     |
| Cayuga County      | Herkimer County    | Seneca County       |
| Chautauqua County  | Jefferson County   | St. Lawrence County |
| Chemung County     | Lewis County       | Steuben County      |
| Chenango County    | Livingston County  | Sullivan County     |
| Clinton County     | Madison County     | Tioga County        |
| Columbia County    | Montgomery County  | Tompkins County     |
| Cortland County    | Ontario County     | Ulster County       |
| Delaware County    | Orleans County     | Warren County       |
| Essex County       | Oswego County      | Washington County   |
| Franklin County    | Otsego County      | Wayne County        |
| Fulton County      | Putnam County      | Wyoming County      |
| Genesee County     | Rensselaer County  | Yates County        |
|                    | Schenectady County |                     |

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States

Census estimated county populations for 2010:

Albany County  
Broome County  
Dutchess County  
Erie County

Monroe County  
Niagara County  
Oneida County  
Onondaga County

Orange County  
Saratoga County  
Suffolk County

Both licensed nursing homes and ACFs are located in these identified rural areas.

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

This regulation imposes no additional paperwork. Although the regulation requires recordkeeping by facilities, including documentation in personnel files and resident clinical or case management records, these records must already be maintained by facilities. Additionally, no professional services are required by this regulation. However, nursing homes may choose to partner with a pharmacy to offer COVID-19 vaccinations for personnel and residents of the facility, rather than receiving and administering the vaccine directly.

**Compliance Costs:**

This regulation requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing

homes cover administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), “starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series.”

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

This regulation is consistent with the existing responsibilities nursing homes and ACFs have to maintain the health and safety of residents, ensure sufficient staffing levels, and ensure staff are free from communicable diseases. Therefore, any adverse impacts are expected to be minimal and are outweighed by the regulation’s health and safety benefits to residents and staff.

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not directly consulted.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.



**Project # 211032-C  
Niagara Hospice, Inc.**

**Program: HOSPICE  
Purpose: Construction**

**County: Niagara  
Acknowledged: February 9, 2021**

**Executive Summary**

**Description**

Niagara Hospice, a currently licensed hospice and not-for-profit corporation located at 4675 Sunset Drive Lockport, New York, requests approval to certify six additional residence beds for a total of 16 residence beds and 10 inpatient certified beds. The additional residence beds will be housed in a one-story, 4,192 sf. addition to an existing wing.

**OPCHSM Recommendation  
Contingent Approval**

**Need Summary**

The applicant currently has a wait list for residence beds. The addition of six residence beds to the hospice facility will allow more patients to receive end-of-life care when there is no active caregiver or when the patient's home is not safe or appropriate.

While NCYRR 790.16 Determinations of Public Need for Hospice does not prescribe a specific methodology for hospice residence bed need, 791.2(d)(2) requires a full review for the addition of hospice residence beds and 794.6 defines the Hospice Residence Service as providing greater than two but not more than sixteen residence beds for those hospices certified to provide the Hospice Residence Service.

**Program Summary**

Niagara Hospice is a deemed provider accredited by the Accreditation Commission for Health Care (ACHC). 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 patients and to prevent recurrent code violations.

**Financial Summary**

Total project costs of \$1,814,569 will be met via accumulated funds from Niagara Hospice operations.

| <u>Budget</u>   | Year One           | Year Three         |
|-----------------|--------------------|--------------------|
| Revenues        | \$2,453,631        | \$2,453,631        |
| Expenses        | <u>\$2,199,987</u> | <u>\$2,199,987</u> |
| Excess Revenues | \$253,644          | \$253,644          |

## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and 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 4006(9)(b) states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of thirty hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1. [AER]
3. 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 project must be completed within one year 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 October 1, 2021 and construction must be completed by January 30, 2022, 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 Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]

Council Action Date

June 3, 2021

## Need and Program Analysis

### Background

Niagara Hospice, Inc., a not-for-profit corporation, currently operates an Article 40 Hospice, serving Niagara county. This project seeks approval to construct and certify six additional residence beds under Article 40 of the Public Health Law.

Niagara Hospice is currently certified for ten inpatient beds and ten residence beds. These beds are located at 4675 Sunset Drive, Lockport, New York 14094. The applicant seeks to certify six additional residence beds and perform requisite construction for a total of 16 residence beds and ten inpatient beds. Upon approval, Niagara Hospice will have 26 certified beds (0 dually certified) and offer the following services:

| Services                    |   |
|-----------------------------|---|
| Audiology                   | Medical Supplies Equipment and Appliances |
| Baseline Services - Hospice | Nursing                                   |
| Bereavement                 | Nutritional                               |
| Clinical Laboratory Service | Pastoral Care                             |
| Home Health Aide            | Personal Care                             |
| Homemaker                   | Pharmaceutical Service                    |
| Hospice Residence           | Physician Services                        |
| Housekeeper                 | Psychology                                |
| Inpatient Certified         | Therapy – Occupational and Physical       |
| Inpatient Services          | Therapy - Respiratory                     |
| Medical Social Services     | Therapy - Speech Language Pathology       |

### Analysis

Hospices can be certified to operate a residence unit of three to 16 beds. Niagara Hospice's average daily census was 180 patients as of June 2020. The projected annual patient caseload is 1,500 for Year One and 1,800 for Year Three. Niagara Hospice reports that there has been a waiting list for admission to their current residence unit since 2010 when the capacity was increased to 10 beds. The additional six beds will improve access to hospice care for patients denied hospice care in nursing homes and assisted living facilities.

The residence is staffed 24/7 with a compilation of LPN's, RN's, RN charge nurse(s), Hospice aides (HHA) and support services staff. The staffing plan for the residence unit includes one Registered Nurse (RN) and one Licensed Practical Nurse (LPN) per 12.5-hour shift and three home health aides per 7.5-hour shift. The applicant intends to offer full time positions to current part time professional and para-professional staff as well as recruit new staff for the expanded residence unit.

This application will have no impact on the counties served or services provided by Niagara Hospice.

### Facility Compliance/Enforcement

Niagara Hospice is a deemed provider accredited by the Accreditation Commission for Health Care (ACHC). 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 patients and to prevent recurrent code violations.

### Conclusion

The applicant's proposal will address their persistent waiting list for hospice residence services. Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance. Upon approval of this application, the need for additional inpatient and dually certified hospice beds in Niagara County will remain unchanged.



## Financial Analysis

### Total Project Cost and Financing

Total project cost, which is for new construction, is estimated at \$1,814,569:

|                            |              |
|----------------------------|--------------|
| New Construction           | \$1,338,806  |
| Site Development           | 75,000       |
| Design Contingency         | 133,881      |
| Construction Contingency   | 66,940       |
| Architect/Engineering Fees | 112,192      |
| Construction Manager Fees  | 80,328       |
| CON Fee                    | 2,000        |
| Additional Processing Fee  | <u>5,422</u> |
| Total Project Cost         | \$1,814,569  |

Project costs are based on a five-month construction period. The applicant will provide equity from accumulated funds to meet the total project cost.

### Operating Budget

The applicant has submitted an operating budget, in 2020 dollars, for Year One and Year Three, summarized below:

|                    | <u>Current</u>   | <u>Year One</u>  | <u>Year Three</u> |
|--------------------|------------------|------------------|-------------------|
| <u>Revenues</u>    |                  |                  |                   |
| Medicare           | \$639,499        | \$1,042,981      | \$1,042,981       |
| Medicaid           | \$544,263        | \$882,067        | \$882,067         |
| Third Party        | \$30,202         | \$57,686         | \$57,686          |
| Private Payer      | <u>\$295,883</u> | <u>\$470,897</u> | <u>\$470,897</u>  |
| Total Revenues     | \$1,509,847      | \$2,453,631      | \$2,453,631       |
| <u>Expenses</u>    |                  |                  |                   |
| Operating          | \$1,304,112      | \$2,003,631      | \$2,003,631       |
| Capital            | <u>100,501</u>   | <u>196,356</u>   | <u>196,356</u>    |
| Total Expenses     | \$1,404,613      | \$2,199,987      | \$2,199,987       |
| Excess of Revenues | \$105,234        | \$253,644        | \$253,644         |
| Patient Days       | 6,005            | 9,608            | 9,608             |

Utilization broken down by payor source appears as follows:

| <u>Payor</u>  | <u>Current</u> | <u>Year One</u> | <u>Year Three</u> |
|---------------|----------------|-----------------|-------------------|
| Medicare      | 44.45%         | 44.44%          | 44.44%            |
| Medicaid      | 41.10%         | 41.10%          | 41.10%            |
| Third Party   | 3.35%          | 3.33%           | 3.33%             |
| Private Payer | <u>11.11%</u>  | <u>11.13%</u>   | <u>11.13%</u>     |
| Total         | 100.00%        | 100.00%         | 100.00%           |

The following is noted with respect to the submitted operating budget:

- Expense and utilization assumptions are based on the facility's historical experience of operating hospice beds.
- Revenues are based on the facility's current reimbursement methodologies for hospice residence beds.
- Effective April 2, 2020, the 2020/2021 Enacted State Budget reduced Medicaid payments by 1.5%, therefore reducing Medicaid revenues in year one and year three. This reduction has been reflected within the budgets.

### Capability and Feasibility

Project costs of \$1,814,569 will be met via accumulated funds from Niagara Hospice. The June 30, 2019 and June 30, 2020 certified financial statements of Niagara Hospice, Inc. are included as BFA Attachment A and indicate the availability of sufficient funds for the equity contribution.

The submitted budget indicates an excess of revenue over expenses of \$253,644 in both Year One and Year Three after projection completion. Revenues are based on current reimbursement methodologies for hospice beds. The submitted budget appears reasonable.

As shown on BFA Attachment A, the entity had an average positive working capital position and an average positive net asset position for the period June 30, 2019 and 2020. Also, the entity achieved an excess of revenues over expenses of \$655,954 for the period June 30, 2019 and 2020.

### Conclusion

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

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## Attachments

BFA Attachment A    June 30, 2019 and June 30, 2020 certified financial statements of Niagara Hospice, Inc.



**Project # 211039-C  
Guthrie Home Health**

**Program:** Certified Home Health Agency  
**Purpose:** Construction

**County:** Tioga  
**Acknowledged:** March 12, 2021

**Executive Summary**

**Description**

Guthrie Home Care (GHC) d/b/a Guthrie Home Health (Guthrie HH), a not-for-profit Certified Home Health Agency (CHHA) currently certified to serve Chemung, Steuben, and Tioga Counties, is seeking approval to add Tompkins and Cortland Counties to its service area through a pilot Complex Care Collaboration Model (CCCM) under Public Health Law §2805-x, New York’s Hospital-Homecare-Physician Collaboration law.

On December 8, 2020, Guthrie HH received approval from the New York State Department of Health for a waiver of Section 760.5 under Title 10 of the New York Codes, Rules, and Regulations which waived the long-term home healthcare need methodology to allow Guthrie HH to submit an application to expand its service area to Cortland and Tompkins Counties. This geographic expansion will allow Guthrie HH to pursue implementation of a pilot Complex Care Collaboration Model (CCCM) under Public Health Law §2805-x, New York’s Hospital-Homecare-Physician Collaboration law. The purpose of the Hospital-Homecare-Physician Collaboration law is to facilitate innovation in hospital, home care agency, and physician collaboration in meeting the community’s health care needs. The CCCM, proposed for an initial five-(5)-year period, creates an innovative continuum of care in which teams led by Guthrie HH CHHA will support patients with complex care needs in all counties served by Guthrie HH to reduce avoidable healthcare utilization, reduce costs and improve health outcomes.

GHC is affiliated with The Guthrie Clinic (TGC), a not-for-profit, integrated health care system designed to offer patients a full spectrum of

health services incorporating primary care, complex specialty care, behavioral health services, surgical services, inpatient care, durable medical equipment services, home health, long-term care, palliative care and hospice care. TGC’s integrated approach is intended to create a better experience for patients and is designed to decrease the cost of the delivery of health care. As part of TGC, Guthrie HH is well positioned to implement the CCCM, which integrates various initiatives, teams, programs, and pilots to provide the backbone of TGC’s Population Health Management infrastructure.

Guthrie HH provides in-home skilled nursing, home health aide services, medical social services, and physical, occupational and speech therapies. Services provided are in accordance with the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation and New York State Department of Health regulations. These services are currently provided to the residents of Chemung, Steuben, and Tioga Counties. As described above, Guthrie HH recently received waiver approval to submit a CON application to add Tompkins and Cortland Counties to the service area of Guthrie HH, counties in which TGC currently has attributed lives under value-based payment contracts, patient referrals and affiliated/employed physicians.

OPCHSM Recommendation  
Approval

### Need Summary

Guthrie Home Care d/b/a Guthrie Home Health applied for, and was granted, a regulatory waiver under the Hospital-Home Care-Physician Collaboration Program, as outlined in Public Health Law 2805-x. The Department approved a waiver of Section 760.5 under Title 10 of the New York Codes, Rules and Regulations which waived the long-term home healthcare need methodology allowing Guthrie Home Care to submit an application to expand its service areas to Cortland and Tompkins County.

Approval of Guthrie Home Care to add Cortland and Tompkins County to its service area to support patients with complex care needs through a Complex Care Collaboration Model (CCCM) will allow Guthrie Home Care to serve their patients under value-based payment/risk arrangements to reduce avoidable utilizations and improve health outcomes.

### Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3606(2).

### Financial Summary

There are no project costs associated with this application. Projected losses for the Guthrie NY CHHA program noted below and working capital needs will be provided by the system, The Guthrie Clinic and Affiliates, which had \$91M of cash and cash equivalents on the balance sheet as of June 30, 2020.

#### Budget (in 000's)

|          | <u>Current</u><br><u>Year</u> | <u>Year</u><br><u>One</u> | <u>Year</u><br><u>Three</u> |
|----------|-------------------------------|---------------------------|-----------------------------|
| Revenues | \$2,632                       | \$3,594                   | \$3,828                     |
| Expenses | <u>\$3,358</u>                | <u>\$4,339</u>            | <u>\$4,532</u>              |
| Net Loss | (\$726)                       | (\$745)                   | (\$704)                     |

## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

**Approval conditional upon:**

1. The project must be completed within one year 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]

Council Action Date

June 3, 2021

## Need and Program Analysis

Guthrie Home Care, a not-for-profit corporation, operates an Article 36 Certified Home Health Agency, Guthrie Home Health. This project requests approval to expand the service area of the Guthrie Home Health CHHA to include the counties of Tompkins and Cortland. TGC currently has attributed lives in Tompkins and Cortland Counties under its value-based payment contracts, through patient referrals and affiliated/employed physicians

Guthrie Home Care d/b/a Guthrie Home Health applied for, and was granted, a regulatory waiver under the Hospital-Home Care- Physician Collaboration Program, as outlined in Public Health Law 2805-x. Pursuant to 2805-x, the Department may waive regulations under Title 10 of the New York Codes, Rules, and Regulations to support voluntary initiatives that support collaboration to improve patient care access and management, patient health outcomes, cost-effectiveness in the use of health care services and community population health. The Department approved of a waiver of Section 760.5 under Title 10 of the New York Codes, Rules and Regulations to waive the long-term home healthcare need methodology to allow Guthrie HH to submit an application to expand its Complex Care Collaboration Model (CCCM) for home care patients in Tompkins and Cortland Counties. Guthrie Home Care has the capacity to serve these patients through its CHHA and will coordinate that service with its extensive physician network in both counties and GCMC in Cortland County.

Upon approval of this project, the Complex Care Collaboration Model will be approved for a five-year period from the date of the waiver approval, December 8, 2020.

Guthrie Home Health is affiliated with The Guthrie Clinic ("TGC"), a not-for-profit integrated healthcare system designed to offer patients a full spectrum of health services. The Guthrie Clinic's system incorporates primary care, complex specialty care, behavioral health services, surgical services, inpatient care, durable medical equipment services, home health, long-term care, palliative care and hospice care. TGC's integrated approach is designed to decrease the cost of the delivery of healthcare and create a better experience for patients.

In addition to the CHHA, the Complex Care Collaboration model would include The Guthrie Clinic's Hospitals and affiliated/employed physicians. The applicant states the proposed CCCM would support the provision of innovative care models for patients under The Guthrie Clinic's Alternate Payment Model and Value Based Payment arrangements.

Under the Complex Care Collaboration Model, Guthrie Home Health will increase access to primary and specialty care services and use home care to facilitate primary care. The applicant states they will also implement an innovative disease-centered program for all patients, including high cost and complex cases. This program will have a goal of maintaining/improving patient health while reducing costly and avoidable hospital and nursing home admissions/readmissions. The CHHA will coordinate with Managed Long-Term Care Plans to ensure high quality care and seamless transition of patients from the institutional setting to the home setting.

Currently, Guthrie Home Health serves Chemung, Steuben and Tioga counties from an office located in Tioga County and a satellite office in Steuben County. The applicant proposes an additional satellite office to be located at 4005 West Road, Cortland, NY 13045 (Cortland County). The applicant anticipates being operational in Tompkins and Cortland Counties by October 1, 2021 as they are currently fully operational with policies and procedures compliant with New York State and Federal regulations already in place which can be easily implemented in Cortland and Tompkins counties.

The Guthrie Clinic has improved health outcomes and contributed to the prevention of unnecessary hospitalizations for the residents of Steuben and Chemung Counties. The improvements include a decrease in COPD and CHF readmission rates (2015 - 2017), reduction in age-adjusted hospitalizations for asthma and cardiovascular disease (2014 - 2016) and an increase in the number of patients visiting a primary care provider (2015 - 2017). The applicant aims to replicate these outcomes in Tompkins and Cortland counties as The Guthrie Clinic's relationship with Guthrie Cortland Medical Center matures.

Additionally, the applicant states that The Guthrie Clinic's extensive physician network provides a resource for home care patients in Tompkins and Cortland counties to experience comparable improvements in health outcomes, resulting in savings to the health care system through reductions in readmissions and unnecessary utilizations.

In Cortland County there are currently two Certified Home Health Agencies (CHHA) and one Long Term Home Health Care Program (LTHHCP). The LTHHCP is operated by the Guthrie Cortland Medical Center, whose parent is The Guthrie Clinic. Upon approval of this application, the LTHHCP will be closed and Guthrie Home Health will begin operations. Guthrie Home Health intends to recruit and hire the individuals currently working for the Guthrie Cortland Medical Center LTHHCP. This transition from the LTHHCP to a CHHA will enhance the care offered to the residents of Cortland County and result in cost savings, expanded access and improved efficiencies related to the provision of home health services.

In Tompkins county there is currently one CHHA. Tompkins County is part of The Guthrie Clinic's service area and as TGC already has an established presence in this county, it is familiar with the community and its needs. Approval of the CCCM will allow more choices in care and an increase in services within the county.

From December 18, 2017 to December 17, 2019, Guthrie Home Health had a total of 650 home health referrals from Cortland County and 74 home health referrals from Tompkins County. The CHHA was unable to serve these patients as the counties were not in the CHHA's approved service area. The applicant states that the inability for Guthrie Home Health to expand into additional counties has been severely limiting. The applicant suggests that approval of this application will remove barriers and allow for streamlining of operations and reduced operating costs.

Guthrie Home Health serves individuals of all ages, with the majority of care being provided to the elderly and geriatric population. The projected growth in the 65 and older population will increase the need for home care services in Cortland and Tompkins County. Through the Complex Care Collaboration Model, Guthrie Home Health will be positioned to meet the needs of the growing elderly population.

This project will have no impact on the services provided by Guthrie Home Health.

| <b>CHHA Quality of Patient Care Star Rating</b><br>as of March 31, 2021 |                               |
|---|-------------------------------|
| <b>CHHA Name</b>  | <b>Quality of Care Rating</b> |
| Guthrie Home Care d/b/a Guthrie Home Health                             | 3.5 out of 5 stars            |

#### Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3606(2).

## Financial Analysis

### Operating Budget

The applicant has submitted an incremental operating budget, in 2021 dollars, for the first and third years, summarized below:

|                     | <u>Current Year (2019)</u> |                    | <u>Year One</u>  |                    | <u>Year Three</u> |                    |
|---------------------|----------------------------|--------------------|------------------|--------------------|-------------------|--------------------|
|                     | <u>Per Visit</u>           | <u>Total</u>       | <u>Per Visit</u> | <u>Total</u>       | <u>Per Visit</u>  | <u>Total</u>       |
| <u>Revenues</u>     |                            |                    |                  |                    |                   |                    |
| Commercial FFS      | \$4,182                    | \$610,539          | \$3,407          | \$872,150          | \$3,351           | \$941,634          |
| Medicare FFS        | \$4,632                    | 1,287,630          | \$4,032          | 1,846,756          | \$3,911           | 1,975,114          |
| Medicare MC         | \$2,257                    | 661,412            | \$2,222          | 750,980            | \$2,208           | 772,961            |
| Medicaid FFS        | \$8                        | 320                | \$4              | 315                | \$4               | 315                |
| Medicaid MC         | \$2,222                    | 84,435             | \$2,006          | 136,464            | \$1,770           | 150,456            |
| Bad Debt            |                            | (101,312)          |                  | (101,312)          |                   | (101,312)          |
| All Other           |                            | <u>88,612</u>      |                  | <u>88,612</u>      |                   | <u>88,612</u>      |
| Total Revenues      |                            | \$2,631,636        |                  | \$3,593,965        |                   | \$3,827,780        |
| <br><u>Expenses</u> |                            |                    |                  |                    |                   |                    |
| Operating           | \$4,325                    | \$3,278,380        | \$3,731          | \$4,197,600        | \$3,607           | \$4,393,264        |
| Capital             | <u>\$106</u>               | <u>80,081</u>      | <u>\$125</u>     | <u>141,045</u>     | <u>\$114</u>      | <u>138,871</u>     |
| Total Expenses      | \$4,431                    | \$3,358,461        | \$3,857          | \$4,338,645        | \$3,721           | \$4,532,135        |
| <br>Net Loss        |                            | <u>(\$726,825)</u> |                  | <u>(\$744,680)</u> |                   | <u>(\$704,355)</u> |
| <br>Visits          |                            | 758                |                  | 1,125              |                   | 1,218              |

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

| <u>Payor</u>   | <u>Current Year</u> | <u>Year One</u> | <u>Year Three</u> |
|----------------|---------------------|-----------------|-------------------|
| Commercial FFS | 19%                 | 23%             | 23%               |
| Medicare FFS   | 37%                 | 41%             | 41%               |
| Medicare MC    | 39%                 | 30%             | 29%               |
| Medicaid MC    | 5%                  | 6%              | 7%                |
| Total          | 100%                | 100%            | 100%              |

The following is noted regarding the first- and third-year budgets:

- Utilization was projected based on the number of referrals sent to other home care agencies in Cortland and Tompkins Counties; projections reflect 10% of those referrals coming to Guthrie HH in Cortland and Tompkins Counties.
- Visits per episode for Medicare cases has been calculated at 10.41 visits based on average visits per episode in Cortland and average visits per episode for Guthrie HH using FY20 averages.
- Commercial and Medicaid visits were determined using Cortland County's historical visits.
- Salary expenses are based on a blend of average hourly rates for the Cortland County LTHHCP as of June 30, 2020 (from cost report information) and Guthrie HH as of December 31, 2020.

### Capability and Feasibility

There are no project costs associated with this application. The working capital requirement is estimated at \$755,356 based on two months of third year expenses. The applicant has indicated that they will provide equity to be derived from ongoing operations to meet the working capital requirements. BFA Attachment A, 2020 Certified Financial Statements of The Guthrie Clinic and Associates indicates the availability of sufficient funds to meet the working capital contribution.

The submitted budget for the Guthrie NY CHHA indicates a net loss of (\$744,680) and (\$704,355) during the first and third years of operation, respectively. During the fiscal year ended June 30, 2020 (FY20), the



CHHA generated an annual operating loss of approximately \$700,000 while the total legal entity, Guthrie Home Care, however, generated a net operating income of approximately \$460,000 due to the success of its Hospice services. Projected net income for Guthrie Home Care for the year ending on June 30, 2021 is expected to be over \$500,000 or a \$40,000 net increase over FY20. This improved performance, despite the impact of COVID-19, is due to a combination of the strong success of Guthrie Hospice and the Guthrie Home Care management team's determination in decreasing losses for Guthrie Home Health PA and NY. With the pilot Complex Care Collaboration Model (CCCM), there is a slight net income projected with the addition of Cortland County and a slight projected loss with the addition of Tompkins County. However, with the integration and coordination of care under the CCCM, the Guthrie Home Care net income is projected to grow to \$485,000 by Year Three. Guthrie Home Care anticipates continuing a positive net income status year after year, and as part of a larger integrated system of care, it is essential to the organization that Guthrie Home Care remain strong and solvent. Thus, Guthrie Home Care, as an overall entity, will be offsetting the losses of the New York CHHA, just as it has in the past and does today, to the extent that losses continue. The budget appears reasonable.

As shown on BFA Attachment A, for the 2019 and 2020 fiscal year ended June 30<sup>th</sup> Guthrie Clinic and Affiliates, has maintained an average negative working capital, an average positive net asset position, and an average positive excess of revenues over expenses. The reason for the negative working capital position is the result of measures taken to mitigate the spread of COVID-19. These measures included postponing elective surgical procedures and non-urgent and routine medical appointments and closing numerous outpatient and ambulatory facilities. The Guthrie Clinic and Affiliates, which had \$91M of cash and cash equivalents on the balance sheet as of June 30, 2020 will cover the projected working capital need and operating losses for the Guthrie NY CHHA.

As shown on BFA Attachment B, as of February 28, 2021, Guthrie Home Care has shown a negative working capital position, positive net asset position, and income from operations of \$331,000.

#### Conclusion

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

## Attachments

- BFA Attachment A Financial Summary, The Guthrie Clinic and Affiliates – 2019 and 2020 Certified Financial Statements
- BFA Attachment B Financial Summary, Guthrie Home Care - Internals as of February 28, 2021



Project # 211035-E
Griffiss Surgery Center

Program: DTC
Purpose: Establishment

County: Oneida
Acknowledged: February 24, 2021

Executive Summary

Description

Griffiss EC, LLC d/b/a Griffiss Surgery Center (Griffiss), an existing New York limited liability company, requests approval to transfer 2% membership interest in an Article 28 freestanding ambulatory surgery center (FASC) to one new member (Ganga Nair, M.D.). The application requires a Full Review because the aggregate membership transfers for the LLC over the last five years is greater than 25%. The Center is in leased space at 105 Dart Circle, Rome (Oneida County). The facility is certified as a multi-specialty. They are not proposing to add or change any services. The Center's existing lease agreement will not change and will remain in place upon approval of this application. The Center performed 6,064 procedures in 2018, 11,500 in 2019, and 11,741 in 2020. Volume plateaued in 2020 because the Center was closed from March 23, 2020 to May 20, 2020 due to the Governor's executive order related to the COVID-19 pandemic.

On January 20, 2021, seven physician members and one hospital member of Griffiss EC, LLC entered into a Membership Purchase Agreement to sell 2% of Griffiss to Ganga Nair, M.D. for \$80,000. The transaction will be finalized upon Public Health and Health Planning Council (PHHPC) approval.

The FASC is current with their SPARCS reporting.

Ownership interest of the operations before and after the request change is as follows:

Table with 3 columns: Members, Current, Proposed. Rows include Rome Memorial Hospital, John Costello, Jr. DO, Patrick Costello, MD, Alexander Harris, MD, Lorna Grant, MD, Aamer Mirza, MD, Ajay Goel, MD, Muhammad Jhandier, MD, Ganga Nair, MD, and Total.

OPCHSM Recommendation Approval

Need Summary
There will be no Need recommendation for this project.

Program Summary
Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

Financial Summary
Ganga Nair, M.D. will purchase 2% interest in Griffiss EC, LLC with equity of \$80,000. There are no project costs associated with this application.

## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

**Approval conditional upon:**

1. The project must be completed within one year 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]

Council Action Date

June 3, 2021

## Program Analysis

### Program Description

There are no programmatic changes as a result of this request; however, staffing is expected to increase by 2.0 FTEs in Year One and 3.0 FTEs in Year Three.

The table below details the proposed change in ownership:

| <b>Member Name</b>       | <b>Current</b> | <b>Proposed</b> |
|--------------------------|----------------|-----------------|
| Rome Memorial Hospital   | 22.0751%       | 21.633598%      |
| John Costello, Jr, D.O.  | 18.3691%       | 18.028178%      |
| Patrick Costello, M.D.   | 11.0380%       | 10.817240%      |
| Alexander Harris, M.D.   | 11.0380%       | 10.817240%      |
| Lorna Grant, M.D.        | 4.3388%        | 4.3388%         |
| Aamer Mirza, M.D.        | 11.0380%       | 10.817240%      |
| Ajay Goel, M.D.          | 11.0380%       | 10.817240%      |
| Mohammad Jhandier, M.D.  | 11.0380%       | 10.817240%      |
| <b>Ganga Nair, M.D.*</b> | -----          | 2.000000%       |
| <b>TOTAL</b>             | 100%           | 100%            |

*\*Member subject to Character and Competence*

### Character and Competence

**Dr. Ganga Nair** is an Ophthalmologist and has been practicing at Costello Eye Physicians and Surgeons for over two years. He was previously employed at Marcia Dunn, M.D., P.C. for over 14 years. He received his medical degree from State University of New York Health Sciences Center at Syracuse College. He completed his residency in Ophthalmology at Long Island Jewish Medical Center. He is board certified in Ophthalmology.

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.

### Conclusion

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

## Financial Analysis

### Membership Purchase Agreement

The applicant has submitted an executed Membership Purchase Agreement which will be effectuated upon Public Health and Health Planning Council (PHHCP) approval of this CON. The terms of the agreement are summarized below:

|                 |  |
|-----------------|--|
| Date:           | January 20, 2021   |
| Seller:         | Rome Memorial Hospital sold 0.441502% membership interest for \$17,660.08; John Costello Jr., D.O. sold 0.367922% membership interest for \$14,716.88; Patrick Costello, M.D. sold 0.220760% membership interest for \$8,830.40; Alexander Harris, M.D. sold 0.220760% membership interest for \$8,830.40; Lorna Grant, M.D. sold 0.086776% membership interest for \$3,471.04; Aamer Mirza, M.D. sold 0.220760% membership interest for \$8,830.40; Ajay Goel, M.D. sold 0.220760% membership interest for \$8,830.40; Muhammad Jhandier, M.D. sold 0.220760% membership interest for \$8,830.40. |
| Buyer:          | Ganga Nair, M.D.   |
| Acquired        | 2% membership interest Griffiss EC, LLC for \$80,000   |
| Further Action: | Ganga Nair, M.D shall deliver banks checks to each seller for the purchase price identified.   |

BFA Attachment A, Ganga Nair, M.D.net worth shows sufficient liquid resources to fund the purchase.

### Capability and Feasibility

Ganga Nair, M.D. will purchase 2% interest in Griffiss EC, LLC with equity of \$80,000. There are no project costs associated with this application. A review of BFA Attachment A, Ganga Nair, M.D. net worth statement shows sufficient liquid resources.

BFA Attachment B, Griffiss EC, LLC's certified financial statements for 2018 and 2019, shows negative working capital, negative equity position, and net income of \$102,417 and \$155,943, respectively. In 2018, Griffiss Surgery Center completed an expansion project to its surgery center. Upon completion of this project, the company underwent changes to their debt structure that contributed to their negative working capital. BFA Attachment C, Griffiss EC LLC's December 31, 2020 internal financial statements shows positive working capital and equity. The Center received supplemental federal stimulus dollars to mitigate the financial impact of the COVID-19 pandemic during April 2020. The Center received approximately \$130,000 from the federal Provider Relief Fund to reimburse for healthcare related expense or lost revenues that were attributable to the COVID-19 pandemic and approximately \$496,000 from the Paycheck Protection Program under the CARES Act.

Net income declined in 2020 from prior year to \$42,882. It was noted in the certified financial statement that the COVID-19 pandemic has resulted a reduction in elective surgeries due to New York State's restrictive measures. The Center was closed from March 23, 2020 to May 20, 2020 and the applicant believes that a certain portion of the deferred procedures will be performed and volume will recover to pre-COVID levels as more people are vaccinated and hesitancy to seek care is reduced.

## Attachments

- BFA Attachment A Ganga Nair, M.D. Net Worth
- BFA Attachment B Griffiss EC, LLC – 2018 and 2019 certified financial statements
- BFA Attachment C Griffiss EC, LLC - December 31, 2020 internal financial statement

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 3rd day of June 2021, 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 two (2) percent interest from existing members to one (1) new member, 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:

211035 E

Griffiss Surgery Center

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. The project must be completed within one year 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]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON*.



**Project # 202273-B  
147 Wellness LLC t/b/k/a  
Midtown Endoscopy & Surgical Center, LLC**

**Program:** Diagnostic & Treatment Center      **County:** New York  
**Purpose:** Establishment and Construction      **Acknowledged:** February 4, 2021

**Executive Summary**

**Description**

147 Wellness, LLC, an existing New York State Limited Liability company, has submitted this application to establish and construct an Article 28 diagnostic and treatment center to be certified as a single-specialty freestanding ambulatory surgical center (FASC) with the following three (3) surgical specialties: gastroenterology; gynecology (non-abortion); and podiatry. The Center will have four procedure rooms and will be in located in leased space at 147 East 26th Street, New York (New York County). Upon approval of this CON application the applicant's legal name will change from 147 Wellness LLC to Midtown Endoscopy & Surgical Center, LLC.

Dr. Shawn Khodadadian M.D. is the sole member of 147 Wellness LLC and will service as the Medical Director. Dr. Khodadadian is also the sole member of 147 East 26th Street LLC, the building owner and landlord. Dr. Khodadadian is currently the medical director and owner of a multi-site private medical practice and office-based surgery practice with three locations in Manhattan.

The facility has signed a Transfer and Affiliation Agreement with Lenox Hill Hospital/Northwell as of November 11, 2020.

Dr. Khodadadian will not personally perform surgical procedures at the proposed Center, but as the Medical Director, he will oversee all surgical procedures performed at the Center. Five non-member surgeons currently practicing

at Dr. Khodadadian's private practice will perform surgical services at the FASC and have provided letters of interest demonstrating their commitment to perform procedures at the proposed Center.

**OPCHSM Recommendation**

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

**Need Summary**

The applicant projects 2,251 procedures in Year One and 3,751 in Year Three, with Medicaid utilization at 3.01% and Charity Care at 2.00% in the third year.

**Program Summary**

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

**Financial Summary**

Total project costs of \$2,923,078 will be funded entirely with equity.

|            | <u>Year One</u>    | <u>Year Three</u>  |
|------------|--------------------|--------------------|
| Revenues   | \$2,084,145        | \$3,473,083        |
| Expenses   | <u>\$2,069,446</u> | <u>\$2,972,970</u> |
| Net Income | \$14,699           | \$500,113          |



## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

**Contingent approval with an expiration of the operating certificate five years from the date of its issuance 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 centers 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 a 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 signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to DOH. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
  - a. Data displaying actual utilization including procedures.
  - b. Data displaying the breakdown of visits by payor source
  - c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery
  - d. Data displaying the number of emergency transfers to a hospital
  - e. Data displaying the percentage of charity care provided
  - f. The number of nosocomial infections recorded during the year reported
  - g. A list of all efforts made to secure charity cases
  - h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]
4. Submission of an executed building lease, acceptable to the Department of Health. [BFA]
5. Submission of a photocopy of an amended and executed certificate of amendment of the applicant's articles of organization, acceptable to the Department. [CSL]
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8. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
9. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]

**Approval conditional upon:**

1. The project must be completed within two 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 December 1, 2021 and construction must be completed by August 1, 2022, 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 submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:  
[https://www.health.ny.gov/facilities/hospitals/docs/hcs\\_access\\_forms\\_new\\_clinics.pdf](https://www.health.ny.gov/facilities/hospitals/docs/hcs_access_forms_new_clinics.pdf). Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: [hospinfo@health.ny.gov](mailto:hospinfo@health.ny.gov) [HSP]

Council Action Date  
June 3, 2021

## Need and Program Analysis

### Program

|   |  |
|---|--|
| <b>Proposed Operator</b>                                    | 147 Wellness LLC <b>t/b/k/a</b><br>Midtown Endoscopy & Surgical Center, LLC  |
| <b>Site Address</b>   | 147 East 26 <sup>th</sup> Street<br>New York, New York 10010 (New York County)   |
| <b>Surgical Specialties</b>                                 | Single Specialty - Gastroenterology<br>Single Specialty - Gynecology<br>Single Specialty - Podiatry  |
| <b>Operating Rooms</b>                                      | 0  |
| <b>Procedure Rooms</b>                                      | 4  |
| <b>Hours of Operation</b>                                   | Monday through Friday 7:00 am to 5:00 pm   |
| <b>Staffing (1<sup>st</sup> Year / 3<sup>rd</sup> Year)</b> | 8.5 FTEs / 14.5 FTEs   |
| <b>Medical Director(s)</b>                                  | Shawn Khodadadian, M.D.  |
| <b>Support Services Agreement and Distance</b>              | Is expected to be provided by:<br>Lenox Hill Hospital/Northwell Health<br>2.9 Miles / 16 minutes   |
| <b>On-call service Emergency, In-Patient and Backup</b>     | Patients who require assistance during off-hours will have the phone number of a 24 hour per day/seven (7) day per week on-call service, to immediately refer the patient to the Center's on-call physician. |

Dr. Khodadadian's current off-based surgical practice has outgrown its space and this application is intended to alleviate space and capacity issues, but all of Dr. Khodadadian's existing practice sites will remain open to provide pre- and post-surgical and consultation visits. All cases to be performed at the proposed FASC will originate from Dr. Khodadadian's existing private practice and consultations.

### Analysis

The service area consists of New York County. The population of New York County in 2010 was 1,585,873 with 595,344 individuals (37.5%) who are 45 and over, which are the primary population group utilizing ambulatory surgery services. Per PAD projection data, this population group (45 and over) is estimated to grow to 703,766 by 2025 and represent 41.2% of the projected population of 1,709,958.

The number of projected procedures is 2,251 in Year One and 3,751 in Year Three. These projections are based on the current practices of participating surgeons. The applicant states that all the procedures are currently being performed in an office-based setting. The table below shows the projected payor source utilization for Years One and Three.

| <b>Payor</b> | <b>Year One</b> |                | <b>Year Three</b> |                |
|--------------|-----------------|----------------|-------------------|----------------|
|              | <b>Volume</b>   | <b>%</b>       | <b>Volume</b>     | <b>%</b>       |
| Commercial   | 1,913           | 84.98%         | 3,188             | 84.99%         |
| Medicare     | 225             | 10.00%         | 375               | 10.00%         |
| Medicaid     | 68              | 3.02%          | 113               | 3.01%          |
| Charity Care | 45              | 2.00%          | 75                | 2.00%          |
| <b>Total</b> | <b>2,251</b>    | <b>100.00%</b> | <b>3,751</b>      | <b>100.00%</b> |

The Center initially plans to obtain contracts with the following Medicaid Managed care plans: BCBS Amerigroup, and United Healthcare Community Plan. The Center will work collaboratively with Federally Qualified Health Centers (FQHC), hospitals, family, and homeless shelters within the service area to provide service to the under-insured. The Center has developed a financial assistance policy with a sliding fee scale to be utilized when the Center is operational. The Center will operate Monday through Friday from 7 am until 5 pm.

The table below shows the number of patient visits for ambulatory surgery centers in New York County during 2017, 2018, and 2019.

| Spec Type                            | Facility Name   | Patient Visits |         |         |
|--------------------------------------|---|----------------|---------|---------|
|                                      |   | 2017           | 2018    | 2019    |
| Gastroenterology                     | Carnegie Hill Endo, LLC                                   | 11,718         | 12,280  | 13,862  |
| Gastroenterology/<br>Pain Management | East Side Endoscopy                                       | 9,498          | 8,828   | 8,812   |
| Multi                                | Fifth Avenue Surgery Center                               | 1,997          | 4,031   | 3,936   |
| Gastroenterology                     | Gramercy Park Digestive Disease Center                    | 9,863          | 11,972  | 12,335  |
| Gastroenterology                     | Gramercy Park DDC-Bennett Ave<br>(opened 4/8/20)          | N/A            | N/A     | N/A     |
| Multi                                | Gramercy Surgery Center, Inc                              | 3,365          | 3,105   | 4,851   |
| Multi                                | Greenwich Village ASC, LLC<br>(opened 10/13/17)           | N/A            | 522     | 1,344   |
| Orthopedics                          | HSS ASC of Manhattan (opened 9/13/17)                     | N/A            | 1,895   | 3,603   |
| Orthopedics                          | HSS West Side ASC (opened 7/16/19)                        | N/A            | N/A     | N/A     |
| Ophthalmology                        | Hudson Yards Surgery Center<br>(opened 6/30/20)           | N/A            | N/A     | N/A     |
| Gastroenterology                     | Kips Bay Endoscopy Center, LLC                            | 9,410          | 9,434   | 10,051  |
| Gastroenterology                     | Liberty Endoscopy Center (opened 1/13/17)                 | N/A            | 5,240   | 6,568   |
| Gastroenterology                     | Manhattan Endoscopy Center, LLC                           | 14,616         | 11,032  | 12,298  |
| Gynecology                           | Manhattan Reproductive Surgery Center<br>(opened 3/27/19) | N/A            | N/A     | N/A     |
| Multi                                | Manhattan Surgery Center                                  | 6,364          | 6,080   | 6,395   |
| Ophthalmology                        | Mid-Manhattan Surgi-Center (closed 4/30/19)               | 3,348          | 3,180   | 426     |
| Multi                                | Midtown Surgery Center                                    | 2,411          | 2,745   | 3,749   |
| Multi                                | NY Center for Ambulatory Surgery<br>(opened 12/13/19)     | N/A            | N/A     | N/A     |
| Ophthalmology                        | Retinal Ambulatory Surgery Center of NY                   | 4,095          | 4,179   | 4,882   |
| Multi                                | SurgiCare of Manhattan, LLC                               | 3,967          | 4,377   | 4,257   |
| Gastroenterology                     | The Endoscopy Center of New York                          | 12,488         | 13,377  | 14,758  |
| Gastroenterology                     | West Side GI  | 17,802         | 18,694  | 17,894  |
| Total Visits                         |   | 110,942        | 120,971 | 130,021 |

#### Character and Competence

The sole member of 147 Wellness LLC is Shawn Khodadadian, M.D.

**Dr. Shawn Khodadadian** has been the Medical Director of Manhattan Specialty Care Multispecialty Practice, an office-based surgical practice, for over five years and has also owned and operated Manhattan Gastroenterology, P.C. for over ten years. He is been an Attending Physician and Voluntary Faculty Member of Weill Cornell NY Presbyterian Hospital for over one year and of NYU Langone Medical Center for over nine years. Dr. Khodadadian received his medical degree from the State University of New York Stony Brook School of Medicine. He completed his residency in Internal Medicine at Lenox Hill Hospital and his residency in Radiation Oncology at State University of New York Health Science Center at Brooklyn. He completed his Fellowship in Gastroenterology at Lenox Hill Hospital. He is board certified in Internal Medicine with a sub-certification in Gastroenterology.

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. Khodadadian disclosed one malpractice suit file on January 16, 2019. The case is regarding a patient who underwent an uneventful colonoscopy on October 4, 2017. The patient was noted to have hit her wrist on a metal bedrail during recovery. She was given ice for the swelling and discharged with a referral to primary care and orthopedics for further evaluation. The patient did not seek follow up care. Three weeks later, the patient reached out and claimed to have fallen in the recovery room after the colonoscopy, causing the wrist injury. Dr. Khodadadian sat with the malpractice carrier on November 16, 2017 and gave the details of the event from the record. Depositions have not been taken at this time and the case is pending.

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

For those patients who do not identify a primary care provider (PCP), the Applicant plans to work closely with its patients to educate them regarding the availability of primary care services offered by local providers, including a broad array of services offered by the Center's back up hospital. Prior to leaving the Center, each patient will be provided information concerning the local availability of primary care services. Prior to leaving the Center, each patient will be provided concerning the local availability of primary care services. The Applicant commits to treating patients based on the need for the procedures without discrimination due to personal characteristics or ability to pay. The Applicant commits to providing charity care for persons without the ability to pay, and to utilize a sliding fee scale for persons who are unable to pay the full charge for services are uninsured. The Applicant has proposed an operating budget that includes 3% Medicaid and 2% Charity Care. The Center will provide colon cancer screenings throughout the community it serves, in addition to the charity care, through free procedures.

The Center intends on using an Electronic Medical Record (EMR) system and to fully integrate and exchange information with an established Regional Health Information Organization (RHIO) with the capability for clinical referral and event notifications. The Center does not intend to become part of any Accountable Care Organization or Medical Home at this time.

#### Conclusion

Approval of this project will provide increased access to podiatry, gynecology, and gastroenterology surgery services in an outpatient setting for the residents of New York County. Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

## Financial Analysis

### Total Project Cost and Financing

Total project cost for renovations and movable equipment, is estimated at \$2,923,078 broken down as follows:

|                            |                    |
|----------------------------|--------------------|
| Renovation & Demolition    | \$1,664,000        |
| Design Contingency         | \$166,400          |
| Construction Contingency   | \$166,400          |
| Architect/Engineering Fees | \$166,400          |
| Construction Manager Fees  | \$41,600           |
| Other Fees                 | \$20,000           |
| Movable Equipment          | \$680,300          |
| Application Fee            | \$2,000            |
| Processing Fee             | <u>\$15,978</u>    |
| <b>Total Project Cost</b>  | <b>\$2,923,078</b> |

Total Project Cost will be funded by the applicant's equity.

### Lease Agreement

The applicant submitted a draft lease agreement, the terms of which are summarized below:

|             |   |
|-------------|---|
| Date:       | TBD   |
| Premises:   | 5,185 Sqft located in space on the first floor and basement level in the building located at 147 East 26th Street, New York (New York County) |
| Landlord:   | 147 East 26 <sup>th</sup> Street, LLC   |
| Lessee:     | 147 Wellness, LLC (Midtown Endoscopy & Surgical Center, LLC)  |
| Term:       | 10 Years  |
| Rental:     | Year 1-10 \$305,100 a year (\$25,425 a month and \$58.84 sqft)  |
| Provisions: | Triple net lease  |

The lease/assignment arrangement is a non-arm's length agreement. The applicant has submitted letters from two New York Licensed Real Estate Brokers attesting that the lease cost per square foot is at fair market value.

### Operating Budget

The applicant has submitted their first year and third-year operating budgets, in 2020 dollars, as shown below:

|                                 | <u>Year One</u>  |                        | <u>Year Three</u> |                         |
|---------------------------------|------------------|------------------------|-------------------|-------------------------|
|                                 | <u>Per Visit</u> | <u>Total</u>           | <u>Per Visit</u>  | <u>Total</u>            |
| <u>Revenue</u>                  |                  |                        |                   |                         |
| Commercial - FFS                | \$ 940.28        | \$1,798,761            | \$940.28          | \$2,997,621             |
| Medicare - FFS                  | \$1,106.21       | \$248,898              | \$1,106.22        | \$414,831               |
| Medicaid - FFS                  | \$536.56         | <u>\$36,486</u>        | \$536.56          | <u>\$60,631</u>         |
| <b>Total Revenue</b>            |                  | <b>\$2,084,145</b>     |                   | <b>\$3,473,083</b>      |
| <u>Expenses</u>                 |                  |                        |                   |                         |
| Operating                       | \$700.78         | \$1,577,449            | \$661.42          | \$2,480,973             |
| Capital                         | <u>\$218.57</u>  | <u>\$491,997</u>       | <u>\$131.16</u>   | <u>\$491,997</u>        |
| <b>Total Expenses</b>           | <b>\$919.35</b>  | <b>\$2,069,446</b>     | <b>\$792.58</b>   | <b>\$2,972,970</b>      |
| <br>                            |                  |                        |                   |                         |
| <b>Net Income</b>               |                  | <b><u>\$14,699</u></b> |                   | <b><u>\$500,113</u></b> |
| <br>                            |                  |                        |                   |                         |
| <b>Utilization (Procedures)</b> |                  | <b>2,251</b>           |                   | <b>3,751</b>            |

The following is noted with respect to the submitted budget:

- The Medicare reimbursement rate is based on the current respective Fee Schedule rate, which is the average rates experienced during 2020.
- The Medicaid reimbursement rate is based on the 2020 Downstate Medicaid APG rate (weighted based on CPT codes) times the discount for Medicaid Managed Care Company Negotiations plus the capital cost per visit.
- The Commercial rate is 85% of the 2020 Medicare FFS rate
- Operating expenses are based on Dr. Khodadadian's experience and the experience of other FASC's in New York State.
- Utilization by payer is based on the existing payer mix of the physicians who will participate at the Center.

Utilization by payor related to the submitted operating budget is as follows:

| <u>Payor</u>     | <u>Year One</u> | <u>Year Three</u> |
|------------------|-----------------|-------------------|
| Commercial - FFS | 84.98%          | 84.99%            |
| Medicare - FFS   | 10.00%          | 10.00%            |
| Medicaid - FFS   | 3.02%           | 3.01%             |
| Charity Care     | <u>2.00%</u>    | <u>2.00%</u>      |
|                  | 100.00%         | 100.00%           |

#### Capability and Feasibility

The total project cost is \$2,923,078 and will be met with owner's equity. BFA Attachment A is the Net Worth Statement for Dr. Khodadadian. It indicates the availability of sufficient funds for the equity contribution to meet the total project cost.

Working capital requirements are estimated at \$495,495 based on two months of third year expenses. Working capital will be funded with owner's equity. BFA Attachment A indicates the availability of sufficient funds to meet working capital needs.

The submitted budgets indicate a net income of \$14,699 and \$500,113 during the first and third years, respectively. Revenues are based on current reimbursement methodologies. The budgets are reasonable.

#### Conclusion

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

## Supplemental Information

#### DOH Comment

The Department reached out to proximate hospitals asking for information on the impact of the proposed ambulatory surgery center (ASC). None of the hospitals responded. Therefore, in the absence of comments from hospitals near 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 | Net Worth Statement of Dr. Shawn Khodadadian |
| BHFP Attachment  | Map  |

## 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 3rd day of June 2021, 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 three-single-specialty ambulatory surgery center for gastroenterology, gynecology, and podiatry surgery services to be located at 147 East 26th Street, New York, 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:

202273 B

FACILITY/APPLICANT:

147 Wellness LLC t/b/k/a Midtown  
Endoscopy & Surgical Center, LLC



APPROVAL CONTINGENT UPON:

**Contingent approval with an expiration of the operating certificate five years from the date of its issuance 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 centers 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 a 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 signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to DOH. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
  - a. Data displaying actual utilization including procedures.
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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 submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:  
[https://www.health.ny.gov/facilities/hospitals/docs/hcs\\_access\\_forms\\_new\\_clinics.pdf](https://www.health.ny.gov/facilities/hospitals/docs/hcs_access_forms_new_clinics.pdf).  
Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: [hospinfo@health.ny.gov](mailto:hospinfo@health.ny.gov) [HSP]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON*.



**Project # 202250-E  
Assured Care Home Health, LLC**

**Program:** Certified Home Health Agency  
**Purpose:** Establishment

**County:** Nassau  
**Acknowledged:** January 7, 2021

**Executive Summary**

**Description**

Assured Care Home Health, LLC requests to be established as the new operator of an existing CHHA currently operated by Long Island Jewish Medical Center (LIJ). The CHHA is currently operated by LIJ and co-operated by Northwell Healthcare, Inc. and is located at 1983 Marcus Avenue, New Hyde Park (Nassau County). It will be relocated into leased space at 100-04 Ditmars Boulevard, East Elmhurst (Queens County). The CHHA is certified to operate in Nassau and Queens Counties providing Home Health Aide, Medical Social Services, Medical Supplies, Equipment and Appliances, Nursing Services, Physician Services, Occupational Therapy Services, Physical Therapy Services and Speech-Language Pathology Services. Upon Public Health and Health Planning Council (PHHPC) approval of this application, the agency will continue as there will be no changes in services.

Jack Basch entered into an Asset Purchase Agreement, (APA) for \$1,500,000 with LIJ for exclusive rights and certain assets of the CHHA. Jack Basch will assign his rights to Assured Home Health Care, LLC and will add a member as disclosed to the Department.

Ownership of the CHHA after the requested change is as follows:

|                               |     |
|-------------------------------|-----|
| <u>Proposed Operator</u>      |     |
| Assured Home Health Care, LLC |     |
| <u>Members</u>                |     |
| Jack Basch                    | 85% |
| Chaim Klein                   | 15% |

Upon approval, 100-04 Ditmars Boulevard LLC (landlord) will enter into a lease agreement with Assured Home Health Care, LLC.

OPCHSM Recommendation  
Contingent Approval

Need Summary  
This change of ownership will not result in any changes to the counties being served or to the services being provided.

Program Summary  
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3606(2).

Financial Summary  
There are no project costs associated with this proposal. The purchase price for the assets is \$1,500,000 to be met via equity from both members proportionally to their membership. The operating budget is as follows:

|            | <u>Year One</u> | <u>Year Three</u> |
|------------|-----------------|-------------------|
| Revenues   | \$938,401       | \$2,064,478       |
| Expenses   | <u>929,100</u>  | <u>1,820,645</u>  |
| Net Income | \$9,301         | \$243,833         |

## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

**Approval contingent upon:**

1. Submission of an executed revised lease agreement, acceptable to the Department of Health. [BFA]
2. Submission of an executed assignments of Rights, Acceptable to the Department of Health. [BFA]
3. Submission of a photocopy of the applicant's amended operating agreement, acceptable to the Department. [CSL]
4. Submission of a photocopy of the seller's certificate of amendment of the certificate of incorporation, acceptable to the Department. [CSL]
5. Submission of the applicant's amended and executed Certificate of Amendment of the Articles of Organization, acceptable to the Department. (CSL)

**Approval conditional upon:**

1. The project must be completed within one year 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]

Council Action Date

June 3, 2021

## Need and Program Analysis

### Program Description

Assured Care Home Health, LLC, a limited liability company, requests approval to become the new operator of Long Island Jewish Medical Center Home Care Department (CHHA) under Article 36 of the Public Health Law.

On August 12, 2020 Long Island Jewish Medical Center, the current operator of the Certified Home Health Agency, entered into an Asset Purchase Agreement (APA) with Jack Basch, who agreed to purchase certain assets of the CHHA and assigned his rights under the APA to Assured Care Home Health, LLC.

Long Island Jewish Medical Center d/b/a Long Island Jewish Medical Center Home Care Department currently serves Queens and Nassau counties from an office located at 1983 Marcus Avenue, New Hyde Park, NY. Upon approval, the applicant intends to relocate the office of the CHHA to 100-04 Ditmars Boulevard, East Elmhurst, NY. There will be no changes to the counties served or services provided as a result of this project. Upon approval, the CHHA will be known as Assured Care Home Health, LLC.

### Character and Competence Review

The membership of Assured Care Home Health, LLC is as follows:

#### **Jack Basch – Member, 85%**

Self-Employed

#### Affiliations

- King David Center for Nursing and Rehabilitation (2014 – Present)
- Crown Heights Center for Nursing and Rehabilitation (2014 – Present)
- Bedford Center for Nursing and Rehabilitation (2015 – Present)
- Linden Center for Nursing and Rehabilitation (2013 – Present)
- Elmhurst Care Center Inc. (1999 – Present)
- Bezalel Nursing Home (1986 – Present)

#### **Chaim Klein, Dentist – Member, 15%**

Owner, York MG

Owner, CK DDS PC Dentistry

#### Affiliations

- Elm York, LLC (ALP)
- Madison York Rego Park, LLC (ALP)
- Madison York Assisted Living Community, LLC (ALP)
- Universal Healthcare/At Your Side Home Care (LHCSA)

A search of the individuals and entities 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, and the Office of Professional Medical Conduct, indicate no issue with the licensure of the health professionals associated with this application.

### **Facility Compliance/Enforcement**

The NYS Department of Health Division of Nursing Homes and Intermediate Care Facilities/IID has reviewed the compliance histories of the affiliated Nursing Homes listed above and reports as follows:

- Bedford Center for Nursing and Rehabilitation was fined a Civil Monetary Penalty of \$6,500 as a result of survey findings on June 10, 2016.

The NYS Department of Health Division of Nursing Homes and Intermediate Care Facilities/IID reported the remaining affiliated Nursing Homes have no histories of enforcement action taken during the time periods indicated above.

The NYS Department of Health Division of Adult Care Facilities and Assisted Living Surveillance reviewed the compliance histories of the affiliated Assisted Living Programs listed above and reports as follows:

- Elm York, LLC was fined \$18,000 pursuant to a Stipulation and Order dated March 6, 2017 for inspection findings on June 21, 2016 for violations of Article 7 of the Social Services Law and 18 NYCRR Part 487.

| <b>CHHA Quality of Patient Care Star Ratings</b><br>as of March 10, 2021                       |                               |
|--|-------------------------------|
| <b>CHHA Name</b>   | <b>Quality of Care Rating</b> |
| Long Island Jewish Medical Center d/b/a Long Island Jewish Medical Center Home Care Department | 3 out of 5 stars              |

#### Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3606(2). The change in operator will result in no changes to the service area or the services being provided by the CHHA.

## Financial Analysis

#### Asset Purchase Agreement

The applicant has submitted an executed Asset Purchase Agreement for the purchase of the CHHA, summarized below:

|                                |   |
|--------------------------------|---|
| Date:                          | August 12, 2020   |
| Purpose:                       | Buyer desires to purchase all rights of the Seller to own and operate the CHHA, and all CHHA's assets.  |
| Seller:                        | Long Island Jewish Medical Center   |
| Buyer:                         | Jack Basch who will relinquish everything to (Assured Care Home Health, LLC)  |
| Assets Acquired:               | Relinquish to New York State pursuant to this Agreement its CHHA license in connection with the application of the Purchaser for his own Certificate of Need for certified home health agency services in the New York Counties of Nassau and Queens.   |
| Excluded Assets:               | All fixed assets deployed in the Seller's CHHA except as set forth:<br>(A) all existing patients.<br>(B) all caregivers and other personnel employed in the Seller's CHHA;<br>(C) all books and records of the Seller's CHHA, including, without limitation, all medical records of patients of such CHHA;<br>(D) the name, logo, trademark, and all intellectual property except set forth in.   |
| Purchase Price:                | \$1,500,000   |
| Payment of the Purchase Price: | \$450,000 deposit held in escrow) applicable to the APA in total, including acquisitions other than the CHHA) to be applied to the overall purchase price at closing. Balance due at closing.   |
| Provision Update:              | December 8, 2020 (The asset purchase agreement has been amended in order for Mr. Jack Basch who purchased the CHHA only, could then sell with written intent 15% of his portion to continue to operate the CHHA that is currently under Long Island Jewish Medical Center. Written documentation in NYSCON indicates that Chaim Klein will own 15% of the facility. Jack Basch as the managing member signed his purchase over to Assured Care Home Health, LLC and the amended sale agreement states that he can now sell membership into the CHHA. To date he has put the accumulated funds to buy the entity and they when the 15% is sold to the named member for \$250,000 estimated at the time of approval. This is not a separate agreement but an amendment to the original agreement. |

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/r 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.

#### Lease Rental Agreement

The applicant has submitted a proposed lease for the site that they will occupy, which is summarized below:

|           |  |
|-----------|--|
| Date:     | November 5, 2020   |
| Premises: | 100-04 Ditmars Boulevard, East Elmhurst, New York, 11369       |
| Landlord: | 100-04 Ditmars Boulevard, LLC                                  |
| Tenant:   | Assured Care Home Health, LLC (f-k-a) We Care Home Health, LLC |
| Term:     | 10-Year  |
| Rent:     | \$60,000 annually or \$5,000 monthly for the term.             |

The applicant has attested that the lease is a non-arm's length arrangement, as the landlord and tenant have an existing relationship. The applicant submitted two (2) letters of rent reasonableness indicating that the rent is reasonable from two New York State realtors.

#### Operating Budget

The applicant has submitted a projected operating budget for first and third year, in 2021 dollars, as summarized below:

|                       | <u>Year One</u> | <u>Year Three</u> |
|-----------------------|-----------------|-------------------|
| <u>Revenues</u>       |                 |                   |
| Commercial FFS        | \$174,621       | \$384,164         |
| Medicare FFS          | \$421,417       | \$927,113         |
| Medicare MC           | \$149,566       | \$329,042         |
| Medicaid FFS          | \$9,869         | \$21,715          |
| Medicaid MC           | \$107,775       | \$237,105         |
| All Other             | \$75,153        | \$165,338         |
| Total Revenues        | \$938,401       | \$2,064,478       |
| <u>Expenses</u>       |                 |                   |
| Operating             | \$929,100       | \$1,820,645       |
| Capital               | <u>0</u>        | <u>0</u>          |
| Total Expenses        | \$929,100       | \$1,820,645       |
| Net Income (Loss)     | <u>\$9,301</u>  | <u>\$243,833</u>  |
| Utilization - Visits* | 9,000           | 19,800            |
| Utilization - Hours** | 2,000           | 4,400             |

\* Nursing, PT, OT, SP, and Medical Social Services visits

\*\*Home Health Aid hours

- The Medicaid 1.5% decreased reimbursement has already been accounted for in the development of the Year One & Three budgets stated in the application.
- Projections are based on historical performance of the CHHA when it was under operation from LIJ and Northwell.

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

| <u>Visits</u>  | <u>Year One</u> | <u>Year Three</u> | <u>Hours</u>   | <u>Year One</u> | <u>Year Three</u> |
|----------------|-----------------|-------------------|----------------|-----------------|-------------------|
| Commercial FFS | 16.26%          | 16.26%            | Commercial FFS | 16.26%          | 16.26%            |
| Medicare FFS   | 43.03%          | 43.03%            | Medicare FFS   | 43.05%          | 43.05%            |
| Medicare MC    | 15.26%          | 15.26%            | Medicare MC    | 15.25%          | 15.25%            |
| Medicaid FFS   | 1.02%           | 1.02%             | Medicaid FFS   | 1.0%            | 1.0%              |
| Medicaid MC    | 11.11%          | 11.11%            | Medicaid MC    | 11.11%          | 11.11%            |
| Charity Care   | 2.0%            | 2.0%              | Charity Care   | 2.0%            | 2.0%              |
| All Other      | 11.32%          | 11.32%            | All Other      | 11.31%          | 11.31%            |
| Total          | 100%            | 100%              | Total          | 100%            | 100%              |

Charity care is expected to be 2%. The applicant states their policy is to assess individual based on income to determine eligibility fee reduced fees and/or charity care. Their commitment includes providing uncompensated services to uninsured patients lacking the financial resources to pay.

#### Capability and Feasibility

Jack Basch will acquire the CHHA via asset purchase agreement for \$1,500,000, funded by member equity, of which \$450,000 is currently held in a mutual escrow account. He will then assign his rights to Assured Care Home Health, LLC. The applicant has submitted an agreement to sell 15% of the membership for \$225,000 to Chaim Klein, which is proportional to the cost of his membership.

The working capital requirement is estimated at \$154,850 based on two months of first year expenses. The \$154,850 will be funded from the members' equity. BFA Attachment A is the net worth statements for the proposed members Assured Care Home Health, LLC, which reveals sufficient resources to meet the equity requirements. BFA Attachment C is the pro forma balance sheet, which shows the entity will start with \$1,654,850 in equity.

The submitted budget projects a net income of \$9,301 and \$243,833 in the first- and third-year budgets, respectively. The budget appears reasonable based on historical utilization.

#### Conclusion

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

## Attachments

- BFA Attachment A    Personal Net Worth Statement- Members of Assured Care Home Health, LLC
- BFA Attachment B    Pro Forma Balance Sheet of Assured Care Home Health, LLC



RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 3rd day of June 2021, 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 Assured Care Home Health, LLC as the new operator of Long Island Jewish Medical Center Home Care Department, a certified home health agency (CHHA) and relocate the CHHA to 100-04 Ditmars Boulevard, East Elmhurst serving the same 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

202250 E

Assured Care Home Health, LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed revised lease agreement, acceptable to the Department of Health. [BFA]
2. Submission of an executed assignments of Rights, Acceptable to the Department of Health. [BFA]
3. Submission of a photocopy of the applicant's amended operating agreement, acceptable to the Department. [CSL]
4. Submission of a photocopy of the seller's certificate of amendment of the certificate of incorporation, acceptable to the Department. [CSL]
5. Submission of the applicant's amended and executed Certificate of Amendment of the Articles of Organization, acceptable to the Department. [CSL]

APPROVAL CONDITIONED UPON:

1. The project must be completed within one year 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]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON*.

STATE OF NEW YORK : DEPARTMENT OF HEALTH  
-----X

IN THE MATTER :  
OF :  
THE PROPOSED DISAPPROVAL BY THE PUBLIC :  
HEALTH and HEALTH PLANNING COUNCIL OF :  
AN APPLICATION FOR a THREE-YEAR EXTENSION : ORDER  
OF THE LIMITED LIFE :

By :  
SHINING STAR HOME CARE, LLC, d/b/a SHINING STAR :  
HOME HEALTH CARE :  
Application No. 171041-E :

-----X

A notice of hearing dated May 10, 2019 was served on Petitioner Shining Star Home Health Care, LLC (Petitioner) to review the proposed disapproval by the Public Health and Health Planning Council (PHHPC) of the application to extend the limited life certification for three years of Petitioner's Certified Home Health care agency. The basis for the proposed disapproval by the PHHPC is the petitioner's failure to provide two per cent charity care as defined in 10 NYCRR 763.11(a)(11).

The hearing was held in Albany, New York, on October 2, 2019, and December 5, 2019, before Jean T. Carney, Administrative Law Judge. The Department of Health appeared by Eric J. Mantey, Esq.; and the Petitioner appeared by Cornelius D. Murray, Esq.

Evidence was received and witnesses were sworn and examined. A transcript of the proceedings was made. Post hearing briefs were submitted, and the record closed on February 20, 2020. The Administrative Law Judge issued her Report and Recommendations on May 15, 2020.

NOW, on reading and filing the Notice of Hearing, the Record herein and the Administrative Law Judge's Report, we hereby adopt the Report of the Administrative Law Judge as our own; and

**IT IS HEREBY ORDERED:**

1. Petitioner's application to extend its limited life for three years is hereby approved.
2. This Order shall be effective upon service on the Petitioner by personal service or by certified or registered mail.

DATED: Albany, New York

, 2020

THE PUBLIC HEALTH COUNCIL  
OF THE STATE OF NEW YORK

By: \_\_\_\_\_

TO: Eric J. Mantey, Esq.  
Senior Attorney  
New York State Department of Health  
Corning Tower Room 2412  
Empire State Plaza  
Albany, New York 12237-0029

Cornelius D. Murray, Esq.  
O'Connell & Aronowitz, P.C.  
54 State Street  
Albany, New York 12207-2501

**STATE OF NEW YORK: DEPARTMENT OF HEALTH**

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In the Matter of

**THE PROPOSED DISAPPROVAL BY THE PUBLIC HEALTH AND HEALTH  
PLANNING COUNCIL OF AN APPLICATION FOR A THREE-YEAR EXTENSION  
OF THE LIMITED LIFE BY**

**SHINING STAR HOME CARE, LLC d/b/a SHINING STAR HOME HEALTH CARE  
APPLICATION NO. 171041-E**

Petitioner,

Pursuant to Article 36 of the Public Health Law (PHL) of the State of New York and Part 760,  
Chapter V, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New  
York (NYCRR)

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**REPORT and RECOMMENDATION**

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To: The New York State Public Health and Health Planning Council

Before: Jean T. Carney, Administrative Law Judge

Held at: New York State Department of Health  
150 Broadway, Suite 510  
Menands, New York 12204  
October 2, 2019 and December 5, 2019  
Record closed on February 20, 2020

Appearances: Shining Star Home Care, LLC, Petitioner  
5922 18<sup>th</sup> Avenue  
Brooklyn, New York 11204

By: Cornelius D. Murray, Esq.  
O'Connell and Aronowitz  
54 State Street  
Albany, New York 12207

New York State Department of Health, Respondent

By: Eric J. Mantey, Esq.  
Corning Tower, Room 2412  
Empire State Plaza  
Albany, New York 12237

## JURISDICTION and APPLICABLE LAW

New York State Public Health Law (PHL) Article 36 sets forth the requirements for establishing and operating home care services agencies. In order to obtain an operating certificate, the proposed Certified Home Health Agency (CHHA) must submit an application to the Public Health and Health Planning Council (PHHPC) for approval. (PHL §3606). The PHHPC considers the public need for the proposed agency; the applicant's character, competence, and standing in the community; the CHHA's proposed financial resources; and "such other matters as it shall deem pertinent." (PHL §3606[2]; 10 NYCRR §760.3). Among the other matters that the PHHPC may deem pertinent in approving an application is whether the proposed agency intends to provide charity care; which is defined as "care provided at no charge or reduced charge for the services the agency is certified to provide to patients who are unable to pay full charges, are not eligible for covered benefits under title XVIII or XIX of the Social Security Act, are not covered by private insurance, and whose household income is less than two hundred percent of the federal poverty level." (10 NYCRR §760.11[a][11]). If the PHHPC proposes to disapprove an application, the proposed CHHA is entitled to a hearing. (PHL §3608).

Shining Star Home Care, LLC (Petitioner, or Shining Star) bears the burden of proof in this matter; and must show by substantial evidence that the PHHPC erred in its proposed determination to disapprove the Petitioner's application to extend its Limited Life certification. Substantial evidence means such relevant proof as a reasonable mind may accept as adequate to support conclusion or fact; less than preponderance of evidence, but more than mere surmise, conjecture or speculation and constituting a rational basis for decision. *Stoker v. Tarantino*, 101 A.D.2d 651, 475 N.Y.S.2d 562 [3<sup>rd</sup> Dept. 1984], *appeal dismissed* 63 N.Y.2d 649 (1984).

## HEARING RECORD

In support of its position, the Petitioner presented documents (Petitioner Exhibits 1-13); the testimony of Frank M. Cicero, President and CEO of Cicero Consultants, VCC, Inc; and the testimony of Yechiel Landau, Managing Member and Majority Owner of Shining Star. The Department of Health (DOH or Respondent) presented documents (DOH Exhibits A-X); and the testimony of George T. Macko, Director of Planning and Licensure at the DOH. The ALJ admitted the Notice of Hearing (ALJ I) on her own motion, and Official Notice was taken of the Patient Protection and Affordable Care Act (ACA), enacted on March 23, 2010. (42 USCS §18001 *et. seq.*). A transcript of the hearing was made, and each party submitted post hearing memoranda and reply briefs.

## FINDINGS OF FACTS

After careful consideration of the record, it is hereby found:

1. The Petitioner was certified January 12, 2012 as a special pilot program CHHA, with a conditional five-year limited life. The population Shining Star serves is limited to individuals in Bronx, Kings, New York, and Queens Counties who have been identified as being a high risk for re-hospitalization due to heart disease, stroke, and diabetes. (Petitioner Exhibit 2; DOH Exhibit F; Testimonies of Mr. Cicero and Mr. Landau).
  
2. Approval of the Petitioner's initial certification was contingent upon the submission of several documents, including a signed agreement with an outside entity to provide annual reports to the DOH; an acceptable plan for providing "no less than 2% charity care in accordance with Section 763.11(a)(11) of Title 10 NYCRR"; an executed building lease; executed and dated Articles of Organization; an executed and dated copy of the Operating Agreement; and any amendments to those sections of the application describing the target population. (DOH Exhibit A; Testimony of Mr. Cicero).

3. Prior to the expiration of its initial certification, Shining Star applied for a three-year extension. This application was reviewed by the DOH; and submitted for consideration to the PHHPC's Establishment Project Review Committee (Committee). The DOH initially did not recommend approval, and the Committee deferred its determination until the DOH recommended approval with conditions and contingencies, which did not include submission of a plan to provide charity care. (Testimonies of Mr. Macko and Mr. Cicero; DOH Exhibits G through K; DOH Exhibit V).

4. On November 29, 2018 the Committee recommended approval to the full PHHPC of the application without the condition or contingency to provide charity care. (DOH Exhibit U).

5. At their meeting on December 13, 2018, the full PHHPC voted to disapprove Shining Star's application based on its failure to provide charity care stating, "[h]ere we have an operator who is not running a successful business who also has been unable to get to two percent of indigent care. If we're ever going to set an example and make it clear, we have expectations and we expect the providers to live up to those expectations they pledge to, this is that opportunity." (DOH Exhibits W and X; Testimony of Mr. Macko).

6. Shining Star was designed to serve post-hospital discharged patients with specific diagnoses. Since the ACA was enacted, virtually all post-hospital discharged patients are insured through Medicare; and many are insured through both Medicare and Medicaid. (Testimony of Mr. Cicero; DOH Exhibit W; Petitioner Exhibit 1).

### DISCUSSION

The only issue here is whether the PHHPC acted rationally when it denied Shining Star's application to extend its certification based solely on Shining Star's failure to provide two percent charity care. At the hearing, the Department conceded that this was the reason for disapproving the



Petitioner's application to extend. The evidence shows that the Petitioner's application was recommended for approval without any condition or contingency requiring a plan for charity care; and the PHHPC has not held other entities to the standard of providing charity care. Therefore, the Petitioner has met its burden of showing that the PHHPC erred in proposing to deny its application.

Shining Star was established to provide home health care services to a narrowly defined, specific population. Specifically, Shining Star provides services to individuals at risk for re-hospitalization for diabetes, heart disease, or stroke. Patients are referred to Shining Star by hospitals upon the patient's discharge; and are covered by Medicare and/or Medicaid as a matter of course. (Testimony of Mr. Landau; DOH Exhibit U). Although many of these patients are either low income or indigent, they do not meet the definition of charity care eligibility because they have health insurance through Medicaid and/or Medicare. (10 NYCRR §760.11[a][11]). The Committee considered this information when recommending approval of Shining Star's application to extend its limited life certification to the full PHHPC. Notably, the Committee's approval was contingent and conditioned on certain factors; but providing charity care was not one of those contingencies or conditions. In voting to disapprove Shining Star's application, the PHHPC acknowledged the Committee's consideration of these factors; but chose to disregard its recommendation.


Instead, the full PHHPC focused on Shining Star's inability to provide two percent charity care, and chose to make an example of the Petitioner, indicating that providing charity care is an important aspect of approving such applications. However, this requirement sets Shining Star up for failure because their target patient population does not meet the definition of charity care. Furthermore, the PHHPC did not follow through with this policy, approving similar applications despite the applicant's failure to meet the two percent charity care requirement. (Testimony of Mr. Cicero; Petitioner Exhibits 1, 8, and 10-13).

The Department posited that Shining Star's application was unique because it is a limited life CHHA, and therefore could not be compared to any other applicant. However, the record reflects that some applicants were similar in that they were established CHHAs who had failed to provide two percent charity care, and yet were approved to continue under new ownership. Additionally, the record reflects that no other initial CHHA application was denied for failure to provide a plan to provide two percent charity care. (Testimony of Mr. Cicero; Petitioner Exhibits 1, 8, and 10-13). Therefore, the PHHPC's disapproval in this matter deviated from the norm, and was unsupported by either precedent or antecedent.

**CONCLUSION and RECOMMENDATION**

The Petitioner showed that the PHHPC erred in disapproving Shining Star's application to extend its certification as a limited life CHHA. This matter is remanded to the PHHPC for reconsideration.

DATED:     May 15, 2020  
           Albany, New York

  
JEAN T. CARNEY  
Administrative Law Judge

## RESOLUTION OF APPROVAL

WHEREAS, the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, has considered any advice offered by any applicable Regional Health Systems Agency, the staff of the New York State Department of Health and the Establishment Committee of this Council; and

WHEREAS, on December 13, 2018, this Council proposed to disapprove the following application for a three-year extension of limited life for CON #072094-E ; and

WHEREAS, following the applicant's request for a public hearing pursuant to said Section 2801-a, such a hearing was held before an Administrative Law Judge, and the Administrative Law Judge has, by her Report and Recommendation dated May 15, 2020 recommended approval of the application; and

WHEREAS, the Public Health and Health Planning Council has considered the record of said hearing and Report and Recommendation; it is hereby

RESOLVED, that this Council, after due deliberation, on this 3<sup>rd</sup> day of June, 2021, hereby proposes to approve the following application for a three-year extension of limited life for CON #072094-E, with the conditions and contingencies specified below; and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified in the application in a manner satisfactory to the Public Health and Health Planning and the New York State Department of Health, the Secretary to 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 the 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 the Department of Health, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

**APPLICATION NUMBER:**

171041 E

**FACILITY/APPLICANT:**

Shining Star Home Health Care  
(Kings County)

**Approval of a three-year extension of the operating certificate from the date of the Public Health and Health Planning Council recommendation letter, contingent upon:**

1. Submission of a signed agreement with an unrelated, independent entity, acceptable to the Department, to provide annual reports to the Department. The reports shall include, but not be limited to:
  - a. Utilization data by payor;
  - b. Data comparing the PQI rates of the communities served by the CHHA from the effective date of the CHHA's operating certificate;
  - c. Data showing Emergency Department visit rates of patients served compared to the general population in the neighborhoods served by the CHHA;
  - d. Data comparing hospital readmission rate of patients served compared to the general population in the neighborhoods served by the CHHA;
  - e. Utilization by the diagnosis of the patients served by the CHHA. [CHA]
2. Submission of a photocopy of the Operating Agreement of Shining Star Home Health Care, LLC, which is acceptable to the Department. [CSL]

**Approval conditional upon:**

1. Services are limited to the special pilot program population of individuals in Bronx, Kings, New York, and Queens Counties identified as being at high risk for hospitalization due to heart disease, stroke, and diabetes.
2. Continued submission of annual reports, prepared by an unrelated, independent entity, providing at a minimum the data required in the contingency, and reporting the percent of patients in compliance with the condition of approval related to the approved special pilot program population. Annual reports must be submitted no later than March 15<sup>th</sup> of each year for the proceeding calendar year. [CHA]

Documentation submitted to satisfy the above-referenced contingencies should be submitted to the Department of Health within sixty (60) days.

RESOLUTION OF DISAPPROVAL

WHEREAS, the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, has considered any advice offered by any applicable Regional Health Systems Agency, the staff of the New York State Department of Health and the Establishment Committee of this Council; and

WHEREAS, on December 13, 2018, this Council proposed to disapprove the following application for a three-year extension of limited life for CON #072094-E ; and

WHEREAS, following the applicant's request for a public hearing pursuant to said Section 2801-a, such a hearing was held before an Administrative Law Judge, and the Administrative Law Judge has, by her Report and Recommendation dated May 15, 2020 recommended approval of the application; and

WHEREAS, the Public Health and Health Planning Council has considered the record of said hearing and Report and Recommendation; it is hereby

RESOLVED, that this Council, after due deliberation, and for reasons stated on the record at the meeting of this Council, on this 3rd day of June, 2021 hereby adopts all 6 numbered Summary of Facts set forth in said Report and Recommendation except those numbered Summary of Facts specifically rejected on the record at the meeting of this Council; and be it further

RESOLVED, that this Council, after due deliberation, and for the reasons stated on the record at its meeting of this Council, of this 3rd day of June, 2021 hereby rejects the Conclusions set forth in said Report and Recommendation; and be it further

RESOLVED, that this Council, on this 3<sup>rd</sup> day of June, 2021 hereby disapproves the following application for the establishment and construction of an eight (8)-station chronic renal disease dialysis center.

APPLICATION NUMBER:

171041 E

FACILITY/APPLICANT:

Shining Star Home Health Care  
(Kings County)



**Project # 171041-E  
Shining Star Home Health Care**

**Program:** Certified Home Health Agency  
**Purpose:** Establishment

**County:** Kings  
**Acknowledged:** January 19, 2017

**Executive Summary**

**Description**

Shining Star Home Care, LLC (Shining Star), a proprietary, Article 36 certified home health agency (CHHA), requests approval for a three-year extension to its limited life operating certification. The agency was established as a special pilot program CHHA, certified to serve individuals at higher risk for hospitalization due to heart disease, stroke and diabetes. The agency is authorized to serve individuals in Bronx, Kings, New York and Queens Counties. The CHHA was approved through CON 072094 with a conditional five-year limited life and began operations effective January 17, 2012. The applicant notified the Department before their limited life expiration, requesting a three-year extension. The CHHA currently operates from leased office space located at 5922 18<sup>th</sup> Avenue, Brooklyn (Kings County).

Shining Star's services are limited to the special pilot program population authorized under its initial operating certificate. The CHHA is certified for the following services: home health aides, medical social services, medical supplies equipment and appliances, nursing, nutrition, occupational therapy, physical therapy, and speech language pathology

The membership of Shining Star Home Care, LLC consists of Yechiel Landau (80%) and Yvette Henriquez (20%).

**OPCHSM Recommendation**

Contingent Approval of a three-year extension of the operating certificate from the date of the Public Health and Health Planning Council recommendation letter

**Need Summary**

Utilization has been significantly below projected visits. In its original 2007 application, Shining Star projected in excess of 175,000 visits by Year Three. Shining Star reports 2,999 visits in 2016 and 4,313 for 2017 (per Cost Reports). The applicant anticipates increased visits over the next three years. The agency did not meet the 2% charity care requirement in any of its five years of operation but is projecting 2% going forward.

**Program Summary**

From its initial date of operation of January 17, 2012 through the present time, Shining Star Home Care, LLC d/b/a Shining Star Home Health Care has remained in compliance with all Conditions of Participation, with no enforcement actions taken against them.

**Financial Summary**

There are no project costs associated with this application. The projected budget is as follows:

|            | <u>Year One</u> | <u>Year Three</u> |
|------------|-----------------|-------------------|
| Revenue    | \$672,132       | \$692,296         |
| Expenses   | 604,084         | 614,633           |
| Net Income | \$68,048        | \$77,663          |

The projected net income is positive going forward, however it is dependent upon the applicant maintaining utilization levels and cost control efforts. The applicant also requires working capital to fund operations, which is to be provided by majority member Yechiel Landau, or as an interest free personal loan from a friend of Mr. Landau's with repayment when the operation becomes more profitable.

## Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

**Approval of a three-year extension of the operating certificate from the date of the Public Health and Health Planning Council recommendation letter, contingent upon:**

1. Submission of a signed agreement with an unrelated, independent entity, acceptable to the Department, to provide annual reports to the Department. The reports shall include, but not be limited to:
  - a. Utilization data by payor;
  - b. Data comparing the PQI rates of the communities served by the CHHA from the effective date of the CHHA's operating certificate;
  - c. Data showing Emergency Department visit rates of patients served compared to the general population in the neighborhoods served by the CHHA;
  - d. Data comparing hospital readmission rate of patients served compared to the general population in the neighborhoods served by the CHHA;
  - e. Utilization by the diagnosis of the patients served by the CHHA. [CHA]
2. Submission of a photocopy of the Operating Agreement of Shining Star Home Health Care, LLC, which is acceptable to the Department. [CSL]

**Approval conditional upon:**

1. Services are limited to the special pilot program population of individuals in Bornx, Kings, New York, and Queens Counties identified as being at high risk for hospitalization due to heart disease, stroke, and diabetes.
2. Continued submission of annual reports, prepared by an unrelated, independent entity, providing at a minimum the data required in the contingency, and reporting the percent of patients in compliance with the condition of approval related to the approved special pilot program population. Annual reports must be submitted no later than March 15<sup>th</sup> of each year for the proceeding calendar year. [CHA]

Council Action Date

**December 13, 2018**

## Need and Program Analysis

### Review Summary

This special pilot program CHHA operates from its sole practice location in leased office space at 5922 18<sup>th</sup> Avenue, Brooklyn, New York 12204. It was approved to serve individuals identified as being at higher risk for hospitalization due to heart disease, stroke, and diabetes, in the approved geographic service area of Bronx County, Kings County, New York County, and Queens County. Shining Star offers the services of home health aide, medical social services, medical supplies/equipment/appliances, nursing, nutritional services, occupational therapy, physical therapy, and speech language pathology.

As required in the Public Health Council conditional approval, annual reports by an outside independent agency have been submitted to NYSDOH for years 2012/2013 through 2017.

In its establishment application, Shining Star Home Care, LLC, d/b/a Shining Star Home Health Agency, cited the NYSDOH Prevention Quality Indicators that reports that low income minority neighborhoods located in the four above named counties have up to two to three times more hospital admissions and readmissions due to heart disease, stroke, and diabetes than the statewide average.

### Background

| Utilization (Visits)      | 072094<br>Projected<br>Year One | 072094<br>Projected<br>Year<br>Three | Actual<br>2013<br>(1 <sup>st</sup> Full<br>Year) | Actual<br>2014 | Actual<br>2015<br>(3 <sup>rd</sup> Full<br>Year) | Actual<br>2016 | Actual<br>2017 |
|---------------------------|---------------------------------|--------------------------------------|--|----------------|--|----------------|----------------|
| Nursing                   | 7,199                           | 21,783                               | 240  | 1,773          | 3,176  | 2,261          | 2,386          |
| Occupational Therapy      | 196                             | 320                                  | 0  | 43             | 16   | 1              | 1              |
| Physical Therapy          | 561                             | 1,336                                | 39   | 278            | 522  | 184            | 1,774          |
| Speech/Language Pathology | 27                              | 57                                   | 0  | 17             | 37   | 1              | 1              |
| Medical Social Services   | 21                              | 307                                  | 2  | 14             | 4  | 12             | 4              |
| Home Health Aide          | 26,748                          | 151,465                              | 1,788  | 3,618          | 2,924  | 540            | 147            |
| <b>Total</b>              | <b>34,752</b>                   | <b>175,268</b>                       | <b>2,069</b>                                     | <b>5,743</b>   | <b>6,679</b>                                     | <b>2,999</b>   | <b>4,313</b>   |

Source: Agency's Cost Reports

### Analysis

The original approval of this CHHA was to permit a special pilot program to serve those individuals at risk for hospitalization due to heart disease, stroke and diabetes in communities within Kings, Queens, Bronx and New York Counties. It is not clear that this CHHA has served a distinctly different special population from that of other CHHAs, nor has the program of care been found to be unique.

In its five years of operation, the CHHA reports that it has served predominantly the target population:

- In 2012 (total of three patients served) and 2013 (total of 24 patients served), the applicant reports that one patient visited an Emergency Department, and two patients were readmitted to a hospital. None of those Shining Star patients was readmitted due to diabetes, heart disease, or stroke. The statewide averages for Emergency Department visits, and potentially preventable hospital readmission rates for Bronx, Kings, New York, and Queens Counties, for years 2012 and 2013, were unreported.
- In 2014, the applicant reports that seven of Shining Star's 205 patients (3.4%) visited an Emergency Department, compared to a statewide average that year of 23.13%, and three of those seven visits were due to unrelated occurrences (one injury due to a fall, one urinary tract infection, and one decline in three or more activities of daily living). Seven of Shining Star's 205 patients (3.4%) were readmitted to a hospital, compared to a potentially preventable hospital readmission rate that year for Bronx, Kings, New York, and Queens Counties ranging from 6.1% to 7.54%. None of those Shining Star patients was readmitted due to diabetes, heart disease, or stroke.
- In 2015, the applicant reports that eight of Shining Star's 214 patients (3.7%) visited an Emergency Department, compared to a statewide average that year of 23.53%, and five of those



eight visits were due to unrelated occurrences (four injuries due to a fall, and one urinary tract infection). Eight of Shining Star's 214 patients (3.7%) were readmitted to a hospital, compared to a potentially preventable hospital readmission rate that year for Bronx, Kings, New York, and Queens Counties ranging from 6.1% to 7.54%. One of those Shining Star patients was readmitted due to diabetes, and none were readmitted due to heart disease or stroke.

- In 2016, the applicant reports two (1.3%) of Shining Star's patients went to the ED, compared with a New York average of 10.7% and a national average of 12.9%. Two (1.3%) of Shining Star's patients were admitted to the hospital, compared to a New York average of 16.4% and a national average of 15.9%.
- Shining Star reports that in 2016 it discontinued its Allscripts clinical software medical record system which had proven to be overly expensive and unreliable for information reporting purposes. Shining Star instead invested in a new clinical software system called Home Care Home Base. The applicant states that implementing this new intake and clinical documentation software system during 2016 affected its ability to accept admissions, process intake data, and properly maintain clinical data during 2016, which was a factor in the decrease in admissions by 74 patients from 2015 to 2016, and the increase in hospital readmissions in 2016. Looking forward, Shining Star had also taken the following initiatives to both increase intake and utilization, and prevent future Emergency Department visits and hospital readmissions:
  - Renegotiating various HMO and MLTCP contracts, resulting in better reimbursement rates for services and improved financial stability
  - Partnering with Relias Learning to customize orientation and inservice education curriculum used to train the CHHA's skilled professionals
  - Creating an advanced wound care program with staff trained as specialists to treat complex wounds, providing an advantage over other CHHAs who typically do not accept such patients
  - Hiring a specialized Case Manager to provide extensive clinical oversight for patients who are at risk for hospital readmission
  - Engaging in weekly conference calls with patients, families, doctors, nurses, and case managers. Patients at higher risk for hospital readmission receive daily telephone calls at home from clinical professionals to ensure proper medications were taken in the proper dosages and at the proper times of day. If additional services or care are required, the clinical professional will immediately contact the patient's nurse to provide timely intervention before an emergency situation arises.
  - Partnering with a particular pharmacy that pre-packages patient medications in small packets, to help ensure the patient is taking the correct dose at the correct time, in order to alleviate medication errors, a leading reason for both Emergency Department visits and hospital readmissions.
- The applicant reports that in 2017 only 12 of Shining Star's 726 patients (1.7%) were discharged to a hospital or Emergency Department. The applicant reports that, per statistics published by the Agency for Healthcare Research and Quality, the average readmission rate for patients seven days after discharge from a hospital was 7.5%, and 30 days after discharge from a hospital was 21.1%.

The applicant reports that three of the three patients served in 2012, 18 of the 24 patients served in 2013, 168 of the 205 patients served in 2014, 161 of the 214 patients served in 2015, 132 of the 152 patients served in 2016, and 672 of the 768 patients served in 2017, had diagnoses that identified the patient as being at higher risk for hospitalization due to heart disease, stroke, or diabetes. Accordingly, 100% in 2012, 75% in 2013, 82% in 2014, 75% in 2015, 87% in 2016, and 87.5% in 2017 of the patients served by Shining Star Home Care, during its first six years of operation, had diagnoses that identified the patient as being at higher risk for hospitalization due to heart disease, stroke, or diabetes.

Shining Star has a 3.5 CMS Quality of Patient Care Star Rating, compared to a NYS average of 3 stars and a national average of 3.5 stars.

The NYSDOH Division of Home and Community Based Services reports that, from its initial date of operation of January 17, 2012, through the present time, Shining Star Home Care, LLC, d/b/a Shining Star Home Health Care, has remained in compliance with all Conditions of Participation, with no history of any enforcement actions taken against this CHHA.

## Financial Analysis

The applicant submitted their current year (2017) results, their half-year 2018 results, and their first and third year operating budgets subsequent to approval, in 2018 dollars, as shown below:

|                       | <u>Current Year</u> | <u>2018 (6 mos)</u> | <u>Year One</u> | <u>Year Three</u> |
|-----------------------|---------------------|---------------------|-----------------|-------------------|
| <u>Revenues</u>       |                     |                     |                 |                   |
| Medicare              | \$74,920            | \$44,732            | \$110,093       | \$113,396         |
| Medicaid              | 22,035              | 90,132              | 57,940          | 59,678            |
| HMO/MLTC*             | 339,341             | 201,202             | 504,099         | 519,222           |
| All Other             | <u>4,407</u>        | <u>0</u>            | <u>0</u>        | <u>0</u>          |
| Total Revenues        | \$440,703           | \$336,066           | \$672,132       | \$692,296         |
| <u>Total Expenses</u> |                     |                     |                 |                   |
| Operating             | \$569,612           | \$229,937           | \$577,225       | \$582,465         |
| Space Occupancy       | <u>22,977</u>       | <u>15,000</u>       | <u>26,859</u>   | <u>32,168</u>     |
| Total Expenses        | \$592,589           | \$244,937           | \$604,084       | \$614,633         |
| Net Income/(Loss)     | <u>(\$151,886)</u>  | <u>\$91,129</u>     | <u>\$68,048</u> | <u>\$77,663</u>   |
| Utilization (visits)  | 4,119**             | 2875                | 5,154           | 5,309             |
| Cost per Visit        | \$143.87            | \$85.20             | \$117.21        | \$115.77          |

\* Represents Dually-Eligible Manage Medicaid/Medicare

\*\* Net Income/Loss differences for 2017 (as submitted by the applicant) would be immaterially different if actual utilization of 4,313 was used as the basis.

The following is noted with respect to the submitted budgets:

- Medicare and Medicaid services are reimbursed on an episodic basis. The applicant projected revenues for Year One based on Shining Star's annualized revenues from January 1, 2018 through June 30, 2018 (certified reports). This amount was then increased by 3% for Year Three to account for inflation.
- HMO/MLTC category represents patients who are dually-eligible for both Medicare and Medicaid. These Medicare and Medicaid plans are managed by HMO/MLTC/FIDA plans pursuant to the New York Managed Long-Term Care mandatory enrollment policy. All other revenues are based on existing rates.
- The first and third year utilization projections are based on averages experienced during the same January through June 2018 period plus charity care.
- Internal reports submitted by the applicant indicate that the number of visits through December 31, 2017 grew to 4,119, representing a 37.3% increase over 2016. During the first six months of 2018, visits totaled 2,875 (1,607 visit during the 1<sup>st</sup> quarter and 1,268 visits in the 2<sup>nd</sup> quarter). On an annualized basis, this shows continued growth over 2017. The budget projects the number of visits to be about 5,154 (around 1,289 visits per quarter).
- The cost per visit declined from \$232 in 2016 to \$144 in 2017. The results stem mostly from the increase in utilization and efficiencies through better management of staff time/productivity. The applicant has also improved information technology through the implementation of a new clinical software system (Home Care Home Base) and has partnered with QIRT (Quality In Real Time) to conduct audits on clinical documentation that is expected to ensure access to data for decisions that support preventing re-hospitalizations. During the first half of 2018, the applicant continued to reduce overall costs through efficiencies.

- Utilization by payor source for the submitted current and projected operating budgets is as follows:

| Payor        | Current Year |       | 2018 (6 Mos.) |       | Year One |       | Year Three |       |
|--------------|--------------|-------|---------------|-------|----------|-------|------------|-------|
|              | Visits       | %     | Visits        | %     | Visits   | %     | Visits     | %     |
| Medicare     | 796          | 19.3% | 411           | 14.3% | 762      | 14.8% | 786        | 14.8% |
| Medicaid     | 311          | 7.6%  | 485           | 16.9% | 422      | 8.2%  | 435        | 8.2%  |
| All Other*   | 3012         | 73.1% | 1,979         | 68.8% | 3,866    | 75.0% | 3,982      | 75.0% |
| Charity Care | 0            | 0%    | 0             | 0%    | 104      | 2.0%  | 106        | 2.0%  |
| Total        | 4,119        | 100%  | 2,875         | 100%  | 5,154    | 100%  | 5,309      | 100%  |

\*Includes Dually-Eligible Managed Medicaid/Medicare

- The applicant plans on reaching 2% Charity Care utilization in Year One and Year Three because of its relationships with Ahavas Chesed, NYC Health + Hospitals' Woodhull Hospital and Coney Island Hospital and the United Jewish Organizations of Williamsburg and North Brooklyn.

In their establishment application, the applicant committed to 2% Charity Care and 67% Medicaid utilization in Year One, and 2% Charity Care and 54% Medicaid utilization in Year Three. The applicant acknowledges that they have not fulfilled that commitment. The decline in Medicaid utilization is attributed to an increase in the number Medicare post-discharge hospital patients served by the agency. Also contributing are the patients classified as "Dually-Eligible Managed Medicaid/Medicare."

To address the utilization issues and the financial results shown above, the applicant has identified Mr. Ari Goldberger as an individual who possesses home care experience and has been informally advising the operator regarding day-to-day operations and developing relationships with local hospitals and several Managed Care Organizations. The applicant indicated that they are realizing the benefit of Mr. Goldberger's experience and resources and have already begun to receive patient referrals. The applicant anticipates entering into a Consulting Agreement.

The applicant cites the following recent activities as beneficial to the long-term performance of the facility: recently renegotiated various Managed Care contracts; increasing reimbursement; implementation of a new clinical software system; a partnership with Quality In Real Time; a partnership with Relias Learning for customized orientation and education curriculum; the creation of an advanced wound care program; hiring of a specialized case manager; and a partnership with a pharmacy to provide pre-packaged patient medication. Paul Rosenstock, M.D. and Robert Goodman, M.D. provide letters of support for the CHHAs mission.

### Capability and Feasibility

There are no project costs associated with this application. The budget demonstrates net income in Year One and Year Three of \$68,048 and \$77,663, respectively. Year One projects a 25.1% increase in utilization over the Current Year 2017. However, using recently provided 2018 half-year utilization data, the Year One projection represents a 10% reduction over 2018 annualized visits. Concurrent with the projected utilization, the applicant projects revenue per visit to increase by 11.1%, going from \$117 in 2018 (annualized) to a budgeted per visit rate of \$130. As noted above, budgeted revenue and utilization projections were based upon actual results obtained during January through June 2018. Per the recently provided certified 2017 data, the cost per visit has declined 38% between the Current Year (2016) and 2017 (going from \$232 in 2016 to \$144 in 2017). Using recently provided 2018 half-year cost data, the Year One projection represents a 38% cost increase (going from \$85 per visit in 2018 to \$117); however, compared to 2017 the Year One projection represents a cost per visit decrease of 18.5% (going from \$144 per visit in 2017 to \$117) supporting the applicant's ongoing efforts to efficiently operate the CHHA.

Working capital is estimated at \$100,681 based on two months of Year One expenses. However, as shown on BFA Attachments A, B and C (Shining Star's certified 2015, 2016 and 2017 financial statements, respectively), the CHHA has been sustaining operating losses. Each year, member contributions and/or member loans were made, and in 2017 Yechiel Landau (80% member) made an equity contribution of \$263,295 and converted a \$733,466 loan to equity, bringing the net assets to a negative \$393,531. BFA Attachment D is the certified financial statement for the first-half of 2018, which shows net income of \$91,129. The applicant further states that a large portion of the \$368,657 in accounts payable are for invoices that the vendors couldn't provide documentation to support their

validity. They are dated three years or older and per the applicant the vendors have not requested payment in the past two years.

The applicant provided a letter of interest from New Capital Ventures, LLC expressing willingness to provide a personal loan to Mr. Yechiel Landau, a majority member of the applicant, in the amount of \$1,410,000 to be used to fund the agency's working capital needs. The letter states that this would be a personal loan between friends, with no interest charged and repayment of the principal amount to be provided whenever funds become available. Capital One bank statements for New Capital Ventures, LLC for the period ending September 30, 2017, indicates sufficient resources are available to fund this transaction. Going forward, Shining Star intends to cover any operating losses with the proceeds of this personal loan, as well as with the personal liquid assets of Mr. Yechiel Landau. The applicant indicated that during its limited life, Mr. Landau has funded operating losses with his personal liquid assets, as well as from the proceeds of other personal loans provided to him from Hiram Capital, LLC (an entity related to New Capital Ventures, LLC).

BFA Attachment A is the 2015 certified financial statements of Shining Star Home Care, LLC. As shown, the entity had a negative working capital position and a negative net asset position in 2015. Also, the entity demonstrated a net loss of \$666,069. BFA Attachments B and C are the certified 2016 and 2017 audited financial statements of Shining Star Home Care, LLC. As shown, the entity had ongoing negative working capital and negative net asset positions and achieved an operating loss off \$493,675 in 2016 and \$151,886 in 2017 (accrual basis). BFA Attachment D is the entity's 2018 certified financials (first six months) which shows negative working capital, negative net assets, and positive net income of \$91,151. The applicant attributes the 2016 loss to low utilization, while 2018 results through June show positive net income based on improved efficiency and increased utilization.

## Attachments

|                  |   |
|------------------|---|
| BFA Attachment A | 2015 Certified financial statement of Shining Star Home Care, LLC               |
| BFA Attachment B | 2016 Certified financial statement of Shining Star Home Care, LLC               |
| BFA Attachment C | 2017 Certified financial statements of Shining Star Home Care, LLC              |
| BFA Attachment D | January-June 2018 Certified financial statements of Shining Star Home Care, LLC |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 13th day of December 2018, 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 request for a three-year extension of limited life for CON #072094-E, 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

171041 E

Shining Star Home Health Care

APPROVAL CONTINGENT UPON:

**Approval of a three-year extension of the operating certificate from the date of the Public Health and Health Planning Council recommendation letter, contingent upon:**

1. Submission of a signed agreement with an unrelated, independent entity, acceptable to the Department, to provide annual reports to the Department. The reports shall include, but not be limited to:
  - a. Utilization data by payor;
  - b. Data comparing the PQI rates of the communities served by the CHHA from the effective date of the CHHA's operating certificate;
  - c. Data showing Emergency Department visit rates of patients served compared to the general population in the neighborhoods served by the CHHA;
  - d. Data comparing hospital readmission rate of patients served compared to the general population in the neighborhoods served by the CHHA;
  - e. Utilization by the diagnosis of the patients served by the CHHA. [CHA]
2. Submission of a photocopy of the Operating Agreement of Shining Star Home Health Care, LLC, which is acceptable to the Department. [CSL]

APPROVAL CONDITIONED UPON:

1. Services are limited to the special pilot program population of individuals in Bornx, Kings, New York, and Queens Counties identified as being at high risk for hospitalization due to heart disease, stroke, and diabetes.
2. Continued submission of annual reports, prepared by an unrelated, independent entity, providing at a minimum the data required in the contingency, and reporting the percent of patients in compliance with the condition of approval related to the approved special pilot program population. Annual reports must be submitted no later than March 15<sup>th</sup> of each year for the proceeding calendar year. [CHA]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON*.