<u>STATE OF NEW YORK</u> PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

AGENDA

December 8, 2022

- 90 Church Street, Conference Rooms 4 A/B, NYC
- Empire State Plaza, Concourse Level, Meeting Room 6, Albany

Immediately following the Committee on Codes, Regulations, and Legislation Meeting (Codes scheduled to begin at 10:00 a.m.)

I. <u>INTRODUCTION OF OBSERVERS</u>

Jeffrey Kraut, Chair

II. APPROVAL OF MINUTES

October 6, 2022 PHHPC Meeting Minutes

III. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

A. Report of the Department of Health

Mary T. Bassett, M.D., M.P.H., Commissioner of Health

B. Report of the Office of Public Health

Ursula Bauer, Ph.D., MPH, Deputy Commissioner, Office of Public Health

C. Report of the Office of Health Equity and Human Rights

Johanne Morne, Deputy Commissioner, Office of Health Equity and Human Rights

D. Report of the Office of Primary Care and Health Systems Management

John Morley, M.D., Deputy Commissioner, Office of Primary Care and Health Systems Management

E. Report of the Office of Aging and Long Term Care

Adam Herbst, Deputy Commissioner, Office of Aging and Long Term Care

IV. ADOPTION OF LETTER TO LEGISLATURE

Adoption of Letter to Legislative Health Committee Chairs

Jeffrey Kraut, PHHPC Chair

V. <u>REGULATION</u>

Report of the Committee on Codes, Regulations, and Legislation

Thomas Holt, Chair of the Committee on Codes, Regulations, and Legislation

For Emergency Adoption

- 20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease)
- 20-07 Addition of Section 2.60 to Title 10 NYCRR (Face Coverings for COVID-19 Prevention)

For Information

22-16 Amendment of Subpart 5-1 of Title 10 NYCRR (Maximum Contaminant Levels (MCLs))

For Adoption

22-11 Amendment of Subpart 5-1 of Title 10 NYCRR (Public Water Systems)

VI. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

A. Report of the Committee on Establishment and Project Review

Peter Robinson, Chair of Establishment and Project Review Committee

<u>APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES</u>

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

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 Application

Acute Care Services - Construction

| | <u>Number</u> | Applicant/Facility | E.P.R.C. Recommendation |
|----|---------------|--|--------------------------------|
| 1. | 221248 C | NYU Langone Hospital – Long Island (Nassau County) Dr. Kalkut - Recusal | 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

<u>CATEGORY 4</u>: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

<u>CATEGORY 5</u>: 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

NO APPLICATIONS

B. <u>APPLICATIONS FOR ESTABLISHMENT AND</u> <u>CONSTRUCTION OF HEALTH CARE FACILITIES</u>

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

CON Applications

Ambulatory Surgery Centers – Establish/Construct

| | <u>Number</u> | Applicant/Facility | E.P.R.C. Recommendation |
|----|---------------|---|-------------------------|
| 1. | 221191 B | Maxillofacial Ambulatory Surgery Center, LLC (Suffolk County) | Contingent Approval |
| 2. | 221206 E | Northern Westchester Facility Project LLC d/b/a Yorktown Center for Special Surgery (Westchester County) | Contingent Approval |
| 3. | 221213 E | Performance Surgical Center, LLC d/b/a Performance Surgical Center (Kings County) | Contingent Approval |

Diagnostic and Treatment Centers – Establish/Construct

| | <u>Number</u> | Applicant/Facility | E.P.R.C. Recommendation |
|----|---------------|---|-------------------------|
| 1. | 221145 B | Apple Care Health (Kings County) | Contingent Approval |
| 2. | 221227 B | Parkchester DTC LLC d/b/a Parkchester Diagnostic and Treatment Center (Bronx County) | Contingent Approval |
| 3. | 221231 B | A Friendly Face Akademy, Corp. (Richmond County) | Contingent Approval |
| 4. | 221265 B | JAL 28 LLC d/b/a A Merryland Health Center (Kings County) | Contingent Approval |

Residential Health Care Facilities – Establish/Construct

| | <u>Number</u> | Applicant/Facility | E.P.R.C. Recommendation |
|----|---------------|--|-------------------------|
| 1. | 192204 E | Highland Nursing Home, Inc. d/b/a North Country Nursing & Rehabilitation Center (St. Lawrence County) | Contingent Approval |
| 2. | 202034 E | Ulster NH Operations LLC d/b/a Golden Hill Center for Rehabilitating and Nursing (Ulster County) | Contingent Approval |
| 3. | 211087 E | The Premier Center for Rehabilitation of Westchester, LLC d/b/a Springvale Nursing and Rehabilitation Center (Westchester 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 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 HAS

NO APPLICATIONS

<u>CATEGORY 5</u>: 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

NO APPLICATIONS

VII. <u>NEXT MEETINGS</u>

January 26, 2023 (Albany and NYC) February 9, 2023 (Albany and NYC)

VIII. ADJOURNMENT

State of New York Public Health and Health Planning Council

Minutes October 6, 2022

The meeting of the Public Health and Health Planning Council was held on Thursday, October 6, 2022 at the Empire State Plaza, Concourse Level, Meeting Room 6, Albany, New York, and 90 Church Street, 4th Floor CR 4 A/B, NYC. Jeffrey Kraut, Chair presided.

COUNCIL MEMBERS PRESENT

| Dr. Howard Berliner – NYC | Mr. Peter Robinson – NYC |
|---------------------------|--|
| Dr. Jo Boufford - NYC | Dr. John Rugge – Albany |
| Dr. Angel Gutiérrez – NYC | Ms. Nilda Soto – NYC |
| Mr. Thomas Holt – NYC | Dr. Theodore Strange - NYC |
| Dr. Gary Kalkut – NYC | Mr. Hugh Thomas - NYC |
| Mr. Scott LaRue – NYC | Dr. Kevin Watkins – Albany |
| Mr. Harvey Lawrence - NYC | Dr. Patsy Yang – NYC |
| Dr. Sabina Lim – NYC | Commissioner Bassett Ex-Officio - Albany |
| Ms. Ann Monroe – NYC | |

DEPARTMENT OF HEALTH STAFF PRESENT

| Dr. Ursula Bauer - Albany | Ms. Kathy Marks – NYC |
|--------------------------------|-------------------------------|
| Ms. Valarie Deetz – Zoom | Dr. James McDonald |
| Ms. Barbara DelCogliano - Zoom | Ms. Marthe Ngwashi - NYC |
| Mr. Mark Furnish – Albany | Dr. John Morley - Albany |
| Ms. Shelly Glock – Albany | Ms. Johanne Morne - Albany |
| Mr. Michael Heeran – Albany | Mr. Travis O'Donnell - Albany |
| Mr. Mark Hennessey - NYC | Mr. Jason Riegert - Albany |
| Mr. Adam Herbst – Zoom | Ms. Claudette Royal - Albany |
| Dr Eugene Heslin – Albany | Ms. Stephanie Schulman - NYC |
| Ms. Celeste Johnson - NYC | Ms. Kimberly Scott - Zoom |
| Mr. Jonathan Karmel - Albany | Ms. Angela Smith - Albany |
| Mr. Michael Kharfen - Albany | Mr. Michael Stelluti - Zoom |
| Ms. Colleen Leonard- NYC | Ms. Jennifer Treacy - Albany |
| Ms. Karen Madden - Zoom | , , , |

INTRODUCTION

Mr. George Macko – Albany

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

MS. SOTO RETIREMENT CONGRATULATIONS

Mr. Kraut congratulated Ms. Soto on her recent retirement from the Albert Einstein College of Medicine and noted that she will continue to serve on the Council. Please see pages 1 and 2 of the transcript.

APPROVAL OF THE MEETING MINUTES OF JUNE 2, 2022, JULY 28, 2022 AND SEPTEMBER 15, 2022

Mr. Kraut asked for a motion to approve the June 2, 2022 Minutes of the Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval. Dr. Gutiérrez seconded the motion. The minutes were unanimously adopted. Please refer to page 2 of the attached transcript.

Mr. Kraut asked for a motion to approve the July 28, 2022 Minutes of the Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval. Dr. Rugge seconded the motion. The minutes were unanimously adopted. Please refer to page 2 of the attached transcript.

Mr. Kraut asked for a motion to approve the September 15, 2022 Minutes of the Special Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval. Dr. Gutiérrez seconded the motion. The minutes were unanimously adopted. Please refer to pages 2 and 3 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Mr. Kraut introduced Dr. Bassett to give the Report on the Activities of the Department.

Dr. Bassett began her report by giving an update on COVID. As of October 5, 2022, New York was running close to 21 cases per 100,000, with 2,425 patients hospitalized with COVID. We are still losing people to COVID. We had 19 new deaths reported through our surveillance system yesterday. As you all are aware, we have reduced the restrictions that we had related to public health measures of masking and distancing. The Department is relying increasingly on the protection that vaccines provide. Vaccination is what has changed the face of COVID and reduced its impact in terms of severity and death. The new Bivalent booster is here and are available. They will greatly improve our ability to protect New Yorkers from the rising rates of transmission that we expect to see in winter months. We are also expecting to see Pfizer and Moderna approve this new Bivalent vaccine for emergency use in children, children five and older for the Pfizer vaccine, which has been really the mainstay of MRNA vaccines or vaccines in general in our state and for children six and over for Moderna. Dr. Bassett encouraged everyone who is eligible to get their booster to go out and get their booster.

Dr. Bassett also noted that the flu season upon us and reminded everyone to get their flu shot as flu cases are on the rise in the state and at this time, flu transmission in the state is considered widespread. To get this point across, we're going to be launching a flu COVID vaccine campaign. The Department is going to be promoting the Bivalent vaccine through paid medium. That will include targeted digital advertising, social media and other means.

Dr. Bassett next spoke on the topic of polio. On July 21, 2022, the Department announced that a young person was diagnosed with paralytic polio who was resident in Rockland County. The Department began looking at wastewater because people polio virus in human guts. The Department began looking at it in Rockland and other counties to see if we could detect polio virus in wastewater in these communities. We found evidence of polio virus in Orange County, Sullivan County, in New York City and Nassau County. This virus has been sequenced and linked genetically to the person who developed clinical paralytic polio. This is the evidence that we have for the ongoing circulation. The Department has continued to detect virus in wastewater and is working hard to address this. The answer is simple to proclaim, but challenging to execute, and that is vaccination. Dr. Bassett explained that the Department is providing operational and outreach and communications support to these counties, working collaboratively with their health departments and with other community partners to share the facts, increase awareness and encourage people to be vaccinated. The declaration of an emergency enabled us to expand our pool of vaccinators for polio, an important part of our response.

Dr. Bassett moved to discuss monkeypox, as she described as something that was really just an artifact of medical textbooks. Until mid-May of this year, when we began the current outbreak of monkeypox, which has spread to involve more than 90 countries and has involved, virtually every state in the United States has diagnosed a person with monkeypox since mid-May. The latest data in October was New York had 3,889 cases. Almost all of these cases are in New York City and in the Downstate area, meaning two thirds of the 334 cases diagnosed outside of New York City have been in Long Island and Westchester. Dr. Bassett stated that on July 28, 2022 she declared monkeypox an imminent threat to public health, and that was followed by the Governor's declaration, and it was subsequently followed by a national act. The Department has provided clinical guidance for the testing of monkeypox through initially all public health labs, but now increasingly also private labs. About a quarter of current testing is done by our Wadsworth Lab and the rest is now done by private labs. The Department is working hard to distribute the vaccine through both federal and local partners.

Dr. Bassett noted that we are encouraged that the rate of increase of monkeypox cases has really slowed. It appears that we have, you know, sort of reached a point where certainly the outbreak is no longer growing. This is true in New York City as well as in the rest of the state. This is the joint action of the affected community as well as the availability of vaccine. The Department continues to engage communities and provide information and work with advocates and activists and the LGBTQ community. We have longstanding relationships with these, principally through our AIDS Institute, but also through other parts of the Department. Dr. Bassett explained that the Council will hear more from Deputy Commissioner for Health Equity and Human Rights, Joanne Morne. Ms. Morne has already talked with you about the importance of the act that the Council is just taking and designating monkeypox as a sexually transmitted

infection. Just to reiterate, the Department does not want a sexually active minor. Regardless of whether parents want their children to be sexually active or whether any adult wants them to. The Department is aware that children report that by the time they finished high school, half have engaged in sexual activity. If you are a young boy engaging in sex with men or boys, we want you to have the right to protect yourself. You have just enabled that. This is simply about access and the protection of our youth.

Dr. Bassett spoke on the topic of the Prevention Agenda. We are on a five year from 2019 to 2024. A plan of the Prevention Agenda, which calls on cross-sector partnerships to address the facts of everyday life that we refer to as social determinants of health that enhance the burden of disease. There are five priority areas for specific action. Most of this work is overseen by our Office of Public Health. Dr. Bassett described the priority areas. They include the prevention of chronic disease, the promotion of a healthy and safe environment, the promotion of health for women, infants and children, the promotion of well-being and the prevention of mental health and substance use disorders, the prevention of communicable diseases. The Prevention Agenda provides communities with recommended evidence based interventions and information on promising practices and guidance, and that emphasizes interventions that don't place blame on individuals for unhealthy patterns, but addresses the need for healthy environments that promote healthy choices and the need for equity across communities. There are action plans around all of these priority areas that are broken down into focus areas, goals and objectives. We're committed to tracking progress with measures that reflect the implementation and impact of evidence based interventions. These are all tracked in the prevention agendas dashboard, which can show progress or challenges. Dr. Bassett stated that you might imagine, the COVID pandemic posed a substantial challenge to the Prevention Agenda and she is very pleased to be talking with you about it as we readdress these important causes of health.

Dr. Bassett described each category beginning with preventing chronic disease. The Department has seen an improvement in the proportion of adults over 50 who have had a colorectal screen. It went from 66.3% to 71.8% in one year. There has been progress in asthma management with asthma related emergency departments in the pediatric age group, and that's people under 18. Fell from 138 in 2016 to 100 in 2019. Medicaid Managed Care members identified with persistent asthma and given the right medications for their asthma management. It has been rising steadily. It was just at 50% in 2014 and had risen to 60% in 2019. Obviously that's progress, but hardly perfect. The Department would like to see that proportion continue to go up. Obesity is a stunning challenge to the health of our nation and our State. The obesity rate in children which had leveled and begun to drop until 2015 has now started to inch up again. We estimate that 13.9% of children, 2 to 4 years old who are in the WIC program are obese. Obesity begins very early. Also important is smoking cessation. The Department has been helping smokers to quit. With smokers enrolled in Medicaid, the proportion dropping from 24.3% to 19.9% in one year. Additionally, we track blood sugar elevations as a measure of diabetes in the population. The Department is hopeful that we are doing better at managing people with diabetes. Blood sugar elevations have fallen between 2019 and 2020. They fell from 69.2% to 60.4%. That was quite a big drop for just one year.

Dr. Bassett stated the next objective is to promote a healthy and safe environment. We have seen a lot of improvements across all categories. Crash related pedestrian fatalities rose, however. The Commissioner noted that we own up to our challenges. Crash related pedestrian fatalities rose from 1.3 to 1.9 per 100,000. The annual number of days that the air quality was above 100, which is unhealthy. That number of days has increased. It was 12 in 2020. It went up to 20 days in 2021. We had hoped to achieve a level of three days by 2024, but at this time our confidence in achieving that is waning. There has been progress. The percent of people living in a certified climate smart community has doubled from 15.1% to 31.3%. That's between 2019 and 2021. The number of homes inspected for lead and other health hazards, as well as homes tested and mitigated for radon, has significantly improved, and public water systems that were awarded infrastructure improvement assistance has doubled from 28 public water systems to 56.

Dr. Bassett next moved to the third objective, promoting healthy women, infants and children. Most of our focus areas, there have been declines, not improvements. We are all very well aware of the rising tide of opioid use, including fatal overdoses and the number of newborns born with neonatal withdrawal symptoms per 1,000 live births has improved despite that from 9.6 6 to 7.9. That's between 2018 and 2019. Additionally, New York is getting more participation in the early intervention program where the proportion of families who meet the state standard for impact on family scale has improved from 67% to 93.9% in 2020. Newborns with neonatal withdrawal and improvements in delivery of services in the early intervention program. There is less rosy news in the maternal mortality rate. That rate rose from 18.1 in 2016 to 19.3 in 2019. The disparity in black and white maternal death rates also widened. The ratio grew from 4.68 in 2014 to 5.31 in 2019. We also saw a reversal of progress in the proportion of births that are preterm from the lowest level in 2015, which was 8.7%, which was pretty close to the prevention agenda goal of 8.3%. We have instead seen a rise from 8.7% to 9.2% in 2019. The percentage of women who talk with a healthcare provider about ways to prepare for a healthy pregnancy fell from 43% to 35%.

Dr. Bassett stated that suicide on a national level has been rising in youth with deaths rising from 4.6 per 100,000 to 6.2. Mental health and substance use disorders are, and many of the focus areas under this pillar showed improvement, despite the fact that we are all aware that people's mental health has truly been challenged in recent years. These data come from before COVID that the proportion of adolescents with major depressive episodes grew from 10.8% in 2018 to 12.9%. There were these improvements. Binge drinking in young adults improved. People who got at least one buprenorphine prescription for opioid use disorder improved. Emergency department visits for any opioid overdose improved slightly. Indicated reports of child abuse and new maltreatment fell.

Dr. Bassett spoke on the last category, communicable diseases, with a heavy focus on COVID, polio and on monkeypox, but there are other communicable diseases which we concern ourselves with, and in this case, sexually transmitted infections, old infections of gonorrhea. These ones we have known of for many, many years. gonorrhea, chlamydia and syphilis are going up and our immunization rate in children has declined. There has been some progress. For example, the immunization of adolescents for HPV, the principal risk factor for a number of common cancers, including among girls, cervical cancer. That proportion rose from 28 to 30, nearly 40% in 2020. The number of newly diagnosed HIV cases declined between 2010 and

2019. I spend some time on all of these issues just to remind all of us of the scope of work of the Health Department. The Department is very much committed to the whole health of the population, which extends beyond the control of microbes to include the environment, non-communicable and chronic disease. She noted that she is very much looking forward to our continued progress on COVID and again encouraged everyone who is eligible for a booster to get boosted, so that we can turn to these and direct department attention to these long standing challenges to the health of our population.

Dr. Bassett concluded her report. To review the complete report and members questions and comments please see pages 3 through 8 of the transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Health Equity and Human Rights

Mr. Kraut introduced Ms. Morne to give the Report on the Activities of the Office of Health Equity and Human Rights.

Ms. Morne introduced herself as the Deputy Commissioner of the newly created Office of Health Equity and Human Rights within the Department of Health. She stated that she is proud to lead this effort as well as this team. The Department's reorganization has created a step towards the department's goal of increasing diversity, equity and inclusion within our workforce as a part of the overarching mission to build a healthier, more equitable New York State. While critical milestones have been achieved by the Department, we know that we must continue to prioritize our response to the persistent, glaring disparities, so gains are realized equitably by all populations. No matter what progress has been made in the department, we cannot achieve our goals to improve health outcomes if some communities remain left behind. The Office of Health Equity and Human Rights is charged with working across the department to address health disparities, as well as to reduce those disparities across racial, ethnic and socioeconomic groups while leveraging data to inform policy and improve overall health outcomes. In brief, the goal is to improve health equity, reduce health disparities, and better support marginalized and underserved communities. The Office is currently made up of three established offices within the department that includes; the AIDS Institute, the Office of Minority Health and Health Disparities Prevention, as well as the Office of Gun Violence Prevention.

Ms. Morne stated the Department is in the process of building an additional office, the Office of Diversity, Equity and Inclusion. Collectively, these offices have a broad portfolio. The AIDS Institute oversees services related to HIV, AIDS, STI's and Hepatitis C. The AIDS Institute also houses the Office of Drug User Health that works towards the health and wellness of individuals who use drugs, as well as supports the LGBTQ Health and Human Services Network. The Office of Minority Health and Health Disparities Prevention works to ensure that all New Yorkers have access to health care services and other support services with an overarching objective to ensure that marginalized communities are prioritized in the efforts that we make to achieve health for all. The Office of Gun Violence Prevention, newly established about a year and a half ago, was developed to focus on the public health impact of gun violence within a number of vulnerable communities across our state. Community engagement is the

foundation of the work that we do across the department and certainly within this office through close allyship with community partners and stakeholders. It is the Department's intention to build on the historic advancements that have been made as it relates to the work that cuts across equity, health care access, promotion of anti-stigma and certainly anti-racist structure as well as the preservation of human rights.

Ms. Morne explained the Department has set a number of ambitious goals for this office to achieve by the end of the year. She gave a few examples, including the establishment of three working groups that will help to inform DOH planning, multiple state agency planning and community stakeholder priority setting. She also stated that the office will be working to initiate the development of the New York State Department of Health, Health Equity and Human Rights Blueprint in an effort to offer a universal set of goals and objectives. The Department will also be working to develop and facilitate Department of Health staff training related to diversity, equity and inclusion. She noted that many of us are already at the table working to establish a department wide definition of health equity as well as health disparities. The Department will continue to do the work regarding data modernization.

Mr. Morne stated that on behalf of the entire team that already has done tremendous work within this office, we look forward to our continued work ahead. We are absolutely committed to working towards the goal of achieving sustainable change, the process of making sustainable improvements that will last over time.

Ms. Morne concluded her report. To view the complete report and Members comments and questions, please see pages 8 through 10 of the transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Public Health

Mr. Kraut introduced Dr. Bauer to give the Report on the Activities of the Office of Public Health.

Dr. Bauer began her report by giving an update on the Office of Public Health's (OPH) work on multiple public health emergencies to include the on going COVID response and our continuing efforts to slow or even stop the spread of MPV, monkey pox and polio along with all of our usual responses. In addition to our unprecedented emergency responses, the Department is also working hard to rebuild the Department and the Office of Public Health. We need to rebuild from the disruption we experienced during COVID when greater numbers of staff retired or left the department, standard operating procedures sometimes fell by the wayside, and expectations of that 24/7 work cycle exhausted staff and reduced morale. These issues continue to affect the department and the office. The Department also needs to rebuild from a decade of declining resources prior to the COVID-19 pandemic, beginning with that hiring freeze back in 2008 that was lifted in 2021 and regular budget cuts to the Department throughout the twenty teens. These left the Department in a weakened condition even before the pandemic arrived. Dr. Bauer noted that she will focus her report on OPH's rebuilding efforts. It is through progress toward rebuilding that we improve our capacity for our emergency response and regain our ability to wholly focus on our public health priorities. The Department has underwent a modest

restructuring back in August and adopted eight strategic priorities to guide our work over the next three years. These strategic priorities do not replace the current efforts, but rather build on them and provide a frame from which to guide our progress. Aspects of the restructuring that affect OPH our rebuild efforts in addition to the exciting new offices that have been created include the location of the regional offices within the Office of Public Health, the transition of our Office of Emergency Preparedness to the Executive Deputy Commissioner and then as you heard from Deputy Commissioner Morne and the transition of the AIDS Institute and Office of Gun Violence Prevention to the new Office of Health Equity and Human Rights. The strategic priorities of particular relevance to the rebuild effort are making DOH a great place to work, making DOH an impactful, collaborative and efficient organization, preparing for the next emergency and strengthening the relationship between the department and the local health departments.

Dr. Bauer explained OPH's rebuild efforts are focused on hiring staff as a top priority, and we've onboarded hundreds of staff in the past year. The progress is slow, however, because the hiring process is slow and we're not in a great hiring environment and because many new hires come from within the ranks of the Department, which is great because we're promoting people and giving people new opportunities. Of course, the Department is also creating another vacancy that needs to be filled. Even as we do all this hiring, more people retire or leave the department for other opportunities. Regaining our full strength will take years and this work is underway. She noted that she is thrilled to welcome the regional offices to the Office of Public Health. The regional offices are critical to the Department's ability to reach into communities, to support the local health departments, and to restore the trust that was shaken during COVID. The regional offices themselves are somewhat fragile structures, though, with no funding stream of their own and dependent on programs for their staff. Many regional office staff, like many OPH staff are grant funded, so they lack the flexibility to address core or emerging public health needs that fall outside their particular scope.

Dr. Bauer stated the Department needs to develop an operating model for the regional offices that ensures that basic structure to each, a basic complement of staff, and a robust ability to engage in communities and provide strategic resources to the local health departments, this work is underway. The success and impact of our public health work is dependent upon the success and impact of our local health departments, like the Office of Public Health and the department overall, LHD's were hard hit by the COVID pandemic response. Losing staff and having difficulty hiring slowed by cumbersome bureaucratic processes. These have plagued all of us in our public health endeavors. In addition, the COVID response severely stressed the relationship between the Department and the local health departments. The Department is working hard to rebuild and strengthen those relationships and partnered to re-establish biweekly leadership meetings with the steering committee and biweekly meetings with the full membership. The Department has also instituted a quarterly meetings with Dr. Bassett and the local health departments. Dr. Bassett is the first commissioner to hold quarterly meetings with the local health departments. In June, we completed more than twenty focus groups with local health department and DOH leaders to identify best practices from our COVID response that we can institutionalize in our partnership going forward. Dr. Bauer noted that the Department is wrapping up now a set of six workshops to establish group norms and supporting behaviors to help OPH and the local health departments solve problems together.

Dr. Bauer announced the rebuild efforts underway also include improving our critical information technology infrastructure and data systems, finalizing plans for the new Wadsworth Center Public Health Laboratory Building and preparing scores of budget proposals to address our long standing and new needs to restore our strength and develop new capabilities and programs. Much of this rebuild effort will be aided by a new grant from the CDC that we expect to receive notice on this month called the Strengthening Public Health Workforce Foundational Capabilities and Data Systems Grant. The Department has applied for about 135 million over five years, with the bulk of those funds dedicated to workforce and frontloaded in year one of the grant. Funding will address longstanding and new challenges to New York's public health infrastructure. OPH proposes to make strategic investments in all three of those areas focusing on workforce with more than eighty new positions proposed. While the grant addresses overall public health capacity, CDC expects us to focus on communities that have been economically or socially marginalized, are located in rural geographic areas or are composed of people from racial or ethnic minorities, or those disproportionately affected by COVID-19 or other public health priorities. Specifically, the Department will deploy these funds, these grant funds to rebuild our Office of Public Health by creating and filling new positions, by expanding environmental health, emergency preparedness and public health laboratory capacity, and by improving the availability and use of workforce wellness opportunities that was another focus of the funding opportunity. This will strengthen the regional office infrastructure, including new staff positions to expand community engagement activities and re-establish a freestanding regional office to serve the seventeen counties in the Capital District. The Department will strengthen relationships with our local health departments through direct provision of funding to local health departments to hire or retain staff or invest in other public health essentials. Collaborations with local health departments to identify and deploy solutions to public health problems. Ongoing and regular communication with our local health departments to foster that strong partnership. The Department will enhance and expand public health training for local health department and OPH staff through the establishment of partnerships and training units within our office, with a focus on public health essentials, understanding and addressing root causes of health inequities and building community engagement to empower, support and transform communities. The Department will establish a multidisciplinary Health, Wealth and Wellbeing Unit for the purpose of exploring health and non-health data, identifying innovative cross-sector solutions and empowering communities to address foundational causes of health inequities. Dr. Bauer also stated that the Department hopes to have resources to advance and align with the work of our data modernization initiative that's currently underway as part of our epidemiology and laboratory capacity grant. Anticipated outcomes over the five year project period include increased hiring of diverse staff, improved organizational processes and systems and progress toward a more modern and efficient data infrastructure. These will lead in the longer term to a stronger and better equipped public health workforce and expanded and stronger capacity to address longstanding and emerging public health challenges and increased availability and effective use of public health and other data to drive program policy and other decision making. Eventually, if sustained, this program of work will result in improved public health outcomes, including reductions in health disparities and inequities.

Dr. Bauer noted that the grant is well-timed to align with the prevention agenda cycle since the 2022-2024 Community Health Assessment and Community Health Improvement plans are due at the end of the year. Planning for the 2025 to 2030 cycle is due to get underway early next year. Dr. Bauer stated that this will be her first engagement with the prevention agenda planning process since she joined the Department about a year ago. She stated that she optimistic that with the Department's progress on the rebuild efforts and a more manageable emergency response demands, we and our local health department and nonprofit hospital partners will be able to make the next six year cycle particularly effective and impactful for New York's communities.

Dr. Bauer concluded her report. To view the complete report and Members comments and questions, please see pages 11 through 15 of the transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Primary Care and Health Systems Management

Mr. Kraut introduced Dr. Morley to give the Report on the activities of the Office of Primary Care and Health Systems Management.

Dr. Morley began his report by stating that with four acute care hospitals and two long term care nursing homes in Western New York notified the Department that a strike vote had taken place in mid September, raising some significant concerns and a great deal of effort came into the department to work in support as this was developing. The tentative agreement has been signed by the two unions, Communication Workers of America and 1199. The contract needs to be ratified we hope, in mid-October. Survey Activity OPCHSM has conducted thirty-one surveys of hospitals end stage renal disease providers over the month of August. That is the most recent reporting month.

Dr. Morley next gave an electronic survey update. The Department continues its five days a week collection of data from hospitals regarding COVID, its activity and capacity. The Department has seen a growing trend of COVID hospitalizations. We also conducted a one time survey looking at obstetrics services in the state. The Department is reviewing that data right now. The Safe Nurse Staffing Act that was passed a year ago and the Department has been working intensely on the committees that have come out of that statute. Additional information on this statute will be provided towards the end of the meeting.

Dr. Morley announced that on September 20, 2022, the Department's Bureau of Emergency Medical Services and the State Trauma Systems convened families, friends and colleagues to honor members of the EMS community who had passed in the line of duty. Ten heroes names were added to the Tree of Life in Albany. The State Emergency Medical Advisory Council meeting took place and there was extensive discussion about the increasing volume of extended offload delays in hospital ER's around the state. The state EMS Council leadership has raised this issue to the attention of the Department, additional response will be forthcoming. The Bureau of Narcotic Enforcement, the drug takeback program continues to roll out statewide, with collection receptacles now available in over 1,300 pharmacies, so far New Yorkers have returned 19,000 pounds of pharmaceutical waste. Additional pharmacies are offering collection receptacles and mailed back envelopes by the day.

Dr. Morley stated under work of the Center for Health Care Policy. The 2023 legislature elected the New York State budget includes an appropriation for 2.5 million for the Nurses Across New York program that will provide loan repayment for registered nurses and licensed practical nurses who make an obligation to work for three years in an underserved area. The legislation includes a provision that the Department of Health shall appoint a stakeholder work group to develop recommendations and to implement any nanny recommendations by September. The work group is comprised of associations representing nurses, general hospitals, long term care and other health care facilities and includes representatives from twenty organizations. The work group met in July, August and September and developed recommendations. A report has been forwarded to the Governor's office. The definition of underserved areas, award amounts and hardships may need to be considered if a nurse cannot fulfill the three year obligation. The Department is currently drafting a solicitation of interest and hope to have it finalized by the end of November and out for public consumption.

Dr. Morley said in response to concerns that have been raised in the past sessions related to primary care in the pandemic and public health emergencies, and thanked the policy office folks for helping to construct the response to the committee related to primary care and the pandemic. The Article 28 of the Public Health Law gives the Department direct regulatory oversight over hospitals, including general hospitals, residential health care facilities and diagnostic and treatment centers, including many but not all of FQHC's. There is not a similar corresponding article within public health that pertains to private medical practices. As such, the Department are statutorily limited in their response to implement surge and flex operations at settings outside of Article 28 institutions. In addition to the legal limitations, state resources would be necessary to monitor the implementation of surge and flex operations and to assist in operations such as helping to divert patients. Based on the

Department's past experience in employing surge and flex operations, the Department believes in an estate disaster emergency that impacts the health care delivery system. Focusing surge and flex operations in acute care settings most efficiently uses such limited resources. Nevertheless, the amendments to Title 10 of the New York Codes and Rules and Regulations Surge and Flex Care Coordination System are not specific to general hospitals, but do cover regulated, quote, health care facilities, end quote. Accordingly, if resources allow and the public health emergency demands it, the Commissioner would have discretion to implement surge and flex operations in D &TC's, including those of FQHC's that fall under Article 28. Lastly Dr. Morley noted that regulations are identical to the Emergency Surge and Flex regulations were published in the State Register as a proposed regulation. The public comment period closed on Article 28. There were no comments related to Surge and Flex outside of Article 28 facilities in those comments.

Dr. Morley concluded his report. To see the complete report please see pages 15 through 19 of the transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Aging and Long Term Care

Mr. Kraut introduced Mr. Herbst to give the Report on the activities of the Office of Aging and Long Term Care.

Mr. Herbst began his report by providing the Council with some background of the new Office of Aging and Long Term Care. The Department set forth some important priorities and reorganized the way we work to better serve New Yorkers. One of those priorities was the creation of the Office of Aging and Long Term Care (OALTC). OALTC will be focused on optimizing the Department's talent and the integration of new systems and increasing diversity as part of our overall mission to build a healthier, more equitable New York. OALTC will be dedicated to the needs of aging and disabled New Yorkers. Mr. Herbst noted that he hopes this new office will help to ensure aging New Yorkers have greater access not only to essential health services, but to appropriate living settings and programs that reduce isolation. The vision we have for this Office and our mission is to foster policy and programs and services that meet the health and long term care needs of all New Yorkers. This includes support to those who seek to age in place, as well as people who choose long term care in nursing facilities. OALTC has an urgency to our mission. New York is already home to the fourth largest population of residents over the age of 65. Almost 20% of the entire state. In the coming decade, we are facing a tidal wave of aging New Yorkers. By 2030, a quarter of our state's population is projected to be over 60. As many of our aging baby boomers will seek the care and security of nursing homes or adult care facilities. There is also nearly 100,000 New Yorkers residing in nursing home facilities and hundreds of thousands receiving home care. Long term care spending accounts for nearly 35% of the total state's Medicaid spending, and that's the state's largest cost driver. We can see this wave approaching and the necessity of our work.

Mr. Herbst noted that the Department needs to shore up our support for New York's most vulnerable population, as Dr. Bassett referred to it earlier. Establishing this new Office of Aging and long term care is an important first step to align the Department's expertise and resources for greater impact not only for aging and disabled New Yorkers, but also for the families and stakeholders and advocates upon who we all rely on. OALTC will be responsible for data management and licensing and surveillance policy and finance, as well as communication programs to help educate and build consensus. OALTC will also weave in programming to address our mission to improve public health and health equity and address the social determinants of health such as transportation, housing and nutrition. By placing the manifold of issues surrounding long term care under one roof, we're not just elevating the issue, but we're giving the new office the overall resources that we need and the power to build a network with one aim. Again, this is to help serve aging New Yorkers and those who seek long term care facilities.

Mr. Herbst stated that one of our most important priorities is to ensure New Yorkers can age in place for as long as possible with dignity and independence and have access to quality care when they need it. The same holds true for all New Yorkers with disabilities. Both those people who need short term rehabilitation and those who require long term care or need additional supports to live meaningful lives in the community. In addition, the Governor's proposed master plan for aging, which will lay the foundation for us to change the landscape of

aging and long term care in our state. A foundation that is designed to enforce the long term care community for the long haul. The master plan will probably be inclusive, focusing on age friendly health systems and public health initiatives. Again, such as housing and transportation, community engagement, rural challenges and telehealth and digital strategies for social engagement. The Department will measure outcomes, but most importantly, we will rely on equity as a driving factor in the master plan. Aiming to open up alternatives to nursing homes and facility based care and will convene with the efforts of the public and the private sector to convene and create communities that promote healthy living and civic engagement.

Mr. Herbst advised that OALTC also wants to look at other ideas, such as walkable communities that promote exercise and reliance less on vehicles. OALTC will spearhead the implementation and the execution of the master plan which will focus on creating a blueprint together for strategies for government and the private sector and the not for profit sector to support older New Yorkers. Ensuring ensure the state has policy and programs and they're coordinated in aligned line to ensure New Yorkers can age in our state with freedom and dignity and independence for as long as possible. The master plan is a response to the approaching wave. The actions the Department is taking now will help us prepare for the challenges ahead. We cannot do this alone. There's already been so much expertise coalescing around the master plan. We are grateful for the inputs from stakeholders and advocates and organizations and welcome insights to continue from all areas across the long term care ecosystem. The Department will certainly rely on the partnership of you as a partner in addressing the health and long term care needs of aging New Yorkers as well.

Mr. Herbst stated that he looks forward to keeping all channels of communication open with the Council as we build a more sustainable and integrated system of care. This includes the areas of the mission from the role of the Ad Hoc Committee to the State Health Improvement Plan, known as the Prevention Agenda that we have spoken about a handful of times already today to the work done in committees and public health discussions, debate on the Committee of Health Planning and the Committee on Codes and Regulations and Legislation, as well as the activities related to the licensure and construction process completed.

Mr. Herbst gave a quick update on six areas that OALTC has already initiated. First, was the reform of various need methodologies. One of the major areas that OALTC has committed to is changing outdated and restrictive need methodologies, especially in Article 36 and Article 40 hospices. Determining public need is crucial for thoughtful health care planning. However, determining public need should serve to strengthen and not hinder the establishment of new facilities and home care services in areas underserved. This must change, and it will. OALTC is now working on improving and streamlining the need methodologies to reflect our current ecosystem. OALTC looks forward to working with the Council on important issues and welcomes feedback and suggestions as we move forward.

Mr. Herbst noted the second is a lifting of the moratorium. The Department recently released the new licensure application process in mid-August. As a result of this new application release, we anticipate a steady increase in the number of applications that you will be asked to review and approve. Again, OALTC looks forward to working with EPRC and the entire membership as we move forward with increasing access to home and community based services. This must be done responsibly and in a reasonable manner that ensures high quality health care for New Yorkers in need of home health services.

Mr. Herbst stated the third is the critical nursing home quality work. He stated he is fully aware that for many years you have led the public discussion on the important question of what nursing home quality should mean. Nursing home operators should be held responsible and accountable to the residents of New York's nursing homes and the families who entrust their loved one's care to these providers. The Department is committed to this important issue and over the next year we'll work to strengthen quality in nursing homes through the New York State legislative and regulatory processes, the executive budget and also thoughtful policy development. The Department looks forward to the Council's support and input. Again, we look forward to partnering with the Council as we not only look to improve the quality of nursing homes, but to do so in an efficient and timely manner.

Mr. Herbst described the fourth area which relates to workforce. The issues of workforce are a major issue and must be addressed by all health care stakeholders. OALTC has listened to members ask the fundamental question, How should the Department consider the quality of CON applications when it comes to workforce considerations, especially when reviewing patient volume projections? Even if an applicant can meet their expected patient volume projections, how will these applicants find and retain qualified staff? These are important threshold questions. They'll be asked to consider by the Department on all CON applications moving forward. OALTC looks forward to working with you in finding common sense approaches to this crucial and growing problem.

Mr. Herbst noted the fifth area is the reform. Earlier this year, you heard from Mr. Friedman, the former New York state Medicaid Director, as he provided an in-depth presentation on the structural alternatives for the program of all inclusive care for the elderly, also known as PACE. OALTC remains committed to working with OHIP and all our external stakeholders and the Council of reviewing ways to improve the states ability to reform the PACE program to promote expansion of this innovative model. OALTC is in the process now working towards that goal by analyzing ways to implement and improve the PACE program. As mentioned at the presentation, the legislature has passed a bill earlier this year to establish a combined licensure and surveillance process for the PACE program. OALTC looks forward to keeping you informed as discussions progress on this legislation. Mr. Herbst stated that the Council will be actively engaged in any policy discussion and regulations adopted to implement this legislative initiative.

Mr. Herbst explained the sixth area, streamlining the way the Department conducts business. The Department has heard the concern raised by members, and the Department is eagerly looking for new ways to address your concerns. Specifically, the members asked how can the Department streamline processes to ensure that they thoroughly reviewed and consider the most important matters related to CON and establishment and construction applications and remove matters of important but at times ministerial implication from your busy and full agendas. As a follow up to this question. OALTC staff now looking for better ways of reforming our work in the upcoming cycle, and will have more comments on this with different solutions very soon and look forward to further conversation with each of you at the upcoming meetings.

Mr. Herbst advised that OALTC will continue to foster community within this critical industry and the need to keep all channels of communication open as we build a more sustainable, integrated system of care. The work ahead of us is certainly expansive and critical for all aging New Yorkers. Mr. Herbst stated that during the next few weeks, the OALTC team and himself will reach out to each of the members to discuss ways the Department can improve upon our work in these areas and get your feedback and ideas.

Mr. Herbst concluded his report. To see the complete report please see pages 19 through 23 of the transcript.

REGULATION

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

Report of the Committee on Codes, Regulation and Legislation

For Emergency Adoption

- 20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease)
- 20-07 Addition of Section 2.60 to Title 10 NYCRR (Face Coverings for COVID-19 Prevention)
- 22-21 Amendment of Section 23.1 of Title 10 NYCRR (Monkeypox Virus to the List of Sexually Transmitted Diseases (STDs)

Mr. Holt introduced for Emergency Adoption of Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease) and motioned for adoption. Dr. Gutiérrez seconded the motion. The motion carried. Please see pages 23 and 24 of the transcript.

Mr. Holt introduced For Emergency Adoption of Addition of Section 2.60 to Title 10 NYCRR (Face Coverings for COVID-19 Prevention). Mr. Holt motions for approval. Dr. Gutiérrez seconded the motion. The motion carried. Please see page 24 of the transcript.

Mr. Holt introduced For Emergency Adoption and noted for the record that the item is on For Information purposes as well the Amendment of Section 23.1 of Title 10 NYCRR (Monkeypox Virus to the List of Sexually Transmitted Diseases (STDs). Mr. Holt motions for approval. Dr. Gutiérrez seconded the motion. The motion carried. Please see pages 24 and 25 of the transcript.

Mr. Holt concluded his report. Mr. Kraut thanked Mr. Holt for his report

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

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

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

Gary Kalkut, M.D. Vice Chair, Establishment and Project Review Committee

A. <u>APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES</u>

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

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

Acute Care Services - Construction

| <u>Number</u> | Applicant/Facility | Council Action |
|---------------|--|---------------------|
| 221218 C | United Memorial Medical Center (Genesee County) Mr. Thomas – Recusal | Contingent Approval |

Dr. Kalkut called application 221218 and noted for the record the Mr. Thomas has a conflict and has exited the meeting room. Dr. Kalkut motioned for approval and Dr. Gutiérrez seconded the motion. The motion to approve carried with Mr. Thomas' recusal. Mr. Thomas returned to the meeting room. Please see page 25 of the transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- **Second Second 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

NO APPLICATIONS

B. <u>APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF</u> HEALTH CARE FACILITIES

<u>CATEGORY 1</u>: Applications Recommended for Approval – No Issues or Recusals,

Abstentions/Interests

CON Applications

Diagnostic and Treatment Centers – Establish/Construct

| <u>Number</u> | Applicant/Facility | Council Action |
|---------------|-------------------------------------|-----------------------|
| 221199 B | Yaldeinu Health Inc. (Kings County) | Contingent Approval |

221212 E Smile New York Outreach, LLC Contingent Approval (Bronx County)

Certificates

Certificate of Dissolution

Applicant Council Action

J.G.B. Health Facilities Corporation Approval

Ambulatory Surgery Centers – Establish/Construct

| <u>Number</u> | Applicant/Facility | Council Action |
|---------------|---|-----------------------|
| 211143 E | AMSC, LLC d/b/a Downtown Bronx, ASC (Bronx County) | Contingent Approval |
| 221095 B | Empire CSS, LLC d/b/a Empire Center for Special Surgery (Richmond County) | Contingent Approval |
| 221224 E | 21 Reade Place ASC, LLC d/b/a Bridgeview Endoscopy (Dutchess County) | Approval |
| 221267 E | Advanced Endoscopy LLC d/b/a Advanced Endoscopy Center (Bronx County) | Approval |
| 221270 E | Endoscopy Center of Niagara, LLC (Niagara County) | Approval |
| 221271 E | Endoscopy Center of Western New York, LLC (Erie County) | Approval |
| 221272 E | Island Digestive Health Center (Suffolk County) | Approval |

Dr. Kalkut next called applications 221199, 221212, J.G.B. Health Facilities Corporation, 211143, 221095, 221224, 221267, 221270, 221271, and 221272. Dr. Kalkut motioned for approval. Dr. Gutiérrez seconded the motion. The motion to approve carried. Please see pages 25 and 26 of the attached transcript

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

| <u>Number</u> | Applicant/Facility | Council Action |
|---------------|---|-----------------------|
| 221268 E | Carnegie Hill Endoscopy, LLC (New York County) Dr. Lim - Recusal | Approval |
| 221269 E | East Side Endoscopy, LLC d/b/a East Side Endoscopy and Pain Management Center (New York County) Dr. Lim – Recusal | Approval |

Dr. Kalkut called applications 221268 and 221269 and noted for the record that Dr. Lim has declared a conflict of interest and has exited the meeting room. Dr. Kalkut motioned for approval, Dr. Gutiérrez seconded the motion to approve. The motion to approve carried with Dr. Lim's recusal. Dr. Lim returned to the meeting room. Please see pages 26 and 27 of the attached transcript

Certified Home Health Agencies – Establish/Construct

| <u>Number</u> | Applicant/Facility | Council Action |
|---------------|--|-----------------------|
| 221184 E | Emerest Certified Home Health Care of NY LLC d/b/a Royal Care Certified Home Health Care of NY (Bronx County) | Contingent Approval |

Lastly, Dr. Kalkut called application 221184 and noted for the record that Mr. LaRue has declared an interest. Dr. Kalkut motioned for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried. Mr. LaRue clarified for the record that he has declared an interest but has voted for approval. Please see pages 27 and 28 of the transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- **Second Second 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

NO APPLICATIONS

Dr. Kalkut concluded his report.

B. Long Term Care Ombudsman Overview

Claudette Royal, Long Term Care Ombudsman, NYS Office for the Aging

Mr. Kraut introduced Ms. Royal to give an overview of the Long Term Care Ombudsman program. To review the complete presentation please see pages 28 through 32 of the transcript.

CLINICAL STAFFING OVERVIEW

Mr. Kraut next introduced Mr. Hennessy and Ms. Schulman to present an overview of clinical staffing.

Mr. Hennessey and Ms. Shulman presented a power point presentation on the laws pertaining to safe staffing to general hospitals. To read the presentation and the members comments, please see pages 32 through 38 of the transcript.

ADJOURNMENT:

Mr. Kraut thanked Mr. Hennessey and Ms. Shulman for their report. He then announced the upcoming PHHPC meetings and adjourned the public portion of the meeting.

NEW YORK STATE DEPARTMENT OF HEALTH PUBILC HEALTH AND HEALTH PLANNING COUNCIL

FULL COUNCIL MEETING OCTOBER 6, 2022 10:15 AM

TRANSCRIPT

ESP, CONCOURSE LEVEL, MEETING ROOM 6, ALBANY 90 CHURCH STREET, 4TH FLOOR, CONFERENCE ROOMS 4A AND 4B, NYC

nysdoh_20221006_1_2.mp3

Mr. Kraut I'm now going to call to order the Public Health and Health Planning Council of October 6th, 2022. As a reminder, I just want to repeat the requirements that we have for our open meetings. It's a public meeting via the webcast. There's a forum that needs to be filled out, which records your attendance at this meeting required by the Commission on Ethics and Lobbying in accordance with Executive Law 166. The form is also posted on the Department of Health's website under www.NYHealth.Gov under Certificate of Need. We ask you to email the completed forms to Colleen.Leonard@Health.NY.Gov before the meeting. Thank you for your cooperation in us complying with this law. We're subject to the Open Meeting Law. Therefore, we're broadcasting over the internet. Keep yourselves on mute when not speaking. Avoid the rustling of papers and stuff. It will pick up personal conversations and chatter we'd like to keep to a minimum. We're doing synchronize captioning as well, and we need to make sure that no one is speaking over each other. It's really hard to do the captioning of two people speaking at the same time. The first time you speak, we'd ask that you identify yourself as a council member or a member of DOH staff. This will be helpful to us. I want to encourage everybody to sign up on the Department of Health Certificate of Need Listserv. We regularly send out important council information and notices as soon as it's available, such as the agenda, the content for the agenda, the meeting dates and policy matters. All the material presented before the council is available online for those to review prior to the meeting. There are also printed instructions on the reference table outside of the meeting rooms on how to join the listsery or just contact Colleen Leonard at the email I had previously done. Today, we're going to hear from Dr. Bassett about the Department of Health activities, followed by Dr. Bauer about the Office of Public Health, followed by Ms. Morne, who's going to give us some insight into her new appointment as Head of the Office of Health Equity and Human Rights, followed by Dr. Morley with the Office of Primary Care and Health Systems Management. Mr. Herbst will be filing a report on the Office of Aging and Long Term Care.

Mr. Kraut I'll ask Mr. Holt to present the regulations for emergency adoption of the Codes Committee.

Mr. Kraut Wait a minute. I think I screwed that up, right?

Mr. Kraut And then what we're going to do after that is we're going to do... Mr. Holt will do Codes Committee, Mr. Robinson will do Establishment Review. We'll hear from Ms. Royal from the Office of Aging, who will present the long term care abandonment project. Finally, Mr. Hennessey and Ms. Shulman will talk about the clinical staff overview.

Mr. Kraut Just before we get to the Establishment Review Committee report, we've batched the applications, so we would ask everybody to take a look at them, make sure there's no issue you have on how we batched them. If there is, please make us aware of it and we'll remove any batched applications.

Mr. Kraut I'd like this time to congratulate Ms. Soto, who's recently retired from her position at the Albert Einstein College of Medicine. She has been a dedicated employee for the past thirty-two years. You've served as the Assistant Dean to the Office of Diversity Enhancement and Director of the Einstein Enrichment Program. We are very thankful that Ms.. Soto has agreed to continue to serve out her term on the council. We appreciate it. We wish you well on the next leg of your professional journey, but we're really pleased it's including a stop and stay here. Thank you very much, Ms. Soto.

Mr. Kraut I need a motion to adopt the June 2nd, 2022 public health meeting minutes.

Mr. Kraut May I have a motion?

Mr. Kraut Dr. Berliner.

Mr. Kraut A second by Dr. Gutierrez.

Mr. Kraut Any issues with the minutes?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut The motion carries.

Mr. Kraut Now, I needed a motion to adopt the July 28th 2022 meeting minutes.

Mr. Kraut Dr. Berliner.

Mr. Kraut A second by Dr. Gutierrez.

Mr. Kraut Any issues or corrections?

Mr. Kraut Hearing none, I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut The motion carries.

Mr. Kraut I need a motion to adopt the September 15th, 2022 special meeting minutes.

Mr. Kraut I have a motion by Dr. Berliner.

Mr. Kraut A second by Dr. Gutierrez.

Mr. Kraut Any issues with those minutes that were provided to you?

Mr. Kraut Hearing none, I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Motion carries.

Mr. Kraut I'll now turn it over to Albany.

Mr. Kraut Dr. Bassett has joined us.

Mr. Kraut Dr. Bassett, welcome.

Mr. Kraut The microphone is yours.

Dr. Bassett Thank you, Mr. Kraut.

Dr. Bassett Good morning, everyone. It's a real pleasure to be back with you today. I'm going to give some guick updates first about what we have called the big three here at the Health Department; that's COVID, polio and monkeypox and then I'll move on to talk about the prevention agenda, which continues to address the leading causes of death in our state. As we settle into the Fall and we all are enjoying the beautiful weather with the morning chill, we want everyone to remember, as Dr. Bauer has reminded us on previous occasions, that COVID is still very much with us. As of yesterday, we were running close to 21 cases per 100,000, and we had 2,425 patients hospitalized with COVID yesterday. We are still losing people to COVID. We had 19 new deaths reported through our surveillance system yesterday. As you all are aware, we have reduced the restrictions that we had related to public health measures of masking and distancing. We are relying increasingly on the protection that vaccines provide. Vaccination is what has changed the face of COVID and reduced its impact in terms of severity and death. The new Bivalent booster is here. The shots are available. They will greatly improve our ability to protect New Yorkers from the rising rates of transmission that we expect to see in Winter months. We're also expecting to see Pfizer and Moderna approve this new Bivalent vaccine for emergency use in children, children five and older for the Pfizer vaccine, which has been really the mainstay of MRNA vaccines or vaccines in general in our state and for children six and over for Moderna. This is a plea I make every time I have a microphone. I want everyone who is eligible to get their booster to go out and get their booster and remind you also that this is flu season upon us. We would like you to get your flu shot as flu cases are on the rise in the state and at this time, flu transmission in the state is considered widespread. To get this point across, we're going to be launching a flu COVID vaccine campaign. We are going to be promoting the Bivalent vaccine through paid medium. That will include targeted digital advertising, social media and other means. So, that's the news on COVID. We have a booster that addresses for the first time our leading circulating variant. That's the BA45 variant. We want everyone who's eligible. That means if you haven't been vaccinated and haven't had COVID in the last two months, you're eligible for the Bivalent booster if you're over 12.

Dr. Bassett Let me turn now to polio. On July 21st, we announced that a young person was diagnosed with paralytic polio who was resident in Rockland County. The department began looking at wastewater, which is a polite word for sewage, because people polio virus in their guts. We began looking at it in Rockland and other counties to see if we could detect polio virus in wastewater in these communities. We found evidence of polio virus in Orange County, Sullivan County, in New York City and Nassau County. This virus has been sequenced and linked genetically to the person who developed clinical paralytic polio. This is the evidence that we have for the ongoing circulation. We've continued to detect virus in wastewater, and we are working hard to address this. The answer is simple to proclaim, but challenging to execute, and that is vaccination. We're providing operational and outreach and communications support to these counties, working collaboratively with their health departments and with other community partners to share the facts, increase awareness and encourage people to be vaccinated. As you know, the declaration of an emergency enabled us to expand our pool of vaccinators for polio, an important part of our response.

Dr. Bassett Let me move on to monkeypox. This was something that was really just an artifact of medical textbooks. Until mid-May of this year, when we began the current outbreak of monkeypox, which has spread to involve more than 90 countries and has involved, I think, where there may be one state that has not had a case diagnosed, but virtually every state in the United States has diagnosed a person with monkeypox since mid-May. We have at this time 3,889 cases. That's the latest data as of Tuesday this week. Almost all of these cases are in New York City and in the Downstate area, meaning two thirds of the 334 cases diagnosed outside of New York City have been in Long Island and Westchester. On July 28th, I declared monkeypox an imminent threat to public health, and that was followed by the Governor's declaration, and it was subsequently followed by a national act. We have provided clinical guidance for the testing of monkeypox through initially all public health labs, but now increasingly also private labs. I think about a quarter of current testing is done by our Wadsworth Lab and the rest is now done by private labs. And we, of course, are working hard to distribute the vaccine through both federal and local partners, which you've heard a bit about already. We are encouraged that the rate of increase of monkeypox cases has really slowed. It appears that we have, you know, sort of reached a point where certainly the outbreak is no longer growing. This is true in New York City as well as in the rest of the state. This is the joint action of the affected community as well as the availability of vaccine. We are continuing to engage communities and provide information and work with advocates and activists and the LGBTQ community. We have longstanding relationships with these, principally through our AIDS Institute, but also through other parts of the department. You will hear more from our Deputy Commissioner for Health Equity and Human Rights, Joanne Morne, who you may have already known as the Director of the AIDS Institute. She has already talked with you about the importance of the act that the council is just taking and designating monkeypox as a sexually transmitted infection. Just to reiterate, we don't want a sexually active minor. Regardless of whether parents want their children to be sexually active or whether any adult wants them to. We know that children report that by the time they finished high school, half have engaged in sexual activity. If you are a young boy engaging in sex with men or boys, we want you to have the right to protect yourself. You have just enabled that. This is simply about access and the protection of our youth.

Dr. Bassett With those words, I'll go on to say a bit about the Prevention Agenda. We are on a five year, I think it's five years anyway. It's 2019 to 2024. A plan of the Prevention Agenda, which calls on cross-sector partnerships to address the facts of everyday life that we refer to as social determinants of health that enhance the burden of disease. There are

five priority areas for specific action. Most of this work is overseen by our Office of Public Health. I'll ask Dr. Bauer to also join me in answering questions about it, if there are some. Let me just go over for you the priority areas. They include the prevention of chronic disease, the promotion of a healthy and safe environment, the promotion of health for women, infants and children, the promotion of well-being and the prevention of mental health and substance use disorders. And, of course, the prevention of communicable diseases, a task that has occupied most of my tenure. The prevention agenda provides communities with recommended evidence based interventions and information on promising practices and guidance, and that emphasizes interventions that don't place blame on individuals for unhealthy patterns, but addresses the need for healthy environments that promote healthy choices and the need for equity across communities. There are action plans around all of these priority areas that are broken down into focus areas, goals and objectives. We're committed to tracking progress with measures that reflect the implementation and impact of evidence based interventions. These are all tracked in the prevention agendas dashboard, which can show progress or challenges. As you might imagine, the COVID pandemic posed a substantial challenge to the prevention agenda. I'm very pleased to be talking with you about it as we readdress these important causes of health. I'm going to go through each of these categories. The first one, as you'll recall, was preventing chronic disease. We have seen an improvement in the proportion of adults over 50 who've had a colorectal screen. It went from 66.3% to 91. Sorry, I misspoke. I wish it were 91, but it went from 66.3% to 71.8% in one year. There has been progress in asthma management with asthma related emergency departments in the pediatric age group, and that's people under 18. Fell from 138 in 2016 to 100 in 2019. Medicaid managed care members identified with persistent asthma and given the right medications for their asthma management. It has been rising steadily. It was just at 50% in 2014 and had risen to 60% in 2019. Obviously that's progress, but hardly perfect. We want to see that proportion continue to go up. Obesity is a stunning challenge to the health of our nation and our state. The obesity rate in children which had leveled and begun to drop until 2015 has now started to inch up again. We estimate that 13.9% of children, 2 to 4 years old who are in the WIC program are obese. Obesity begins very early. Also important is smoking cessation. We have been helping smokers to guit. With smokers enrolled in Medicaid, the proportion dropping from 24.3% to 19.9% in one year. Additionally, we track blood pressure. I mean, sorry. Blood sugar elevations as a measure of diabetes in the population. We're hopeful that we're doing better at managing people with diabetes. Blood sugar elevations have fallen between 2019 and 2020. They fell from 69.2% to 60.4%. That was guite a big drop for just one year. The next objective is to promote a healthy and safe environment. That's seen a lot of improvements across all categories. Crash related pedestrian fatalities rose however. I'm going to tell you the bad news. That's how we work in public health. We own up to our challenges. Crash related pedestrian fatalities rose from 1.3 to 1.9 per 100,000. The annual number of days that the air quality was above 100, which is unhealthy. That number of days has increased. It was 12 in 2020. It went up to 20 days in 2021. We had hoped to achieve a level of three days by 2024, but at this time our confidence in achieving that is waning. There has, as I've said, been progress. The percent of people living in a certified climate smart community has doubled from 15.1% to 31.3%. That's between 2019 and 2021. The number of homes inspected for lead and other health hazards, as well as homes tested and mitigated for radon, has significantly improved, and public water systems that were awarded infrastructure improvement assistance has doubled from 28 public water systems to 56. The third objective, promoting healthy women, infants and children. Most of our focus areas, there have been declines, not improvements. We're all very well aware of the rising tide of opioid use, including fatal overdoses and the number of newborns born with neonatal withdrawal symptoms per 1,000 live births has improved in spite of that from 9.6

to 7.9. That's between 2018 and 2019. I hope our more recent data will confirm that. Additionally, we're getting more participation in the early intervention program where we, the proportion of families who meet the state standard for impact on family scale has improved from 67% to 93.9% in 2020. That was the good news. Newborns with neonatal withdrawal and improvements in delivery of services in the early intervention program. There is less rosy news in the maternal mortality rate. That rate rose from 18.1 in 2016 to 19.3 in 2019. The disparity in Black and white maternal death rates also widened. The ratio grew from 4.68 in 2014 to 5.31 in 2019. We also saw a reversal of progress in the proportion of births that are preterm from the lowest level in 2015, which was 8.7%, which was pretty close to the prevention agenda goal of 8.3%. We have instead seen a rise from 8.7% to 9.2% in 2019. The percentage of women who talk with a healthcare provider about ways to prepare for a healthy pregnancy fell from 43% to 35%. Suicide, and this is a national observation, has been rising in youth with deaths rising from 4.6 per 100,000 to 6.2. Mental health and substance use disorders are, and many of the focus areas under this pillar showed improvement, despite the fact that we are all aware that people's mental health has truly been challenged in recent years. These data come from before COVID that the proportion of adolescents with major depressive episodes grew from 10.8% in 2018 to 12.9%. There were these improvements. Binge drinking in young adults improved. People who got at least one buprenorphine prescription for opioid use disorder improved. Emergency department visits for any opioid overdose improved slightly. Indicated reports of child abuse and new maltreatment fell. The last category is about communicable diseases, and you all know that we have been heavily focused on COVID, on polio and on monkeypox, but there are other communicable diseases which we concern ourselves with, and in this case, sexually transmitted infections, old infections of gonorrhea. I mean, these ones we've known of for many, many years. Gonorrhea, chlamydia and syphilis are going up and our immunization rate in children has declined. There has been some progress. For example, the immunization of adolescents for HPV, the principal risk factor for a number of common cancers, including among girls, cervical cancer. That proportion rose from 28 to 30, nearly 40% in 2020. The number of newly diagnosed HIV cases declined between 2010 and 2019. I spend some time on all of these issues just to remind all of us of the scope of work of the health department. We are very much committed to the whole health of the population, which extends beyond the control of microbes to include the environment, non-communicable and chronic disease. I very much look forward to our continued progress on COVID. That's why I want everyone who is eligible for a booster to get boosted, so that we can turn to these and direct department attention to these long standing challenges to the health of our population.

Dr. Bassett With that, I'd be happy to answer any questions and I'll conclude my remarks.

Mr. Kraut Thank you. Thank you very much, Commissioner, for that extensive report.

Mr. Kraut This is the Ask Commissioner part of the council meeting.

Mr. Kraut Any council members here or in Albany have any questions?

Mr. Kraut I'll turn it over to Dr. Boufford first.

Dr. Boufford Thank you very much. I want to thank you for bringing up and reminding us about the prevention agenda. I really very much value the ongoing work of the department in the face of the acute challenges that you've had. I know this council and the Public Health Committee of the Council have been quite eager to restart, if you will, our sort of ongoing conversations on the prevention agenda, as well as the issue of maternal

mortality, which had been an early concern of the council. In fact, I think as long as 4 to 5 years ago had sort of generated paper that has led to the Governor's commission and much of the other activity that's going on. I just want to thank you for raising that again. We look forward to working with you to put these other elements back on the public health agenda.

Mr. Kraut Thank you.

Mr. Kraut Any other questions?

Mr. Kraut Dr. Kalkut.

Dr. Kalkut Thanks again for the report, covering a whole spectrum of problems that we face. I had a question about COVID and the CDC mask suggestions or recommendations that were from a couple of weeks ago, which allowed facilities to in non-high transmission areas to change masking requirements right now. Dp you anticipate the state weighing in on that or commenting on that announcement from the CDC?

Dr. Bassett Yes.

Dr. Bassett Thanks.

Dr. Kalkut Is that a problem?

Dr. Bassett I think of the principal location where we have continued to require masking: our health care facilities, which include nursing homes. We have continued that as a universal requirement, not only in patient facing areas, but throughout the facility. I don't know if you've had a chance to look recently at the map on transmission. You have to look for it because if you Google, you know, COVID levels, you'll end up with a different map, which shows what the CDC now calls community levels, which measures basically hospitalizations and hospital capacity as the principal sort of determinants of what the level will be after cases past a certain point. If you look at the transmission map, the last time I looked at that, which was a couple of days ago there updated actually today. We can all look at it today. The map on transmission was still all red, meaning that we as a state continue to be in the highest level of transmission. We're going to hold on to masking in settings which has elderly people who are, of course, our most vulnerable, the people who are getting infected, getting hospitalized and dying are principally people over the age of 65 during our current period. We really want to be very careful. I hope that that answers your question. We continue to meet the CDC guidance. I don't expect that that will change or that we will drop masks in health care settings. We no longer have masks required in schools, public indoor places, transport, except for the individuals who choose to wear them. I hope that we'll all work to try and reduce the amount of stigma that is attached to mask wearing. I have had the experience personally on numbers of occasion of entering the hall where I'm the only person present who is wearing a mask. I hope that we can get to the point where, you know, where that person and in this case, that person was me, doesn't feel like we've possibly done something wrong. Everybody should take the action that they need to protect themselves. In hospital settings, we are going to continue. People don't choose to end up in the hospital. We're going to continue to maintain the protection of masks. In this case, we are fully consistent with CDC guidance.

Dr. Kalkut The map is as red as it was a few days ago for New York State. The CDC comments that three quarters of the counties in the United States are still considered high

transmission rates. It's a small part that would even consider these regs following it directly.

Dr. Kalkut Thank you.

Mr. Kraut Any other members of the council?

Mr. Kraut Anybody in Albany?

Mr. Kraut Commissioner, thank you so much for the report. We look forward to our next visit.

Mr. Kraut I want to introduce Ms. Morne, who's going to give a report on the activities of the Office of Health Equity and Human Rights.

Ms. Morne Good morning. Thank you again. As said, my name is Johanne Morne. I am the Deputy Commissioner of the newly created Office of Health Equity and Human Rights within the Department of Health. I'm proud to lead this effort as well as this team. The department's reorganization has created a step towards the department's goal of increasing diversity, equity and inclusion within our workforce as a part of the overarching mission to build a healthier, more equitable New York State. While critical milestones have been achieved by the department, we know that we must continue to prioritize our response to the persistent, glaring disparities, so gains are realized equitably by all populations. No matter what progress has been made in the department, we cannot achieve our goals to improve health outcomes if some communities remain left behind. The Office of Health Equity and Human Rights is charged with working across the department to address health disparities, as well as to reduce those disparities across racial, ethnic and socioeconomic groups while leveraging data to inform policy and improve overall health outcomes. In brief, the goal is to improve health equity, reduce health disparities, and better support marginalized and underserved communities. The office is currently made up of three established offices within the department that includes; the AIDS Institute, the Office of Minority Health and Health Disparities Prevention, as well as the Office of Gun Violence Prevention. Additionally, we are in the process of building an additional office, the Office of Diversity, Equity and Inclusion. Collectively, these offices have a broad portfolio. The AIDS Institute oversees services related to HIV, AIDS, STI's and Hepatitis C. The AIDS Institute also houses the Office of Drug User Health that works towards the health and wellness of individuals who use drugs, as well as supports the LGBTQ Health and Human Services Network. The Office of Minority Health and Health Disparities Prevention works to ensure that all New Yorkers have access to health care services and other support services with an overarching objective to ensure that marginalized communities are prioritized in the efforts that we make to achieve health for all. The Office of Gun Violence Prevention, newly established about a year and a half ago. was developed to focus on the public health impact of gun violence within a number of vulnerable communities across our state. Community engagement is the foundation of the work that we do across the department and certainly within this office through close allyship with community partners and stakeholders. It is our intention to build on the historic advancements that have been made as it relates to the work that cuts across equity, health care access, promotion of anti-stigma and certainly anti-racist structure as well as the preservation of human rights. We've set a number of ambitious goals for this office to achieve by the end of the year. I'll offer just a few examples, including the establishment of three working groups that will help to inform DOH planning, multiple state agency planning and community stakeholder priority setting. We'll be working to initiate the development of the New York State Department of Health, Health Equity and Human Rights Blueprint in an effort to offer a universal set of goals and objectives. We will also be working to develop and facilitate Department of Health staff training related to diversity, equity and inclusion. Many of us are already at the table working to establish a department wide definition of health equity as well as health disparities. We will continue to do the work regarding data modernization. On behalf of the entire team that already has done tremendous work within this office, we look forward to our continued work ahead. We are absolutely committed to working towards the goal of achieving sustainable change, the process of making sustainable improvements that will last over time.

Ms. Morne Thank you.

Mr. Kraut Thank you very much.

Mr. Kraut Is there any comments or questions?

Mr. Kraut Dr. Boufford.

Dr. Boufford Again, just to welcome you, Commissioner Morne.

Dr. Boufford Excuse me.

Dr. Boufford To say how important it is for your arrival and consolidating the number of the areas that have been looking at the issue of vulnerable populations and diversity, equity and inclusion. This has been a a gap in the work on the prevention agenda that many of the local communities who are charged to identify two of the five goals in their action planning going forward, in addition to one area of health disparity to work on in their communities. Many of them have requested technical assistance support and other help in this area. I'll be coming to you to talk to you about that very quickly. I think it's very encouraging. We look forward to working with you on the further development of this area of the prevention agenda.

Ms. Morne Thank you very much.

Mr. Kraut I'll just put in my \$0.02 since you kind of went through it. It's a passion of mine. You talked about the importance of getting data and using that data. In probably no other policy agenda will good data drive good policy. I implore you to work with your colleagues to get the most important database that we have that has not been available to providers and researchers and people that are interested in this is the all claims database. The only database the state has that we can actually visualize a journey and where people seek care and where they have problems accessing care. I would hope that your group would have some influence on getting that data into the public domain, so we could start using it for the types of objectives that you raised. I'm not asking you to respond. I'm just making another plea to another person maybe that might be able to do something about it.

Mr. Kraut Mr. Lawrence.

Mr. Lawrence Harvey Lawrence, a member of the council. Commissioner Morne, I'd like to commend you because this is a pretty ambitious agenda that you've established. Working at a community health center, we see disparities, especially related to chronic disease, many of which have existed in our neighborhoods for decades. We've had all types of approaches to address them, but none seem to really be able to get out in front

and make meaningful changes in the lives of the people that we serve. Beyond the broad policy goals and objectives, I think the real measure of success is whether we reduce obesity, we reduce hypertension, whether we reduce diabetes, rates of cancer. In Brooklyn, we have probably the highest rate of prostate cancer. That has persisted for a while. I welcome this opportunity, but I also know that at some level you got to cut through some of the policy and really look to how do you make meaningful change in the system that results in meaningful improvements in the lives of people in many of the neighborhoods that are served by community health centers around the state. I just needed to welcome you, because this is something that at the State Association of Community Health Centers we've been looking at and working about, talking about and strategizing around how do we, in fact, move the needle in a pretty dramatic way to improving outcomes?

Mr. Kraut Thank you.

Mr. Kraut I'm just going to ask if we could wait a moment. We have a technical problem which we need to resolve. I'll come back to Ms. Soto next for a question. We have a problem where we're not being visible on Zoom. The folks in this room. Is that correct?

Mr. Kraut In Albany.

Mr. Kraut They can't see us. They blacked out over here. We're permanently black. They need to reset the system. They just asked us to pause for a minute until we can do so.

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Ms. Soto I'm the past Chair for the New York State Minority Health Council. One of the things that I was listening and I honed in on that we are looking at not only diversity and inclusion, but that key equity piece, because we have, over the years New York State has worked at identifying and increasing. As you pointed out, and we continue to have marginalized communities, individuals in terms of access. I was pleased to hear that it's not only going to be diversity inclusion, but the issue of equity.

Ms. Morne Thank you.

Mr. Kraut Any other questions?

Mr. Kraut Well, we're obviously, you know, as part of the prevention agenda, as Dr. Boufford said, and the issues Ms. Soto just brought up. We're looking forward to working with you and for other times to come here and work with our committees and to advance your agenda, which is 100% aligned with what we want to do. We want to spend more time on things that have higher value for the state with respect to public health and health equity. I think you'll have a great partner in this council. We wish you well.

Ms. Morne Thank you very much.

Mr. Kraut Thank you.

Ms. Morne I look forward to our work together.

Mr. Kraut Thank you.

Mr. Kraut I'll now turn to Dr. Bauer to give her report on the activities of public health. Again, I apologize for skipping over you.

Dr. Bauer Thanks so much.

Dr. Bauer Good afternoon. Ursula Bauer, Deputy Commissioner for Public Health. Thank you for this opportunity. As Dr. Bassett noted, we've been working hard to address our multiple public health emergencies to include the on going COVID response and our continuing efforts to slow or even stop the spread of MPV, monkey pox and polio along with all of our usual responses. In addition to our unprecedented emergency responses. we're also working hard to rebuild the Department and the Office of Public Health. We need to rebuild from the disruption we experienced during COVID when greater numbers of staff retired or left the department, standard operating procedures sometimes fell by the wayside, and expectations of that 24/7 work cycle exhausted staff and reduced morale. These issues continue to affect the department and the office. We also need to rebuild from a decade of declining resources prior to the COVID-19 pandemic, beginning with that hiring freeze back in 2008 that was lifted in 2021 and regular budget cuts to the department throughout the twenty teens. These left the department in a weakened condition even before the pandemic arrived. Today, I'll focus my report on OPH's rebuilding efforts. It's through progress toward rebuilding that we improve our capacity for our emergency response and regain our ability to wholly focus on our public health priorities. As you've heard previously, the department underwent a modest restructuring back in August and adopted eight strategic priorities to guide our work over the next three years. These strategic priorities don't replace our current efforts, but rather build on them and provide a frame from which to guide our progress. Aspects of the restructuring that affect OPH our rebuild efforts in addition to the exciting new offices that have been created include the location of the regional offices within the Office of Public Health, the transition of our Office of Emergency Preparedness to the Executive Deputy Commissioner. And then, as you heard from Deputy Commissioner Morne and the transition of the AIDS Institute and Office of Gun Violence Prevention to the new Office of Health Equity and Human Rights. The strategic priorities of particular relevance to the rebuild effort are making DOH a great place to work, making DOH an impactful, collaborative and efficient organization, preparing for the next emergency and strengthening the relationship between the department and the local health departments. OPH's rebuild efforts are focused on hiring staff as a top priority, and we've onboarded hundreds of staff in the past year. The progress is slow, however, because the hiring process is slow and we're not in a great hiring environment and because many new hires come from within the ranks of the department, which is great because we're promoting people and giving people new opportunities. Of course, we're also creating another vacancy that needs to be filled. Even as we do all this hiring, more people retire or leave the department for other opportunities. Regaining our full strength will take years and this work is underway. I'm thrilled to welcome the regional offices to the Office of Public Health. The regional offices are critical to the department's ability to reach into communities, to support the local health departments, and to restore the trust that was shaken during COVID. The regional offices themselves are somewhat fragile structures, though, with no funding stream of their own and dependent on programs for their staff. Many regional office staff, like many OPH staff are grant funded, so they lack the flexibility to address core or emerging public health needs that fall outside their particular scope. We need to develop an operating model for the regional offices that ensures that basic structure to each, a basic complement of staff, and a robust ability to engage in communities and provide strategic resources to the local health departments. This work is underway. The success and impact of our public health work is dependent upon the success and impact of our local health departments, like the

Office of Public Health and the department overall, LHD's were hard hit by the COVID pandemic response. Losing staff and having difficulty hiring slowed by cumbersome bureaucratic processes. These have plagued all of us in our public health endeavors. In addition, the COVID response severely stressed the relationship between the department and the local health departments. We're working hard to rebuild and strengthen those relationships. We've partnered to re-establish biweekly leadership meetings with the steering committee and biweekly meetings with the full membership. We've also instituted a quarterly meetings with Dr. Bassett and the local health departments. I understand she's the first commissioner to hold quarterly meetings with the local health departments. In June, we completed more than twenty focus groups with local health department and DOH leaders to identify best practices from our COVID response that we can institutionalize in our partnership going forward. We're wrapping up now a set of six workshops to establish group norms and supporting behaviors to help OPH and the local health departments solve problems together. Our rebuild efforts underway also include improving our critical information technology infrastructure and data systems, finalizing plans for the new Wadsworth Center Public Health Laboratory Building and preparing scores of budget proposals to address our long standing and new needs to restore our strength and develop new capabilities and programs. Much of this rebuild effort will be aided by a new grant from the CDC that we expect to receive notice on this month called the Strengthening Public Health Workforce Foundational Capabilities and Data Systems Grant. We applied for about 135 Million over five years, with the bulk of those funds dedicated to workforce and frontloaded in year one of the grant. Funding will address longstanding and new challenges to New York's public health infrastructure. OPH proposes to make strategic investments in all three of those areas focusing on workforce with more than eighty new positions proposed. While the grant addresses overall public health capacity, CDC expects us to focus on communities that have been economically or socially marginalized, are located in rural geographic areas or are composed of people from racial or ethnic minorities, or those disproportionately affected by by COVID-19 or other public health priorities. Specifically, we will deploy these funds, these grant funds to rebuild our Office of Public Health by creating and filling new positions, by expanding environmental health, emergency preparedness and public health laboratory capacity, and by improving the availability and use of workforce wellness opportunities that was another focus of the funding opportunity. We'll strengthen the regional office infrastructure, including new staff positions to expand community engagement activities and re-establish a freestanding regional office to serve the seventeen counties in the Capital District. We'll strengthen relationships with our local health departments through direct provision of funding to local health departments to hire or retain staff or invest in other public health essentials. Collaborations with local health departments to identify and deploy solutions to public health problems. Ongoing and regular communication with our local health departments to foster that strong partnership. We'll enhance and expand public health training for local health department and OPH staff through the establishment of partnerships and training units within our office, with a focus on public health essentials, understanding and addressing root causes of health inequities and building community engagement to empower, support and transform communities. We'll establish a multidisciplinary Health, Wealth and Wellbeing Unit for the purpose of exploring health and non-health data, identifying innovative cross-sector solutions and empowering communities to address foundational causes of health inequities. Finally, we hope to have resources to advance and align with the work of our data modernization initiative that's currently underway as part of our epidemiology and laboratory capacity grant. Anticipated outcomes over the five year project period include increased hiring of diverse staff, improved organizational processes and systems and progress toward a more modern and efficient data infrastructure. These will lead in the longer term to a stronger and better equipped public

health workforce and expanded and stronger capacity to address longstanding and emerging public health challenges and increased availability and effective use of public health and other data to drive program policy and other decision making. Eventually, if sustained, this program of work will result in improved public health outcomes, including reductions in health disparities and inequities. The grant is well-timed to align with the prevention agenda cycle. As you know, the 2022-2024 Community Health Assessment and Community Health Improvement plans are due at the end of the year. Planning for the 2025 to 2030 cycle is due to get underway early next year. This will be my first engagement with the prevention agenda planning process since I joined the department about a year ago. I'm optimistic that with our progress on the rebuild efforts and a more manageable emergency response demands, we and our local health department and nonprofit hospital partners will be able to make the next six year cycle particularly effective and impactful for New York's communities.

Dr. Bauer Thank you.

Mr. Kraut What an agenda you've just laid out. We wish you well. We're here as a dependable partner. One of the things, obviously, we've all had to focus on the urgent, sometimes displacing the important and the work that we'd like to return to that's aligned and frankly, integral to some of the objectives you spoke about is the work of our public health committee and focusing on the prevention agenda along with our planning committee. What's the most critical need that we have now is to restart and align our committees agenda with that of the department and to ensure that the department provides the resources to that committee to begin its work. We're going to look forward to that. I know Dr. Boufford has plans to schedule some of those meetings, and we expect to resume the work in earnest in the weeks and months ahead. I really do thank you. I think we're just, I think, delighted with the ideas and objectives that you've laid out.

Mr. Kraut Is there any other questions?

Mr. Kraut I'll got Dr. Boufford and then Dr. Gutierrez.

Dr. Boufford Thanks, Dr. Bauer.

Dr. Boufford Obviously, you know that how encouraging it is to hear what you're saying. As Jeff said, I just to reinforce what he said. I think the other piece that's really important in the discussion you have opened is the potential links for public health prevention agenda related social determinants of health activity in relation to the new waiver. That's I guess the latest version has gone in. It is pending at this point. I think discussions, you know, with the Office of Planning, with the Medicaid office and others relative to the important potential for improving conditions in communities along with the health care agenda in the waiver is something that I hope we can also take up.

Dr. Boufford Thank you for that.

Dr. Bauer Thanks very much, Dr. Boufford.

Dr. Bauer I'll just say it's a real priority of Dr. Bassett to leverage the health care side and the public health side of the department and ensure that we're working together. We've had those discussions in her Cabinet meetings and really look forward to leveraging the resources and talent on the council to make that happen.

Dr. Bauer Thank you.

Dr. Gutierrez Thank you, Dr. Bauer.

Dr. Gutierrez I have over five decades of involvement with medicine, and I want to make a remark that Dr. Boufford has heard me made before. I find that as a community have very short memories. We don't remember. We don't realize that many of us are here today because of public health. Forgotten the advancements in longevity brought by public health. We find ourselves defending what we do when in fact, I feel that we ought to be celebrating what we have achieved at the same time that we tell people that in order to defeat a disease, we need to do certain things that cannot be avoided. As a medical student, I saw polio aplenty. I saw smallpox. I saw listeria. I saw typhoid fever. Those things were keeping infectious disease hospitals full all the time. We don't see that anymore. My children know about it because I talk to them about it. My granddaughters know nothing about this. They wonder why we have to worry about polio. They wonder why we have to worry about measles. Educating the public, I believe, ought to be a duty of the health department. I'm making this remark once again, because I would like to see some part of the health forum dedicated to education beginning at the school level.

Dr. Gutierrez Thank you.

Mr. Kraut Thank you so much.

Mr. Kraut Ms. Monroe.

Ms. Monroe Thank you, Dr. Bauer.

Ms. Monroe This was very exciting. You said you asked for 135 Million from the federal government. Did you get it all?

Mr. Kraut I think you applied.

Dr. Bauer That's what we applied for. It's over five years. We will hear this month what our funding amount is.

Ms. Monroe You don't know yet if you're getting any of it or are you...I'm just wondering where you are in the process of the things you talked about.

Dr. Bauer We submitted our application on August 15th. We are quite confident that we will receive an award. I anticipate every health department will receive an award. The question will be what the amount of that award is. CDC had a very complicated three page funding calculation. They put us through a lot of work to come up with the amount that we could apply for. I anticipate they will fund us fairly close to that amount.

Ms. Monroe I just want to be sure that some of the agenda that you laid out is achievable, even if we don't get the full amount. We'll be looking forward to hearing that from you.

Mr. Kraut We'll see where we're permitted to help. Just echoing, you know, what you're basically saying, what Dr. Bauer said, and particularly the cogent comments of Dr. Gutierrez. Next year is the 110th year of the Public Health Council in New York State. We're the steward of a mission that has gone unbroken and met tremendous challenges over the past hundred and ten years. I think it's exciting of some of the direction that Dr.

Bassett, Dr. Bauer, Ms. Morne has laid out. That's not to negate Dr. Morley and Mr. Herbst who's following them. I just thought I'd take this opportunity to say this is a good time to reset the priorities of the council and focus on what can make the maximum impact on the health of all New Yorkers.

Mr. Kraut Dr. Bauer, I thank you so much. I appreciate you. Obviously stimulated a lot of conversation.

Mr. Kraut Dr. Morley, we'd love to hear from you on the Office of Primary Care and Health Systems Management.

Dr. Morley Thank you very much, Mr. Chairman.

Dr. Morley My report will be a little briefer than in the past. I'll start out with four acute care hospitals and two long term care nursing homes in Western New York notified us, the department, that a strike vote had taken place in mid September, raising some significant concerns and a great deal of effort came into the department to work in support as this was developing. We're happy to report that a tentative agreement has been signed by the two unions. Communication Workers of America and 1199. That needs to be ratified and will be ratified, we hope, in mid-October. Survey Activity OPCHSM has conducted thirtyone surveys of hospitals end stage renal disease providers over the month of August. That's the most recent reporting month. Electronic survey update. The department continues its five days a week collection of data from hospitals regarding COVID, its activity and capacity. We've seen a growing trend of COVID hospitalizations, unfortunately, and you've heard that. We also conducted a one time survey looking at obstetrics services in the state. We're reviewing that data right now. The Safe Nurse Staffing Act that was passed a year ago. We've been working intensely on the committees that have come out of that statute. Additional information on this statute will be provided towards the end of the meeting. The Bureau of Emergency Medical Services. On September the 20th, the department's Bureau of EMS and State Trauma Systems convened families, friends and colleagues to honor members of the EMS community who had passed in the line of duty. Ten heroes names were added to the Tree of Life in Albany. The State Emergency Medical Advisory Council meeting took place. There was extensive discussion about the increasing volume of extended offload delays in hospital ER's around the state. The state EMS Council leadership has raised this issue to the attention of the department, and additional response will be forthcoming. The Bureau of Narcotic Enforcement. The drug takeback program continues to roll out statewide, with collection receptacles now available in over 1,300 pharmacies so far to which New Yorkers have returned 19,000 pounds of pharmaceutical waste. Additional pharmacies are offering collection receptacles and mailed back envelopes by the day. The Center for Health Care Policy. The 2023 legislature elected the New York State budget includes an appropriation for 2.5 Million for the Nurses Across New York program that will provide loan repayment for registered nurses and licensed practical nurses who make an obligation to work for three years in an underserved area. The legislation includes a provision that the Department of Health shall appoint a stakeholder work group to develop recommendations and to implement any nanny recommendations by September. The work group is comprised of associations representing nurses, general hospitals, long term care and other health care facilities and includes representatives from twenty organizations. The work group met in July, August and September and developed recommendations. A report has been forwarded to the Governor's office. The definition of underserved areas, award amounts and hardships may need to be considered if a nurse cannot fulfill the three year obligation. We're currently drafting a solicitation of interest and hope to have it finalized by the end of November and

out for public consumption. In response to concerns that have been raised in the past sessions related to primary care in the pandemic and public health emergencies, I'd like to thank our policy office folks for helping to construct the response to the committee related to primary care and the pandemic. The Article 28 of the Public Health Law gives the Department direct regulatory oversight over hospitals, including general hospitals, residential health care facilities and diagnostic and treatment centers, including many but not all of FQHC's. There is not a similar corresponding article within public health that pertains to private medical practices. As such, the department are statutorily limited in their response to implement surge and flex operations at settings outside of Article 28 institutions. In addition to the legal limitations, state resources would be necessary to monitor the implementation of surge and flex operations and to assist in operations such as helping to divert patients. Based on the department's past experience in employing surge and flex operations, the department believes in an estate disaster emergency that impacts the health care delivery system. Focusing surgeon flex operations in acute care settings most efficiently uses such limited resources. Nevertheless, the amendments to Title 10 of the New York Codes and Rules and Regulations Surge and Flex Care Coordination System are not specific to general hospitals, but do cover regulated, quote, health care facilities, end quote. Accordingly, if resources allow and the public health emergency demands it, the Commissioner would have discretion to implement surge and flex operations in DNTC's, including those of FQHC's that fall under Article 28. Finally, I should note that regulations are identical to the Emergency Surge and Flex regulations were published in the State Register as a proposed regulation. The public comment period closed on Article 28. There weren't any comments related to Surge and Flex outside of Article 28 facilities in those comments.

Dr. Morley That's my report, Mr. Chairman.

Dr. Morley If you've got any questions, I'd be happy to take them.

Dr. Morley Thank you.

Mr. Kraut Thanks so much, Dr. Morley.

Mr. Kraut I'll open up the questions.

Mr. Kraut Dr. Berliner first, then Dr. Boufford.

Dr. Berliner Thank you, Dr. Morley.

Dr. Morley I'm struggling to hear you.

Dr. Berliner Can we get a report on the status of freestanding emergency rooms around the state?

Dr. Morley We can and we would be willing to talk to you offline just to collect more idea of what it is you're looking for. Is it just a number or more than that?

Mr. Kraut When we approved the development of freestanding emergency departments through CON, when they had a requirement to file an annual report and we laid out the data that they were required to report back to us. Our understanding is everybody has filed those reports and they just need to be kind of coalesced into this is our impression of what has happened and what the benefits and what are the challenges. I think we'll take it

offline, but a lot of the work has supposedly been done already by applicants, but not necessarily has it been reported back to us. We'll follow that up with you.

Mr. Kraut Now, we'll turn it to Dr. Boufford.

Dr. Boufford Thanks. Dr. Morley.

Dr. Boufford I appreciate your responding to our expressed concern several times about the failure to include broader primary care providers and local health departments in this sort of response, initial response to COVID and in surge and flex regulations that were promulgated which largely really focused on acute care hospitals. I appreciate the legal constraints that you lay out, and that's very helpful to know. It's very important to know. I think the primary concern, which I still have, is that the primary care providers that you legally, let's say that way, legally have authority over as well as local health departments. Really, there has been no vehicle for engaging them in conversation around the preparation for a regular vehicle. Let's talk about the rebuild. The revision of the COVID response. That remains the problem from what we know from what we've been told. I would say that you've certainly helped explain the limitations in the surge and flex regulations up to now. Now, with that understood, I think it would be really important to think about how there might be a convening to begin to look at the implications of the current surge and flex for community health centres and local health departments that do come under the auspices because the issue was people feeling they could have done more. This council put together a paper about two years ago with a number of sessions sort of laying out the thinking about that. Very much wish to be more helpful and more directly involved in future response to future pandemics. I think that's pretty hard to do unless you're prepared for that. The current surge and flex does a really great job of sending signals and preparing the acute hospital industry and their links for the next round, but not addressing the primary care and the local health department participation and the way that we had envisioned. I just want to say that. I hope we can continue getting something going in that space. The second thing I wanted to ask that I had mentioned this, I think at the last council meeting. If we can't do it today, because I know we have a lot of reports, but certainly for the next time. I think we had been interested in knowing what the current language was that linked the prevention agenda to the CON process for acute hospitals. The council had been on the record before COVID, really wanting to see that and wanting to see conversations about the extension of that, of linking to the prevention agenda, to certificates of need. As you pointed out, there are some limits to that. Again, moving beyond acute care hospitals and in view of the fact that for the last couple of rounds, there have been some hospitals that have really indicated they've not made any participation in the prevention agenda in their application and others indicating they've not invested in that process. Again, may I ask the next time we hear about that. I'd love to perhaps have some thoughts from you all about how do we moving forward involve other than the acute hospitals in planning for the next surge and flex or the next epidemic now rather than scrambling at the last minute.

Dr. Boufford Thank you.

Dr. Morley We're certainly more than interested in continuing the discussion, in the dialogue as to what else can be done. I have to apologize. I'm embarrassed. I was provided information that I didn't include in this report. It was an oversight on my part. It was to include the questions that were asked in the CON as it relates to that agenda. I promise you we will have it in the next report. You know that this is something that we're interested in continuing the dialogue on. You also heard you mentioned local health

departments. Dr. Bauer on the public health side has got that up and running full bore. The commissioners attendance at those meetings is certainly something that's going to trigger and stimulate additional discussion about their role in this. We do want to be on the same page with those folks and we recognize that they have a lot to contribute.

Mr. Kraut Mr. Robinson, then Mr. Lawrence.

Mr. Robinson Thank you, Mr. Kraut.

Mr. Robinson It wasn't coming through.

Mr. Robinson Is it coming through now?

Mr. Robinson Which is that as we look at trying to recover the health system broadly from the loss of staff and the other struggles that came about as a result of going through the pandemic. It is clear to us that the key to sort of unlocking this and moving it forward is actually resolving issues relating to long term care. The importance of the state making strategic investments both in workforce and regulatory flexibility and reimbursement in the long term care sector. Right now, hospitals and emergency departments across the state are backed up. A lot of that back up is due to the fact that nursing homes can't accept transfers of alternate level of care patients who need to be in nursing homes to nursing homes. We think that should be a budget priority specifically for the Medicaid program for this coming year in order to start to rebalance the health system and ensure that people who need access to hospitals, emergency rooms and other health care settings are able to get it. That particular issue to our way of thinking, is the biggest block. I'm bringing this up not in response to your report, but more because of the fact that the budget process is now underway in the executive branch. This is the time for you and the other members of the Health Department to consider your input to that process.

Mr. Robinson Thank you.

Mr. Kraut Mr. Lawrence.

Mr. Lawrence Thank you, Dr. Morley, for addressing in outlining the legal structure for FQHC's and for other providers to be involved with the surge and flex. I think one of the things that at least has been articulated over time is that we did not want to have a health care system where people were operating in silos that the best care for New Yorkers or care where there's an integrated approach to the delivery of services, especially in neighborhoods that are underserved. I believe in many of those neighborhoods, the primary go to place for services often are community health centers across the state. One of the things that I would like to ask is, do we have a sense for what is happening with primary care? I've heard a number of and seen a number of reports where it's felt that the primary care is inadequately funded across the state and that really going into the next year and the year after that, there's going to be a bunch of hurt and pain emanating from primary care providers. They are dealing with a cost structure that has been impacted as all others have been impacted by COVID in terms of the labor force and other costs that have gone up. I guess what I'm trying to get to is, could the department really do an assessment on what's happening in primary care so that we understand where we are with that critical element and provider in the delivery system, especially in underserved neighborhoods. I think that's critically important to have such an assessment and also to understand the critical role that primary care providers played throughout the pandemic, first doing testing and then administration of vaccines, in addition to all of the other work

that we do in terms of chronic disease and just wellness work. I don't know whether this is the forum to request that, but I think it is critically important that we have such an assessment and we know what is happening with a key component of our system.

Mr. Kraut Well, Dr. Morley, it's fortuitous that Ms. Morne is to your right, because the two of you will be attached to the hip on those issues. Because they do overlap, if you think about it substantially.

Mr. Kraut Mr. Thomas and then I just don't want to lose a quorum, because we have to take some votes. We have another speaker. I just want to keep making sure.

Mr. Thomas Hugh Thomas, member of the council. This is directed both Dr. Morley and Commissioner Herbst. I want to just enthusiastically second Mr. Robinson's comments about the state of throughput and long term care and its effect on acute care facilities. Dr. Morley, thank you to the Department for reaching out directly to the region during the conversations. It's great news to hear that there's a tentative vote. Obviously, our system and Mr. Robinson system would have been impacted by that. The department is in constant project with us, so we appreciate it. Commissioner Herbst, just for you in particular, I think the number in our region is 1,300 nursing home beds off line. All the acute care facilities are backing up. That's actually regional. I heard from New Jersey, Connecticut and Downstate last week similar problems. Very specifically would urge you and you don't have to respond today, Commissioner, but the program, we have a couple of very specific and important facilities in our region that have requests in and I understand that there's a process and that there's not limit the least amount of funding. I understand the challenge, but I would urge you to look carefully at that in the context of really what is a just a stock throughput process pretty much all over, maybe not so much Downstate, but certainly in our region. I would urge you to take a look at those applications as you can, and hopefully we'll have an announcement in terms of your intent to distribute those funds in the coming weeks.

Mr. Thomas Thank you.

Mr. Kraut Thank you, Dr. Morley.

Mr. Kraut That's a nice introduction to Mr. Herbst, who, as you know, has recently, as part of the reorganization of some of the department's activity, is heading up the Office of Ageing and Long Term Care. We've asked him today to kind of give us an overview of the organization of that office and some of its agenda items and priorities.

Mr. Kraut Mr. Herbst.

Mr. Herbst Good morning. I guess it's good afternoon now. I'm pleased to be back with you all for today's conversation. I would like to give some background on our new office and I would also like to provide some updates on a handful of projects before I finish today. As you've now heard a few times in late July, early August, our department set forth some important priorities and reorganized the way we work to better serve New Yorkers. One of those priorities was the creation of the Office of Aging and Long Term Care, or OALTC, another acronym that the department will be putting into place. We're focused on optimizing the department's talent and the integration of new systems and increasing diversity as part of our overall mission to build a healthier, more equitable New York. OALTC will be dedicated to the needs of aging and disabled New Yorkers. I hope this new office will help to ensure aging New Yorkers have greater access not only to essential

health services, but to appropriate living settings and programs that reduce isolation. The vision we have for this office and our mission is to foster policy and programs and services that meet the health and long term care needs of all New Yorkers. This includes support to those who seek to age in place, as well as people who choose long term care in nursing facilities. We have an urgency to our mission. New York is already home to the fourth largest population of residents over the age of 65. Almost 20% of the entire state. In the coming decade, we are facing a tidal wave of aging New Yorkers. By 2030, a quarter of our state's population is projected to be over 60. As many of our aging baby boomers will seek the care and security of nursing homes or adult care facilities. There is also nearly 100,000 New Yorkers residing in nursing home facilities and hundreds of thousands receiving home care. Long term care spending accounts for nearly 35% of the total state's Medicaid spending, and that's the state's largest cost driver. We can see this wave approaching and the necessity of our work. We need to shore up our support for New York's most vulnerable population, as Dr. Bassett referred to it earlier. Establishing this new Office of Aging and long term care is an important first step to align the department's expertise and resources for greater impact not only for aging and disabled New Yorkers, but also for the families and stakeholders and advocates upon who we all rely on. OALTC will be responsible for data management and licensing and surveillance policy and finance, as well as communication programs to help educate and build consensus. We'll also weave in programming to address our mission to improve public health and health equity and address the social determinants of health such as transportation, housing and nutrition. By placing the manifold of issues surrounding long term care under one roof, we're not just elevating the issue, but we're giving the new office the overall resources that we need and the power to build a network with one aim. Again, this is to help serve aging New Yorkers and those who seek long term care facilities. One of our most important priorities is to ensure New Yorkers can age in place for as long as possible with dignity and independence and have access to quality care when they need it. The same holds true for all New Yorkers with disabilities. Both those people who need short term rehabilitation and those who require long term care or need additional supports to live meaningful lives in the community. In addition, I referred to the Governor's proposed master plan for aging, which will lay the foundation for us to change the landscape of aging and long term care in our state. A foundation that's designed to enforce the long term care community for the long haul. The master plan will probably be inclusive, focusing on age friendly health systems and public health initiatives. Again, such as housing and transportation, community engagement, rural challenges and telehealth and digital strategies for social engagement. We'll measure outcomes, but most importantly, we'll rely on equity as a driving factor in the master plan. We'll aim to open up alternatives to nursing homes and facility based care and will convene with the efforts of the public and the private sector to convene and create communities that promote healthy living and civic engagement. We also want to look at other ideas, such as walkable communities that promote exercise and reliance less on vehicles. OALTC will spearhead the implementation and the execution of the master plan. We'll focus on creating a blueprint together for strategies for government and the private sector and the not for profit sector to support older New Yorkers. We'll ensure the state has policy and programs and they're coordinated in aligned line to ensure New Yorkers can age in our state with freedom and dignity and independence for as long as possible. The master plan is a response to the approaching wave that I mentioned earlier. The actions we're taking now will help us prepare for the challenges ahead. We cannot do this alone. There's already been so much expertise coalescing around the master plan. We're grateful for the inputs from stakeholders and advocates and organizations and welcome insights to continue from all areas across the long term care ecosystem. We'll certainly rely on the partnership of you as a partner in addressing the health and long term care needs of aging New Yorkers as

well. I look forward to keeping all channels of communication open with you as we build a more sustainable and integrated system of care. This includes the areas of the the mission from the role of the Ad Hoc Committee to the State Health Improvement Plan, known as the Prevention Agenda that we've spoken about a handful of times already today to the work done in committees and public health discussions, debate on the Committee of Health Planning and the Committee on Codes and Regulations and Legislation, as well as the activities related to the licensure and construction process completed. I'd like to now move and give some guick updates on six areas that OALTC has already initiated. First, was the reform of various need methodologies. One of the major areas that OALTC has committed to is changing outdated and restrictive need methodologies, especially in Article 36 and Article 40 hospices. Determining public need is crucial for thoughtful health care planning. However, determining public need should serve to strengthen and not hinder the establishment of new facilities and home care services in areas underserved. This must change, and it will. OALTC is now working on improving and streamlining the need methodologies to reflect our current ecosystem. OALTC looks forward to working with you on important issues and welcomes feedback and suggestions as we move forward. Second is a lifting of the moratorium. As you're aware, the department recently released the new licensure application process in mid-August. As a result of this new application release, we anticipate a steady increase in the number of applications that you will be asked to review and approve. Again, OALTC looks forward to working with EPRC and the entire membership as we move forward with increasing access to home and community based services. This must be done responsibly and in a reasonable manner that ensures high quality health care for New Yorkers in need of home health services. Third is the critical nursing home quality work. I'm fully aware that for many years you have led the public discussion on the important question of what nursing home quality should mean. Nursing home operators should be held responsible and accountable to the residents of New York's nursing homes and the families who entrust their loved one's care to these providers. We are committed to this important issue and over the next year we'll work to strengthen quality in nursing homes through the New York State legislative and regulatory processes, the executive budget and also thoughtful policy development. We'll look forward to your support and input. Again, we look forward to partnering with you as we not only look to improve the quality of nursing homes, but to do so in an efficient and timely manner. Fourth is the issues related to workforce. The issues of workforce are a major issue and must be addressed by all health care stakeholders. OALTC has listened to members ask the fundamental question. How should the department consider the quality of CON applications when it comes to workforce considerations, especially when reviewing patient volume projections? Even if an applicant can meet their expected patient volume projections, how will these applicants find and retain qualified staff? These are important threshold questions. They'll be asked to consider by the Department on all CON applications moving forward. OALTC looks forward to working with you in finding common sense approaches to this crucial and growing problem. Fifth is the reform. Earlier this year, you heard from Brett Friedman, the former New York state Medicaid Director, as he provided an in-depth presentation on the structural alternatives for the program of all inclusive care for the elderly, also known as PACE. OALTC remains committed to working with OHIP and all our external stakeholders and you of reviewing ways to improve the states ability to reform the PACE program to promote expansion of this innovative model. OALTC is in the process now working towards that goal by analyzing ways to implement and improve the PACE program. As mentioned at the presentation, the legislature has passed a bill earlier this year to establish a combined licensure and surveillance process for the PACE program. We look forward to keeping you informed as discussions progress on this legislation. You will be actively engaged in any policy discussion and regulations adopted to implement this legislative initiative. Sixth, and finally is streamlining the way we

conduct business. We've heard the concern raised by members, and we're eagerly looking for new ways to address your concerns. Specifically, I'm referring to at the last meeting you asked, how can we streamline processes to ensure that you thoroughly review and consider the most important matters related to CON and establishment and construction applications and remove matters of important but at times ministerial implication from your busy and full agendas. As a follow up to this question, I have OALTC staff now looking for better ways of reforming our work in the upcoming cycle, and I'll have more comment on this with different solutions very soon and look forward to further conversation with each of you at the upcoming meetings. Once again, we believe is a vital partner in working with the department on Health Care Policy and OALTC wants to engage with you in discussing the prevention agenda that Dr. Bassett has discussed now, and to work closely with all of our committees and get your input and final approval. It will help lessen the need to overstretch the indispensable time that uses at these meetings and discuss aging and long term care projects and concerns. I hope that OALTC will continue to foster community within this critical industry. We need to keep all channels of communication open as we build a more sustainable, integrated system of care. The work ahead of us is certainly expansive and critical for all aging New Yorkers. During the next few weeks, the OALTC team and I will reach out to each of you to discuss ways we can improve upon our work in these areas and get your feedback and ideas. I also look forward to being present at any committee and presentations to provide more detail as you may deem important for the aging and long term care sector.

Mr. Herbst Thank you.

Mr. Herbst I welcome any comments or questions you may have.

Mr. Kraut Thank you, Mr. Herbst, for that great overview. Again, it's a packed agenda. You'll find a very, I think, engaged and meaningful partner on many of the items you raised.

Mr. Kraut Does anybody have any questions?

Mr. Kraut I'll start with Mr. La Rue, go to Dr. Boufford then, Ms. Monroe.

Mr. La Rue Good afternoon. Thank you for the presentation. I don't have a specific question. I just want to acknowledge and share our appreciation with the department for the way it's been reorganized in creating this focus on long term care. It's something that the group here has been discussing for a number of years. We're really excited that you're leading this effort. We look forward to working with you to improve the life of older New Yorkers.

Mr. Herbst Thank you very much.

Dr. Boufford As I say formally, I'll associate myself with Mr. La Rue's comments. Really terrific intervention also, in your holistic view. I just want to make two comments. One, you referred to the prevention agenda several times, which is terrific. One thing that I think we sometimes forget about it there are objectives for older persons in each of the overall goals of the prevention agenda. This was a long conversation that we had in creating the latest version of the prevention agendas, rather than having an isolated goal for aging or for older people, we would embedded in each of the five goals. It'll be great to really look specifically at that in relation to the priorities set by local communities for the areas they're going to work on. The other thing is a friendly amendment to the name of your office,

which would be to call it the Office of Healthy Aging and Long Term Care. I think you could still say OAL, because O would be OH, right? ALTC. I wanted to put that on the possibility range early on in your existence.

Mr. Kraut She just wants to get to you before you order the T-shirts.

Mr. Herbst I think the mugs and pencils have been ordered.

Mr. Kraut Ms. Monroe.

Ms. Monroe Yes.

Ms. Monroe Thank you very much.

Ms. Monroe I really like the way you've structured the six areas. Each one of them cries out for data. That means baselines and goals and progress. I think if you can work with us to incorporate that kind of data into the work that we're doing, I think we'll be far ahead. Very often we're talking in general terms or we're given numbers verbally, and it's hard to contain all of those. I'd like to see you develop almost a dashboard that could be reported on that has, as I said, baseline and progress and goals that we could look at every time as a dashboard, but maybe spend our time on the two or three things that emerge from the dashboard as most important to discuss. Again, thank you for the work you're doing. I think we all look forward to real progress on these issues.

Mr. Herbst Thank you.

Mr. Kraut Thank you, Mr. Herbst, so much for again, for the report.

Mr. Kraut I'm now going to ask Mr. Holt, which I had jumped to right away when I started the meeting. I guess I just didn't want to lose the ability to have a quorum for a vote. Please give us the report on Codes, Regulations and Legislation.

Mr. Holt Thank you, Mr. Kraut.

Mr. Holt I will note that when I originally spoke, I said good morning and I will now be able to say good afternoon.

Mr. Kraut As long as you don't say good night.

Mr. Holt At today's meeting of the Committee on Codes, Regulations and Legislation, the committee reviewed and voted to recommend adoption of the following emergency regulations for approval to the full council. The first being the investigation of communicable disease. Staff from the department presented the Regulation to the Committee on Codes and are available to the council should there be any questions of the members.

Mr. Holt I move to accept this regulation.

Mr. Kraut I have a motion from Mr. Holt. I have a second by Dr. Gutierrez.

Mr. Kraut Are there any questions from the council?

Mr. Kraut I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Dr. Watkins as well.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Holt Second regulation presented by the department staff was regarding face coverings for COVID-19 prevention. Staff are available should there be any questions.

Mr. Holt Otherwise I so move the adoption of this regulation.

Mr. Kraut I have a motion from Mr. Holt. I have a second by Dr. Gutierrez.

Mr. Kraut Are there any questions or comments from the council?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Dr. Watkins also voted yes.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Holt The last regulation that we consider related to monkeypox virus, adding it to the list of sexually transmitted disease. Staff presented to the committee and they're available should there be any questions.

Mr. Holt Otherwise, I so move the adoption of this regulation.

Mr. Kraut Thank you much.

Mr. Kraut I have a motion from Mr. Holt. I have a second by Dr. Gutierrez.

Mr. Kraut Are there any additional questions or comments by the counsel?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut All those opposed?

Mr. Kraut Abstentions?

Mr. Kraut Dr. Watkins voted yes in Albany.

Mr. Kraut The motion passes.

Mr. Holt Mr. Chairman, this completes my report.

Mr. Kraut Mr. Holt, thank you very much. Thank you very much for running a wonderful meeting this morning. We deeply appreciate it.

Mr. Kraut I'm now going to turn to Dr. Kalkut to give the report on the actions of the Establishment and the Project Review Committee.

Dr. Kalkut We will start with 2 2 1 2 1 8 C, United Memorial Medical Center in Genesee County. There's a conflict and recusal by Mr. Thomas who's left the room. This is to certify a new extension clinic at 8103 Oak Orchard Road in Batavia, providing primary care, other medical specialties and a single specialty ambulatory surgery center services, gastroenterology. The department and the committee both voted for approval with contentions and contingencies.

Dr. Kalkut I so move.

Mr. Kraut I have a motion by Dr. Kalkut, second by Dr. Gutierrez.

Mr. Kraut Are there any questions on this application?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Dr. Kalkut Our next is a set of applications that we're going to bundle. I believe there's ten applications in here. I will go through them. First is 2 2 1 1 9 9 B, Health Inc. in Kings County. This is to establish and construct a new diagnosis and treatment center at 1663rd Street, Brooklyn, to provide primary care and other medical specialty services. Both the department and the committee recommend approval with conditions and contingencies. 2 2 1 2 1 2 E, Smile New York Outreach LLC in Bronx County. This is to transfer 100% of ownership interest from one withdrawing member to a new member within the sole member LLC. Both the department and the committee recommend approval with a condition and a contingency. Next is a certificate of Debt Solution JGB Health Facilities Corporation. This request consents for filing to dissolve JGB Health Facilities Corp. Approval is recommended by both the department and the committee. 2 1 1 1 4 3 E, AMSC LLC doing business as Downtown Bronx ASC in Bronx County. This is to transfer 100% of membership interest in AMSC LLC doing business as Downtown Bronx ASC. The department and committee recommend approval with conditions and contingencies with

an expiration of the operating certificate three years from the date of the completion of the application. 2 2 1 0 9 5 B, Empire CSS LLC doing business as Empire Center for Special Surgery. This is to establish and construct a new Multispecialty Ambulatory Surgery Center at 4855 Hylan Boulevard in Staten Island. The department and the committee recommend approval with condition and contingencies with expiration of the operating certificate five years from the date of issuance. 2 2 1 2 2 4 E, 21 Reade Place ASC LLC doing business as Bridgeview Endoscopy in Dutchess County. This is to transfer 41.665% ownership to five new members of the sole member LLC. Recommendation from the department and the committee approval with a condition. 2 2 1 2 6 7 E, Advanced Endoscopy LLC, DBA Advanced Endoscopy Center in Bronx County. This is to transfer 10.71213% ownership from the three withdrawn Class B members to one new member LLC. The department and committee recommend approval with a condition. 2 2 1 2 7 0 E, Endoscopy Center of Niagara LLC in Niagara County. This is to transfer 49% ownership interest from one withdrawing Class A member LLC to two new Class A member LLC. The department and committee recommend approval with a condition. 2 2 1 2 7 1 E, Endoscopy Center of Western New York, LLC in Erie County. This is to transfer 100% ownership from fifteen withdrawing members to two new member LLC. The department and committee recommend approval with a condition. 2 2 1 2 7 2 E, Island Health Center in Suffolk County. This is to transfer 10% ownership interest from three withdrawing members to one new member LLC. The department and committee recommend approval with a condition.

Dr. Kalkut I so move.

Mr. Kraut I have a motion by Dr. Kalkut to move these applications. A second by Dr. Gutierrez.

Mr. Kraut Does anybody have a question on any one of the applications that have been placed in this batch?

Mr. Kraut Because you're just as a backup facility.

Mr. Kraut Thank you.

Mr. Kraut Dr. Strange will declare an interest of the Staten Island application.

Mr. Kraut If there's no other comments, I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Dr. Kalkut 2 2 1 2 6 8 E, Carnegie Hill Endoscopy, LLC in New York County. There's a conflict in recusal by Dr. Lim, who's left the room to transfer 18.66% ownership interest from three withdrawing Class B members to one new member LLC. The department and committee recommend approval with a condition. 2 2 1 2 6 9, East Side Endoscopy LLC

doing business as East Side Endoscopy and Pain Management Center in New York County. Again, a conflict and recusal by Dr. Lim, who was out of the room. This is to transfer 41.926 ownership interest from three withdrawing members to a new member LLC 83.333% interest from two withdrawing members two existing members within two member LLC and 9.306 from an existing member to a new member within a member LLC. Department and committee recommend approval with a condition.

Dr. Kalkut I so move.

Mr. Kraut I have a motion by Dr. Kalkut. I have a second by Dr. Gutierrez. Dr. Lim has left the room.

Mr. Kraut Are any questions on these applications?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Kraut Please ask Dr. Lim to enter the room and say goodbye to Mr. La Rue.

Mr. Kraut Are you declaring an interest?

Mr. Kraut Oh, because it says abstain.

Dr. Kalkut 2 2 1 1 8 4 E, Emerest Certified Home Health Care of New York LLC doing business as Royal Care Certified Home Health Care of New York. This is in Bronx County. This is to establish Emerest Certified Home Health Care of New York LLC as the new operative Cabrini Certified Home Health Agency, a certified home health agency currently operated by Cabrini of Westchester and relocated to 798 Southern Boulevard in the Bronx. The department and committee recommended approval with conditions and contingencies.

Dr. Kalkut I so move.

Mr. Kraut I have a motion. I have a second by Dr. Gutierrez.

Mr. Kraut Any discussion here?

Mr. Kraut Mr. La Rue.

Mr. La Rue I just want to clarify I abstained in the committee meeting.

Mr. Kraut I reread it wrong.

Mr. La Rue Thank you.

Mr. Kraut It's declaring an interest.

Mr. La Rue After consulting with counsel.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut The motion carries with an interest.

Mr. Kraut Thank you.

Dr. Kalkut That concludes the review. .

Mr. Kraut Thank you very much, Dr. Kalkut.

Mr. Kraut That concludes that report.

Mr. Kraut I'll now turn to Ms. Royal, who's going to give us an overview of the long term care ombudsman's office.

Mr. Kraut I'm assuming she's in Albany.

Ms. Royal I am.

Ms. Royal I'll try to be quick, cause I know we're several hours in. The goals for today would be to give you the mission and the values of the Long Term Care Ombudsman Program. We refer to it as LTCOP, another acronym. The administration and structure of the program.

Mr. Kraut I'm sorry. Could we please have the camera on Ms. Royal, because we can't see her.

Mr. Kraut Thank you.

Mr. Kraut Go ahead.

Ms. Royal That's okay.

Ms. Royal We wanted to talk about the roles and the responsibilities of a certified ombudsman, which is both paid staff and volunteers. Our role for the comments and the nursing home ownership and transfer or establishment process, which is essentially why we are here. Our program mission is to serve as an advocate and resource for older adults and persons with disabilities who live in long term care facilities. Anyone in any long term care facility is who we serve.

Ms. Royal Next slide.

Ms. Royal Sorry, I'm not telling you.

Ms. Royal Our program values, which the very main thing for this program is to be a resident centered focus.

Mr. Kraut I'm sorry, but the slides are not being advanced and we can't see them. You're just on the title page.

Ms. Royal Looks like they're working on it. I'll wait for them to catch up.

Mr. Kraut Just continue and we'll catch up.

Ms. Royal Okay.

Mr. Kraut That's fine.

Ms. Royal Our program values is primarily to be always resident centered focus. Everything that we do in this program is based on what a resident wants. We also have a primary goal to always maintain confidentiality. Anything a resident brings to us is confidential unless they give us permission to share that information. We're also trying to be accessible to residents. Our goal is to be available to residents when they need us. Prevention is another program value. We're working to prevent residents to ensure their rights are not violated and to be free of abuse, neglect and exploitation. Resident Empowerment and Autonomy. We're always looking to provide residents with tools to be as autonomous as possible so that they can advocate for themselves as well. Complaint resolution. Resolution is a key piece here because we're not looking to Band-Aid issues that they have. The goal is to have long term resolution to the issues that they may have to follow up and ensure those things are continued to be resolved and aren't popping up again. We're also having to be objective. This can be a difficult thing for an ombudsman, because what we may feel is in the best interest of a resident. They may want a totally different thing. We have to remain focused on what their goal is and to be objective and everything that we're doing for the residents. We wanted to give a basic overview of the administration of the program. The Older Americans Act, which is administered by the Administration on Community Living ACL, requires each state to establish an independent office of the state long term care ombudsman. In New York, we are administratively housed within the Office for the Aging and we provide advocacy services through a network of regional programs. At the state office, there there's myself as the state ombudsman who oversees the whole program. I have a senior assistant state ombudsman. We have three assistant state ombudsmen who supervise the regional programs. Across the state, we have fifteen regional programs and each of the assistant state ombudsman are assigned five to oversee. In each region there's a coordinator of that program and they're responsible for recruiting and training the volunteers throughout the state. They are responsible for being the regular presence in the nursing homes and adult care facilities that we serve. To be a certified ombudsman, there's a lot to do. You have to follow a thirty-six hour certification training. It's a very intense program talking about the roles and responsibilities of being an ombudsman. And then after your certification, training for all the years following that you have to now complete eighteen hours of continuing education throughout each program year. That's a requirement from ACL. Our volunteers commit two to four hours a week in their facilities that they're assigned to, to provide those advocacy services. The duties of an ombudsman are to identify, investigate and resolve complaints made by or on behalf of residents. We do work with families as well, but primarily they're on behalf of all residents. We inform residents about obtaining services from the program. When we're doing our regular visits and facilities, we would be providing residents with information on how to access us if they need us. We generally

touch base with any new residents that are coming into a facility so they're aware of our program. The facilities do have to provide information to all residents about the ombudsman program as well at least twice a year. We also represent residents interests before governmental agencies. With legislators, we advocate for things that residents are asking for us to work with them on. We work with our partner agencies throughout the state as well to improve the quality of care and quality of life for residents. We do promote and provide assistance to resident and family councils. We work with facilities that may not have a resident council to help develop one and help them facilitate those meetings as well as family councils. Especially since COVID, one of the positive things that came out of that was in some facilities being able to develop family councils through Zoom, so that allows more families to participate in those meetings and be more involved in the care of their loved ones. We do have access to all facilities and all residents at any time. We also have access to resident records as it relates to a complaint investigation that we may be working on. We can't have untethered access to a record, but if we're working on a specific complaint, we may access portions of that record. We are always to be provided with a list of the residents currently in the facility so that we can meet with new residents as they come in. Essentially, what is an ombudsman? We are an advocate for residents. That is the primary focus. We are an educator. We provide education to residents. We provide education to the community. We provide education to facilities staff and also families. We are a mediator at times for between a resident and possibly a roommate, their family, the facility. We may mediate issues to help resolve them for them. We're also a negotiator. Sometimes we have to negotiate with families, residents and facilities to try to come to an agreeable solution. Ultimately, we're a problem solver and an advocate for a resident. What we are not is a long term care facility regulator, a licensing surveyor, an inspector or investigator. We are not an adult protective services investigator. We are not a provider of direct care. We cannot provide any direct care to residents when we're in the facility by federal requirements. The last thing that we are not is a mandated reporter. That's important to know because that seems to be kind of contrary to our work, but we are not allowed to report any type of abuse or neglect without a resident's permission or their family if they are unable to do so or their guardian. We do encourage residents to report abuse. We may work on finding a solution to that in another way. We may talk with other residents. Ultimately, if the resident does not want us to report abuse, we're unable to do that. LTCOP and Department of Health have similar roles, but different. Both Department of Health and LTCOP oversight entities for long term care facilities. Department of Health looks more whether a facility is meeting regulatory standards and they have the ability to issue citations for non-compliance. We look at any expression of dissatisfaction that a resident may bring to us. We're looking for resolution to that at that time. We're not able to issue citations. We may file complaints on the things that we see, but we're not able to ultimately evaluate whether that meets the regulatory compliance. Department of Health andLTCOP both have presence in facilities, but those presents are different. Department of Health visits facilities for inspections, generally annual inspections or a complaint that they may receive. That would be the reasons generally that they're attending or visiting a facility. We visit more frequently. The purpose of our visits are to develop a rapport with residents and develop a trusting relationship with them, and also to develop a working relationship with the facility to help mediate the issues that residents may raise. We are there to provide education and information to residents, families and even facility staff while we're addressing concerns. We have more of a regular presence. Both agencies receive and investigate complaints, but we investigate differently. Department of Health is assessing the regulatory compliance. That is their role. We may be looking at more possible causes for a problem. We're trying to work with a facility to resolve that issue prior to it rising to the level of a regulatory need. We want to help a facility solve an issue before it has to escalate to the need to involve Department of Health. We do collaborate with

Department of Health. We have a good working relationship. We now have a dedicated online complaint form for the Ombudsman programs to file complaints with Department of Health and also a dedicated hotline number to Department of Health to file our complaints. We are also involved in Department of Health's annual inspection survey and exit conference. We know when they're there to visit a facility for a survey. We are able to attend the exit conference and provide information to Department of Health. We also have relationships at the regional level. Our regional offices from the Office and Program of Department of Health may reach out to each other with questions, you know, inform them of things that may be happening in a facility that we're able to that's not resident specific. We also work at the state level, the State Department of Health, the central office and us. We have a conversation fairly regularly, just to keep each other updated and share information. There is a collaboration between the two agencies. The ultimate goal, to improve the lives and ensure the quality of care for residents. The LTCOP recommendations, which is mainly the reason that we're here, is part of Chapter 141 of the laws of 2021, where the long term care program would comment on any ownership, transfers or establishment of new facilities. We wanted to give you some information on how we come to those comments, because our role isn't enforcement, our role is very different. We have different avenues of how we develop our comments. All at the beginning, Department of Health will inform us of any applications for ownership, transfer or establishment. We review those applications. We're focusing on the facilities that are currently owned or operated by proposed owners. That's inclusive of adult care facilities. If a proposed owner does also have stake in a adult care facility, we're going to look at our information related to that adult care facility as well. We review our data in our data system related to how many complaints they may have had, how many visits we've had to that facility in the past three years. We look at what types of complaints those are. Are we visiting on a routine basis? We also look at if there's abuse complaints. We would be really focusing on those if there's frequent abuse complaints in those facilities. We have calls with our regional programs to gather the overall information on a facility. While they're doing those routine visits we want to know, do the residents appear to be; comfortable, happy? Their conversations with them. Do they feel that the residents are accepting of the facility and how it's managed? We talk to the resident counsels. What type of input we get from the resident counsels and what types of complaints that the resident counsel may bring to us. We ask about what type of relationship the facility administration has with the long term care ombudsman program. If we're bringing them an issue, are they willing to work with us to try to resolve that for a resident, or is it an adversarial relationship? We ask about activities. What types of activities the residents have available? Do they seem to attend them? We ask about food issues. Food is a big thing in facilities. I mean, that's a key piece to some residents lives is their meals. We ask about those types of things. Also the cleanliness of the facility or the structure of the facility. Are their concerns with how it's being taken care of? We take into consideration a whole lot of observations, interactions and the actual data and complaints that we see before we make our recommendation. Ultimately, once that's been decided upon with gathering all that information, we submit our recommendation to you to review our recommendation. I attend the council meetings as well.

Ms. Royal And that is it.

Ms. Royal Thank you for giving me the opportunity to provide you with some information.

Mr. Kraut Ms. Royal, thank you so much for that. That was a very cogent and clear explanation of the office. We're really looking forward, as you outlined, you have a role to play in our review. We're particularly interested as it applies to the character and

competence of operating the facilities to focus it, you know, and that, you know, every place has issues that they need to address. Hopefully you and your colleagues are great mediators to make sure individual ones. We're particularly looking at patterns. We want to look at, you know, it has to rise to something that's substantive, that's documented, and it's just not one and dones. We think that it's a welcome addition of information that we believe is critical in evaluating candidates of competence and character to operate these facilities.

Mr. Kraut Thank you very much.

Mr. Kraut Unless there's something burning, I just I see I'm losing the room. I have one other presentation. I'd really like to get to it. Unless anybody has any questions for Ms. Royal, I'll hold off.

Mr. Kraut Thank you so much.

Mr. Kraut I appreciate it.

Ms. Royal Thank you.

Mr. Kraut Thank you.

Mr. Kraut Now, I'll turn the mic over to Mr. Hennessey and Ms. Shulman, who is going to give us a overview of clinical staffing.

Mr. Hennessey Thank you very much.

Mr. Hennessey My name is Mark Hennessey. I'm the Director at the Center for Health Care Provider Services and Oversight.

Mr. Kraut Just pull it a little closer.

Mr. Hennessey Try to talk as quick as I can.

Mr. Hennessey We're here today to talk to you a little bit about safe staffing standards for hospitals. There's two different laws that deal with safe staffing. One deals with hospitals, the other one deals with nursing homes. Today, we're specifically only talking about hospitals.

Mr. Hennessey Could have the next slide, please.

Mr. Hennessey The legislature worked on a law and passed that law. The law was signed on June of 2021. The law outlines a lot of the different lessons that were learned by facilities as well as by people that work in facilities during the pandemic. It really focuses on the idea of making sure that there's sufficient staffing to help reduce errors, complications, adverse patient care events and also support the idea of retaining skilled staff. We see a lot of information about those kinds of issues as we do work and investigations. This law really seems to amplify the idea of making sure that there's sufficient staffing to provide care to individuals who are in those facilities. There's also a couple of sections within the law that specifically talk about evidence based staffing standards. There's a little bit we're going to talk about later on about that. Also the importance of transparency. A lot of the data and information that's collected through this

process is actually available on the State Department of Health's website almost in real time from when we get it. There's a real emphasis on that as well.

Mr. Hennessey Go to the next slide, please.

Mr. Hennessey There's a couple of terms that exist within the law that we thought it was important to make sure that folks are aware of. General Hospital. Not going to reread the regulation, but this is the normal definition which is applicable to general hospitals. Within the law, there's the designation that each of the general hospitals is required to supply one of these safe staffing plans to the department. And then that safe staffing plan it's require that each of those safe staffing plans have a description of the patient care unit, which is a unit within that hospital that provides direct patient care. There's been some discussion on who is it applicable to? Who is not applicable to? The law is actually applicable to any of those patient care units. The last one and this is, I promise, the last definition we'll talk through here is ancillary members of the frontline team. These are folks who are not RN's, not LPN's, but a patient care technician, certified nursing assistants and other nonlicensed staff who help with nursing or clinical tasks. You'll understand, in maybe a slider to why it's important for us to talk about that definition.

Mr. Hennessey If we could have the next slide, please.

Mr. Hennessey All of the hospitals were required to establish a clinical staffing committee. They were allowed to create those as new committees or assign the functions of a committee to an existing one. Specifically, in the cases where there is a collective bargaining agreement and it provides for a staffing committee that CBA is then going to really take the place of any of the rest of the structure that exists.

Mr. Hennessey Next slide, please.

Mr. Hennessey As I mentioned earlier, there's a real emphasis on making sure that the workers view is represented on those clinical staff and committees. At least half of the members are required to be registered nurses, LPN's or again, that term I talked about earlier, which is the AMFT's. They generally speaking, are people provide direct care to patients. They require that at least half of those members are people that fit that category, but then up to one half of the members are also selected by a general hospital administration. The Chief Financial Officer, the Chief Nursing Officer, directors of those patient care units are people that are mentioned specifically as folks who should be within this committee. In the case that there's no CBA, the members of the committee may be selected by their peers. How that selection takes place. If there is a CBA, there's a selection of RN's, LPN's and the AMFT's, according to the respected CBA. Another point that's raised is the importance of making sure that people who participate in these clinical staffing committees are given the opportunity to do so while being paid for their normal rate of pay. We have started to take receipt of some complaints in certain circumstances where there complaints that are raised about I wasn't allowed to go and work in the clinical staffing committee. We thought it was important to note that. And all of this, I should say, is really meant in part to you know, I don't think we've ever done a walk through of this new law. We want to make sure that you had more than just sort of the pencil sketch of things that you might otherwise get. Those clinical staffing committees are required to come up with that plan. They can do it in a number of different ways. They can use specific guidelines or ratios, matrixes or grids. When we've looked at some of the plans that have come in and we'll talk about how they come in a little bit, it has led to them looking a little bit different. The nice thing, again, is if you go on the department's website, you can look

at any of the plans that we've collected thus far. There are, I think, over 200 of them, but you will see that they look a little bit different in form of function because each of these hospitals is a little bit different. Those clinical staffing committees then are supposed to do a semi-annual review of the clinical staffing plan. The last piece is that they're supposed to review and respond to complaints as they come in and do an assessment. In circumstances where the department is going to do some work on one of those complaints or the plans, that kind of stuff, we may be working with the clinical staffing plan to get a greater understanding of what they know.

Mr. Hennessey Next slide, please.

Mr. Hennessey That Clinical Staffing committee adopts a clinical staffing plan. For each of those patient care units, there can be consensus that is reached where there's agreement on what those staffing levels should be. There can also be non consensus and in that case, the Chief Executive Officer is allowed to make a decision that's sort of a tiebreaker decision. When they submit those clinical staffing plans to us or the hospitals do, at that point it's really important for the CO in that case to designate to us and point out to us, here's the reason why we couldn't reach consensus.

Mr. Hennessey At this point, I'll hand it over to Stephanie Shulman, who's the Director of the Division of Hospitals Diagnostic Treatment Centers.

Ms. Shulman Let me talk to you about the rest of the clinical staffing.

Ms. Shulman Better?

Ms. Shulman Good.

Ms. Shulman I'm a little shorter than Mark.

Ms. Shulman Now, we'll talk a little bit about the implementation itself of the clinical staffing plans. Beginning on January 1st, 2023, and annually after that, hospitals are required to implement their clinical staffing plans that they adopted on July 1st of the previous calendar year. They also need to implement any subsequent amendments and assign personnel to each patient care unit in accordance with the plan. Under Public Health Law, 2805 T, each patient care unit within the hospital is required to have a separate clinical staffing plan. This plan needs to be posted so people in the hospital can see it and review it. It must include the actual daily staffing for that shift on that unit, as well as the relevant clinical staffing plan. Therefore, there will be some units that may not run three shifts and their clinical staffing plan would be reflective of that.

Ms. Shulman Next slide, please.

Ms. Shulman Regarding the annual clinical staffing plan submission. The plan is required to be submitted to the department by the Chief Executive Officer of the facility or their designee by July 1st of every year. It must be handed in. We will be reminding them if it's not handed in prior to that time. All data submitted must be accurate and needs to be compliant with Section 2805 T. If the adopted clinical staffing plan is amended, hospitals need to submit that to the department within thirty days of adoption. All of those clinical staffing plants, as described earlier, are posted on the department's website. When a staffing plan is amended, the previous one is taken down. The new amended staffing plan is put on the website. The statute is very specific regarding quality indicators, and these

include the number of RN's, LPN's and unlicensed personnel providing direct care. Those unlicensed personnel are really important, because they assist the professional staff in providing that level of care that the patient needs. This information must be expressed in actual numbers in terms of total hours of nursing care per patient. This includes adjustment for case mix and acuity. That's important because not every unit on the hospital is the same. As a percentage of patient care staff and must be broken down for total patient care staff for each unit and each shift. All of these methods for determining these clinical staffing plans need to be recorded and available to the department for review. Data regarding complaints, investigation of these complaints, findings as the result of the investigation and then degree of compliance must also be provided to the department.

Ms. Shulman Next slide, please.

Ms. Shulman There is an annual report requirement in the statute. The department is required to draft an annual report. This annual report does include the number of complaints submitted to the department, the outcome of these complaints, the number of investigations conducted and then the costs associated for these complaint investigations. The statute also requires a stakeholder work group. That workgroup is comprised of members of the hospital associations and the unions who represent nurses and the other ancillary members of the front line team. The stakeholder group will review that annual report prior to its submission. The department is required to finalize and submit an annual report by December 31st, 2022. That report is submitted to the Governor, the Speaker of the Assembly, the Temporary President of the Senate, and the Health Committee Chairs.

Ms. Shulman Next slide, please.

Ms. Shulman The statute also requires the development of an independent advisory committee. The Independent Advisory committee must consist of nine experts. Three of those experts are individuals who have knowledge and specialized in nursing practice, quality of nursing care or patient care standards. Three additional individuals are representatives of the unions who represent nurses. There's an additional three members who represent the general hospitals. This advisory committee is tasked with evaluating the effectiveness of the Clinical Staffing committee, review of the annual report and making recommendations to the Speaker of the Assembly, the temporary President of the Senate, and the Chairs of both of the Health Committees of the Assembly and the Senate.

Ms. Shulman Next slide, please.

Ms. Shulman Regarding the status of our deliverables, the annual report. We're currently collecting and compiling all complaints related to staffing submitted to the department and following up on those potential investigations. The statutory deadline for this is December 31st, 2022. We're also in the process of developing regulations regarding both the uniform collection of nursing quality indicators. We've already have reviewed some data collected as we described earlier. The staffing plans are currently posted on the department's website. We're making revisions to ensure that we have uniform data collection. We found in some of the plans that were received. Acronyms were used. We want these plans to be very comparable and very easy to be able to analyze and collate. We're working on all of that standardisation internally. The statutory deadline for that is also December 31st, 2022. Regarding the development of regulations, we're also working on the development of those, and that's a work in progress at this point in time.

Unidentified Speaker I'm just not sure if Dr. Morley's still on. I thought he might want to say something at the end of this.

Dr. Morley Still here.

Mr. Kraut Dr. Morley, would you like to add anything? Just because I'm going to lose the room in a little while.

Dr. Morley Into two seconds, I can tell you that it was our hope that we were going to be able to do some more on regulations, but this has been the statute. We've done it because, A, the statute was a long time ago, over a year. Two, it was complicated. Three, it was detailed. Negotiations are still taking place. Now, I have a high confidence level that we'll have regulations that we will review with you provide some education on at the December meeting.

Mr. Kraut Well, I think this is a critically important kind of background for that discussion. At least I'm glad you did it now, so we'll have some good sense of context.

Mr. Kraut I do want to open it up and take the opportunity, because what we don't want to do is you work on regulations, come back to us and then we start asking all kinds of questions.

Mr. Kraut If anybody has any comments. Remember, they have limited ability to ask very direct answers.

Mr. Thomas This statute is quite detailed as you both mentioned. Inside of it there is an enormous amount of discretion and definitional things. When you're talking about 24/7 365 operations in general hospitals of a varying acuity. I guess, my only comment would be as you're developing your regulations and I'm sure you're in communication with operations folks, you've got an independent committee that includes general hospital operators that you'd be really sensitive to potentially some unintended consequences as you develop your regulations. You don't have to comment now, but there's a whole I mean, we have eight hospitals in our system, so we're doing this and just the precision of the statute pretty good, but now the regulations could really enhance or really detract from the ultimate goal from our perspective. Just a request. No need to respond. I'm sure you're seeking input from a lot of people, a lot of people with interest in this. No lack of opinions, I'm sure.

Mr. Hennessey The only thing I will add because I think it's important. I think we're always open to listening to anyone who has a viewpoint on this topic and pretty much any other topic we work on. I will say that in the work that we've done thus far, we've received a lot of information back from hospitals that really has told the story of what you're just talking about, that there is a level of complication and a level of specialization that you see in different types of care, but specifically from hospital to hospital, hospital that makes a level of uniqueness that we're trying to harmonize a lot of different sort of capabilities to get to there.

Mr. Kraut I suspect that's going to be your major challenge is because just no two patient units are identical, as you said. No two hospitals in any particular area. It has to have flexibility with respect to situational awareness. Obviously, everybody wants to staff at an optimum level. But if you can't recruit that staff, as you heard your actually the colleagues from the Department of Health today acknowledge we're having issues Upstate in particular and frankly, throughout, you know, you can have a regulation, but if you can't

recruit and it's very clear given the environment of the reasons why we can't, we have to work on solutions that allow us to do that. And that's, frankly, a little outside of the statute of the regs. There's a lot of interconnect.

Mr. Hennessey Thank you for saying that, Mr. Kraut.

Mr. Hennessey That requires flexibility in terms of individuals, training, care plans, etc. In some point the statute, the language and your regulations are going to conflict and ultimately collide with reality. Reality is what Mr. Kraut just said. Now, hopefully it's a pendulum and it'll swing back and we won't be having this conversation in a couple of years. While you're developing your regulations, you're hearing that.

Mr. Kraut Dr. Boufford has one comment.

Dr. Boufford It's sort of a question. I think it was raised by the presentation. Many of these elements were part of the nurse staffing standards regs that you brought forward. This is really, really, really helpful. You raised two magic words, workforce and quality, which we don't talk much about. I was just curious as to using that and the workforce issues. Obviously, Dr. Gutierrez has been on this for the last four or five years. Where does the input to us from that? Do those two categories come from? Not these clinical standards, but looking I know they're part of the waiver budget implied. There would be investment in workforce and workforce development. We had a little bit on what's going on with the Public Health Fellowship. It wasn't exactly, you know, it's useful, but not in depth. The same thing on the quality side. Do we address those two issues? Are they sitting somewhere where we could at least have a presentation about them if they're not in our remit?

Mr. Kraut Just specifically, we've had discussions here about joining the Interstate Compact that allows us access to licensed personnel from other states. That obviously would be a major help in addressing some of these things. There are things that are outside of DOH and Department of Education, Licensing and the pipeline issues as well. They're not necessarily in the department's purview, but they're certainly related. It's a complicated enough issue as it is. You guys have a responsibility to kind of move this along and bring it back to us.

Mr. Kraut I'll give Dr. Gutierrez the final word.

Dr. Gutierrez Somebody who has been removed from the trenches of hospital work and clinical care for a long time now, I still hear the calls from the people that are still in the trenches of what they have to do and what they cannot do because they don't have the time. It's a request for flexibility and try to appear not draconian on this, because I don't think that unless you put that in front of you, you're not going to have a high level of success soon.

Mr. Kraut Let me put a pin in the conversation. You've heard flexibility is the key word when you bring it back to this council for approval and review. We wish you well. We're here to work with you. We understand what needs to be done. There's a time frame to get this started. Please, at our next so let me just use this. I want to remind everybody that the next meeting of the council is going to be--.

Mr. Kraut I'm sorry.

Mr. Kraut John, did you want to speak?

Dr. Morley That's okay. I just wanted to remind folks that the legislature did identify money. We are creating in OPCHSM, the Center for Workforce Innovation. We're in the process of hiring a director and then we'll be hiring about eight or nine folks. This will be a part of my report going forward.

Mr. Kraut Great.

Mr. Kraut That's what Dr. Boufford was saying. Where's the money?

Mr. Kraut The next meeting of the council is going to be on November 17th in Albany and New York City for committee day, and on December 8th in Albany and New York City for the council meeting. On the eighth in particular, please try to have your schedules, arrange it. It's in both places. Both here and New York City. We may need a little more time to go through an agenda. I particularly just want to thank Colleen Leonard and Michael and the rest of the staff. She's now operating out of two locations simultaneously dealing with things. As you saw this morning with the Codes Committee, with a number of people to speak, it's very, very complex. I just want to also thank Celeste Johnson who is our Associate Commissioner and Regional Director for the support in helping us down here in New York City in particular. We really thank you. We know how much harder this is. Hopefully, the legislature will revisit some of the Zoom options for public and open meetings.

Mr. Kraut With that, I have a motion to adjourn the Public Health and Health Planning Committee meeting.

Mr. Kraut So moved, Dr. Berliner.

Mr. Kraut Second.

Mr. Kraut We are adjourned.

Mr. Kraut Thank you so much.



PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

Empire State Plaza, Corning Tower, Room 1805 Albany, New York 12237 (518) 402-0964 PHHPC@health.ny.gov

December 8, 2022

Senator Gustavo Rivera Chair, Senate Health Committee Assemblyman Richard Gottfried Chair, Assembly Health Committee New York State Legislature The Capitol Albany, NY 11237

Re: Nursing Home Minimum Direct Resident Care Spend Section 415.34 Title 10 NYCRR Nursing Home Staffing Requirements Sections 415.2 and 415.3 Title 10 NYCRR

I am writing at the request of the members of the NYS Public Health and Health Planning Council (PHHPC) regarding our recent review and approval of regulations to implement the two important pieces of legislation referenced above that were enacted as part of the 2021-2022 Executive Budget.

At the outset we want to commend both the Executive and the Legislative branches for addressing what PHHPC believes is an important issue, the quality of care delivered in New York State's nursing homes. As an oversight body we had struggled with this issue for years because of a lack of legislative and regulatory clarity. PHHPC welcomes the establishment of regulatory standards which attempt to more clearly define operating parameters related to strengthening the quality of care provided in skilled nursing facilities.

However, during our review of these specific proposed regulations at our November 17th Codes Committee hearing and subsequent full PHHPC Council meeting, our members were placed in a difficult position of having to approve a proposed regulation that closely conformed to the enacted statute but, in our view, did not fully address the complex realities of the operating environment that health care providers are now confronting. In particular, the current critical health care staffing shortage is having a profound impact on the provision of health care across the care continuum within New York State and we knowingly approved a regulation that a significant number of nursing home providers cannot comply with.

As you are aware, PHHPC is comprised of informed health professionals representing a continuum of interests and stakeholder groups including consumers, and we reluctantly approved the regulations because we were advised that delaying such action would have potentially resulted in significant penalties imposed on the nursing home industry and that the Commissioner would not have been granted discretionary enforcement powers to help interpret some of the more challenging statutory provisions. Therefore, even though many relevant issues were raised, PHHPC believed a failure to act at this juncture, may have undermined the intent to improve the quality of care rendered in New York State nursing homes. PHHPC acknowledges that this is not the best process to develop, discuss, and approve meaningful regulations.

PHHPC strongly believes that if the legislation were drafted today, with knowledge of the impact of the current staffing crisis, the statute would have anticipated some of the issues; certain definitions would be enhanced, and provisions broadened to improve the legislative intent of the statute.

In the coming months PHHPC members will be working closely with DOH staff, within the parameters of the enacted statute, to revise the regulations, where change or clarity may be warranted. However, some of the changes we seek may require legislative action. Therefore, as issues arise and are brought to your attention, it is PHHPC's fervent hope that the legislature will consider amending parts of these two statutes to address new, complex issues that were not previously anticipated and support efforts to achieve greater accountability for nursing home quality of care.

If invited, I and members of PHHPC would be available to discuss our concerns and ideas in greater detail.

Respectfully,

Jeffrey Kraut

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, Sections 2.1 and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, Section 2.6 is repealed and a new Section 2.6 is added, Section 405.3 is amended and a new Section 58-1.14 is added, to be effective upon filing with the Secretary of State, to read as follows:

Subdivision (a) of section 2.1 is amended to read as follows:

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting:

* * *

[Monkeypox] Mpox

* * *

Section 2.5 is amended to read as follows:

A physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such specimens as may be designated by the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination:

* * *

[Monkeypox] Mpox

* * *

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. Such investigations and response activities shall, consistent with any direction that the State Commissioner of Health may issue:
 - (1) Verify the existence of a disease or condition;
 - (2) Ascertain the source of the disease-causing agent or condition;
 - (3) Identify unreported cases;
 - (4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
 - (5) Collect and submit, 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) With the training or assistance of the State Department of Health, examine 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) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Take 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 and response activities.
 - (1) The State Commissioner of Health may elect to lead investigation and response 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 another state or states 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 and response activities pursuant to paragraph (1) of this subdivision, local health authorities shall take all reasonable steps to assist in such investigation and response, 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 or

response 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.

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:

(d) Records and reports. Any information, records or documents provided to the department shall be subject to the applicable provisions of the Public Health Law, Mental Hygiene Law, Education Law, and the Public Officers Law in relation to disclosure. The hospital shall maintain and furnish to the Department of Health, immediately upon written request, copies of all documents, including but not limited to:

* * *

- (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 and disease 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 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.

New section 58-1.14 is added to read as follows:

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.

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 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.

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.

Legislative Objectives:

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

The legislative objective of PHL § 2803 includes, among other objectives, authorizing PHHPC, 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.

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.

Needs and Benefits:

These regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to monitor the spread of disease, including actions related to investigation and response to a disease outbreak.

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

Part 2 Amendments:

- Amend sections 2.1 and 2.5 to reflect The World Health Organization's (WHO) decision to change the name of "monkeypox" to "Mpox" in an effort to reduce the stigma that monkeypox comes with and deal with possible misinformation falsely suggesting that monkeys are the main source of spreading the virus.
- Repeal and replace current section 2.6, related to investigations, to clarify existing local health department authority.

- Sets forth specific actions that local health departments must take to investigate a case, suspected case, outbreak, or unusual disease.
- Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
- While the Department works collaboratively with local health departments on a variety of public health issues, including disease control, this regulation clarifies the authority for the Commissioner to lead disease investigation activities under certain circumstances (i.e., where there is potential for statewide impact, multiple jurisdictions impacted, or impact on one or more New York State jurisdictions and another state or states), while working collaboratively with impacted local health departments. In all other situations, local health departments retain the primary authority and responsibility to control communicable disease within their respective jurisdictions, with the Department providing assistance as needed.
- Codify in regulation the requirement that local health departments send reports to the Department during an outbreak.

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).

Part 58 Amendments

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases
 - Requires the Commissioner to designate those communicable diseases that require prompt action, and to make available a list of such diseases 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 results, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

COSTS:

Costs to Regulated Parties:

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.

The requirement that hospitals submit syndromic surveillance reports when requested 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.

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 imposes any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

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. 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:

These emergency regulations will become effective upon filing with the Department of

State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19

pandemic is consistently and rapidly changing, it is not possible to determine the expected

duration of need at this point in time. The Department will continuously evaluate the expected

duration of these emergency regulations throughout the aforementioned 90-day effective period

in making determinations on the need for continuing this regulation on an emergency basis or

issuing a notice of proposed rulemaking for permanent adoption. This notice does not constitute

a notice of proposed or revised rule making for permanent adoption.

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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 imposes 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 44 counties have a population of less than 200,000 based upon 2020 United States Census data:

| Greene County | Schoharie County |
|--------------------|--|
| Hamilton County | Schuyler County |
| Herkimer County | Seneca County |
| Jefferson County | St. Lawrence County |
| Lewis County | Steuben County |
| Livingston County | Sullivan County |
| Madison County | Tioga County |
| Montgomery County | Tompkins County |
| Ontario County | Ulster County |
| Orleans County | Warren County |
| Oswego County | Washington County |
| Otsego County | Wayne County |
| Putnam County | Wyoming County |
| Rensselaer County | Yates County |
| Schenectady County | |
| | Hamilton County Herkimer County Jefferson County Lewis County Livingston County Madison County Montgomery County Ontario County Orleans County Oswego County Otsego County Putnam County Rensselaer 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
Dutchess County
Dutchess County
Erie County
Oneida County
Oneida County
Onondaga County
Onondaga 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, 405 and 58.

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.

EMERGENCY JUSTIFICATION

Where compliance with routine administrative procedures would be contrary to public interest, the State Administrative Procedure Act (SAPA) § 202(6) empowers state agencies to adopt emergency regulations necessary for the preservation of public health, safety, or general welfare. In this case, compliance with SAPA for filing of this regulation on a non-emergency basis, including the requirement for a period of time for public comment, cannot be met because to do so would be detrimental to the health and safety of the general public.

New York continues to experience significant community levels of COVID-19 disease with very densely populated areas at "high" and many highly populated counties at "medium." New York still has a 7-day average of over 3,400 cases per day, and over 2,700 people in the hospital affected by COVID each day. Regrettably, New York still averages 31 deaths per day associated with COVID-19.

Severe Acute Respiratory Syndrome Coronavirus -2 (SARS-CoV2) still mutates, although the current dominant strain is BQ1, a subvariant of Omicron, new more contagious variants continue to emerge, with CH1 the latest to emerge in New York and the country. The threat from emerging variants includes their unknown virulence affecting morbidity and mortality. It is also unknown how well existing vaccines or pharmacotherapeutics will protect against emerging variants.

New York is currently experiencing widespread Influenza cases and hospitalizations. Review of the Weekly Surveillance Report, week ending November 19, 2022 demonstrate this increase. Influenza, (Flu), has multiple strains, currently, in New York, Flu A, H3 strain is more common and has arrived much earlier than preceding years. Cases of Flu are increasing all over the state with largest increases currently in the Western Region. The increase of Flu, along with

COVID and other respiratory viruses has presented undue stress on the health care system in the state.

New York is also addressing the impact of Ebola Virus Disease, Sudan strain and the impact on the country. New York is at higher risk, since although there are only 5 airports where individuals from the affected area arrive in the United States, two of these airports (JFK and Newark) are in the greater metropolitan New York area. At present, over 350 people have been screened and over 50 people are being monitored; however, there are currently no active cases.

Furthermore, as stated in the declaration of the State disaster emergency Executive Order 21, a polio outbreak has affected multiple counties in the State of New York, with one paralytic case and detections of genetically related virus in six counties, indicating circulation and transmission of the virus likely in hundreds of people.

The emergency regulations are needed to continue requiring clinical laboratories to report all test results, including negative and indeterminate results, for communicable diseases such as COVID-19, polio and Ebola; mandate hospitals to report syndromic surveillance data; and permit the Commissioner to direct hospitals to take patients during a disease outbreak such as COVID-19 or Ebola.

Based on the ongoing burden of multiple outbreaks seen across the state, the Department has determined that these regulations are necessary to promulgate on an emergency basis to control the spread of highly contagious communicable diseases in New York State.

Accordingly, current circumstances necessitate immediate action, and pursuant to the State Administrative Procedure Act Section 206(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 201, 206, and 225 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 adding a new Section 2.60, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.60 is added to read as follows:

- 2.60. Face Coverings for COVID-19 Prevention.
- (a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, any person who is two years of age or older and able to medically tolerate a face-covering may be required to cover their nose and mouth with a mask or face-covering when: (1) in a public place and unable to maintain, or when not maintaining, physical distance; or (2) in certain settings as determined by the Commissioner, which may include schools, public transit, homeless shelters, correctional facilities, nursing homes, and health care settings, and which may distinguish between individuals who are vaccinated against COVID-19 and those that are not vaccinated. The Commissioner shall issue findings regarding the necessity of face-covering requirements at the time such requirements are announced.
- (b) Businesses must provide, at their expense, face-coverings for their employees required to wear a mask or face-covering pursuant to subdivision (a) of this section.

- (c) large-scale indoor event venues with more than five thousand attendees shall require patrons to wear face coverings consistent with subdivision (a) of this section; may require all patrons to wear a face covering irrespective of vaccination status; and may deny admittance to any person who fails to comply. This regulation shall be applied in a manner consistent with the federal Americans with Disabilities Act, New York State or New York City Human Rights Law, and any other applicable provision of law.
- (d) No business owner shall deny employment or services to or discriminate against any person on the basis that such person elects to wear a face-covering that is designed to inhibit the transmission of COVID-19, but that is not designed to otherwise obscure the identity of the individual.
- (e) For purposes of this section face-coverings shall include, but are not limited to, cloth masks, surgical masks, and N-95 respirators that are worn to completely cover a person's nose and mouth.
- (f) Penalities and enforcement.
 - (i) A violation of any provision of this Section is subject to all civil and criminal penalties as provided for by law. Individuals or entities that violate this Section are subject to a maximum fine of \$1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the Section shall constitute a separate violation under this Section.
 - (ii) All local health officers shall take such steps as may be necessary to enforce the provisions of this Section accordance with the Public Health Law and this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new Section 2.60 is sections 201, 206, and 225 of the Public Health Law.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State

Department of Health ("Department") to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing 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. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other 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, with a disproportionate risk of severe illness for older adults, those who have serious underlying medical health conditions and those who are unvaccinated.

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. Thereafter, the situation 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.

Now, more than two years after the first cases were identified in the United States COVID-19 continues to impact New York State. Beyond the ongoing COVID-19 burden in communities, certain settings such as nursing homes and health care settings, have been at increased risk for transmission. These regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. The regulations are necessary to permit flexibility to allow the Department to quickly adapt to changing circumstances related to the spread of COVID-19 and increasing transmission rates.

COSTS:

Costs to Regulated Parties:

As part of ongoing efforts to address COVID-19, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the

state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Costs to Local and State Governments:

State and local government are authorized to enforce civil and criminal penalties related to the violation of these regulations, and there may be some cost of enforcement, however such costs are anticipated to be minimal as these provisions continue existing enforcement requirements.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

As part of ongoing efforts to address COVID-19, local governments have been partners in implementing and enforcing measures to limit the spread and/or mitigate the impact of COVID-19 within their jurisdictions since March of 2020. Further, local governments have separate authority and responsibilities to control disease within their jurisdictions pursuant to PHL § 2100 and Part 2 of the State Sanitary Code.

Duplication:

There is no duplication of federal law.

Alternatives:

The alternative would be to not promulgate these emergency regulations. However, this alternative was rejected, as the Department believes this regulation will facilitate the Department's ability to respond to the evolving nature of this serious and ongoing communicable disease outbreak.

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 filing with the Department of State and will expire, unless renewed, 60 days from the date of filing. As COVID-19 is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 60-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling-making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address COVID-19, businesses and local government have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, this regulation will not have a significant impact on or cost to small business and local government.

Compliance Requirements:

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

Professional Services:

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

Compliance Costs:

As part of ongoing efforts to address COVID-19, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, this regulation will not have a significant impact.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As part of ongoing efforts to address COVID-19, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, 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:

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 44 counties have an estimated population of less than 200,000 based upon the 2019 United States Census county populations projections:

| Allegany County | Greene County | Schoharie County |
|--------------------|-------------------|---------------------|
| Broome County | Hamilton County | Schuyler County |
| Cattaraugus County | Herkimer County | Seneca County |
| Cayuga County | Jefferson County | St. Lawrence County |
| Chautauqua County | Lewis County | Steuben County |
| Chemung County | Livingston County | Sullivan County |
| Chenango County | Madison County | Tioga County |
| Clinton County | Montgomery County | Tompkins County |
| Columbia County | Ontario County | Ulster County |
| Cortland County | Orleans County | Warren County |
| Delaware 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 2019 United States Census population projections:

Albany County Niagara County Saratoga County

Dutchess County Oneida County Suffolk County

Erie County Onondaga County

Monroe County Orange County

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

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

Compliance Costs:

As part of ongoing efforts to address COVID-19, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the

state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As part of ongoing efforts to address COVID-19, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, 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.

JOB IMPACT STATEMENT

The Department of Health has determined that this regulatory change is necessary to prevent further complete closure of the businesses impacted, and therefore, while there may be lost revenue for many businesses, the public health impacts of continued spread of COVID-19 are much greater.

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other 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, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

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. Thereafter, the situation 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.

Now, more than two years after the first cases were identified in the United States, New York continues to experience significant community levels of COVID-19 disease with very densely populated areas at "high" and many highly populated counties at "medium." New York still has a 7-day average of over 3,400 cases per day, and over 2,700 people in the hospital affected by COVID each day. Regrettably, New York still averages 31 deaths per day associated with COVID-19. Beyond the ongoing COVID-19 burden in communities, certain settings such as nursing homes and health care settings, have been at increased risk for transmission.

Severe Acute Respiratory Syndrome Coronavirus -2 (SARS-CoV2) still mutates, although the current dominant strain is BQ1, a subvariant of Omicron, new more contagious variants continue to emerge, with CH1 the latest to emerge in New York and the country. The threat from emerging variants includes their unknown virulence affecting morbidity and mortality. It is also unknown how well existing vaccines or pharmacotherapeutics will protect against emerging variants.

To that end, these regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. Based on the foregoing, the Department has determined that these emergency regulations are necessary to permit flexibility to quickly adapt to changing circumstances and increasing transmission rates and control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

SUMMARY OF EXPRESS TERMS

This notice of proposed rulemaking amends 10 NYCRR Subpart 5-1 to include individual maximum contaminant levels (MCL) of 0.0000100 mg/L or 10 parts per trillion (ppt) for perfluorodecanoic acid (PFDA) perfluoroheptanoic acid (PFHpA), perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic Acid (PFNA); includes a combined MCL of 0.0000300 mg/L or 30 ppt for PFDA, PFHpA, PFHxS, PFNA, perfluorooctanic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) referred to collectively as perfluoroalkyl substances-6 (PFAS6); and establishes the first list of emerging contaminants (ECs) as well as notification levels for this list of ECs in accordance with Public Health Law § 1112. New sections, subdivisions, paragraphs and tables were added, and additional updates made to ensure clarity with implementation. This regulation applies to all community water systems and all non-transient noncommunity water systems.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 225 and 1112 of the Public Health Law, Subpart 5-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective April 1, 2023 for emerging contaminant monitoring, notification levels, and changes to maximum contaminant level monitoring requirements for perfluoroalkyl substances, and January 1, 2025 for maximum contaminant levels, to read as follows:

Existing subdivisions (ai)-(bn), (bo) and (bp)-(dn) of section 5-1.1 are re-lettered to be subdivisions (aj)-(bo), (bq) and (bs)-(dq), respectively. New subdivisions (ai), (bp), and (br) are added to section 5-1.1 to read as follows:

(ai) *Emerging Contaminant* means any physical, chemical, microbiological or radiological substance listed as an emerging contaminant pursuant to section 5-1.52 Table 3B of this Subpart.

(bp) *Notification Level* means the concentration level of an emerging contaminant in drinking water that the Commissioner has determined, based on available scientific information, warrants public notification and may require actions, which may include enhanced monitoring and activities to reduce exposure, pursuant to section 5-1.102 of this Subpart.

(br) perfluoroalkyl substance-6 (PFAS6) means the sum of the concentration of perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), perfluorononanonic acid (PFNA), perfluorodecanoic acid (PFDA), perfluorohexanesulfonic acid (PFHxS) and perfluoroheptanoic acid (PFHpA).

* * *

Subdivision 5-1.30(d) is modified to read as follows:

(d) Notwithstanding anything to the contrary in section 5-1.12, 5-1.23, 5-1.51 or 5-1.77 of this Subpart, if the public water system fails to comply with the treatment technique and/or the monitoring requirements of subdivision (a), (b), (c) or (g) of this section, fails to install the filtration and/or disinfection treatment required by this section or fails to comply with the avoidance criteria requirements contained in subdivision (c) of this section, the system violates this Subpart and shall make State and public notification, including any required mandatory health effects language. Pursuant to subdivision (c) of this section, if at any time the raw water turbidity exceeds five nephelometric turbidity units, the system shall consult with the State within 24 hours of learning of the exceedance. Based on this consultation, the State may determine that the exceedance constitutes a public health hazard, [as found]as defined in section 5-1.1[(bz)](cc)(4) of this Subpart, which requires a Tier 1 notification. When consultation does not take place within the 24-hour period, the water system must distribute a Tier 1 notification no later than 48 hours after the system learns of the violation. Ground water systems that are required to provide 4-log virus treatment, surface water systems and ground water under the direct influence of surface water (GWUDI) systems that use chemical disinfection must notify the State whenever residual disinfectant levels in the water entering the distribution system are less than the specified concentration pursuant to subdivisions (b) and (c) of this section. Any water system that uses chemical disinfection must make State notification whenever disinfectant residual levels entering the distribution system are not restored within four hours.

* * *

Subdivision 5-1.51(a) is modified to read as follows:

(a) The maximum contaminant levels, maximum residual disinfectant levels, notification levels and treatment technique requirements are listed in section 5-1.52 tables 1 through 7 of this Subpart. In the case where an MCL, MRDL or treatment technique requirement is exceeded, notwithstanding anything to the contrary contained in section 5-1.12 of this Subpart, the supplier of water will take the necessary steps to comply with this section, to ensure the protection of the public health, including the undertaking of remedial feasibility studies and the installation of a suitable treatment process. Compliance with the MCLs, MRDLs, notification levels and treatment technique requirements shall be determined by the procedures contained in section 5-1.52 tables 1 through 7 of this Subpart.

Subdivision 5-1.51(b) is modified to read as follows:

(b) The minimum monitoring requirements for each contaminant are listed in section 5-1.52 tables 8A through 12 and 15A of this Subpart. Unless otherwise specified, [except for] monitoring at public water systems with fewer than 15 service connections and which serve fewer than 25 persons, [where monitoring] will be at State discretion. For this section, State discretion shall mean requiring monitoring when the State has reason to believe an MCL, MRDL or treatment technique requirement has been violated, the potential exists for an MCL, MRDL or treatment technique violation, a contaminant level is equal to or exceeds a notification level or a contaminant may present a risk to public health.

Subdivision 5-1.51 (g) is amended to read as follows:

(g) Monitoring and reporting frequencies for specific contaminants may be established at State discretion whenever the State believes that a potential exists for an MCL or MRDL violation, for

<u>emerging contaminants at or above a notification level</u> or a contaminant may present a risk to public health.

A new subdivision (q) is added to section 5-1.51 as follows:

(q) The effective date of the PFAS6 MCL and the MCLs for PFNA, PFHxS, PFHpA and PFDA in section 5-1.52 table 3 is April 1, 2023. The supplier of water must comply with all requirements of this Subpart no later than January 1, 2025, except between April 1, 2023, and December 31, 2024 the supplier of water shall comply with 5-1.78(d) and (e) of this Subpart when an MCL is exceeded.

A new subdivision (r) is added to section 5-1.51 as follows:

(r) The Department, at its discretion, may provide financial assistance for compliance with the monitoring requirements in section 5-1.52 table 9E, to any public water system serving fewer than 10,000 persons upon showing that the costs associated with testing drinking water in compliance with this section would impose a financial hardship.

Section 5-1.52, Table 3 is amended to read as follows:

Table 3. Organic Chemicals Maximum Contaminant Level Determination

| Contaminants MCL Type of water system Determination of MCL violation | | | | |
|---|----------------------|---|---|--|
| Contaminants | (mg/L) | Type of water system | Determination of IVICL Violation | |
| General organic chemicals Principal organic contaminant (POC) Unspecified organic contaminant (UOC) Total POCs and UOCs | 0.005 0.05 0.1 | Community, NTNC and Transient [N]noncommunity (TNC) | If the results of a monitoring sample analysis exceed the MCL, the supplier of water shall collect one to three more samples from the same sampling point, as soon as practical, but within 30 days. An MCL violation occurs when at least one of the confirming samples is positive and the average of the initial sample and all confirming samples exceeds the MCL. | |
| Perfluoroalkyl substance-6 (PFAS6) ⁶ | 0.0000300 | Community, NTNC and TNC | If the results of a monitoring sample analysis exceed the MCL for PFAS6 as defined in Subdivision 5-1.1(br) of this Subpart, the supplier of water shall collect one to three more samples from the same sampling point, as soon as practical, but within 30 days. An MCL violation occurs when each of the PFAS6 confirming samples is positive ⁷ and the average of the initial PFAS6 sample and all confirming samples exceeds the MCL. ⁸ | |
| Disinfection byproducts ^{2,3} | | Community and NTNC | For systems required to monitor quarterly, the results of all analyses | |
| Total trihalomethanes | 0.080 | | at each monitoring location per quarter shall be arithmetically | |
| Haloacetic acids | 0.060 | | averaged and shall be reported to the State within 30 days of the public water system's receipt of the analyses. A violation occurs if the average of the four most recent sets of quarterly samples at a particular monitoring location (12-month locational running annual average (LRAA)) exceeds the MCL. If a system collects more than one sample per quarter at a monitoring location, the system shall average all samples taken in the quarter at that location to determine a quarterly average to be used in the LRAA calculation. If a system fails to complete four consecutive quarters of monitoring, compliance with the MCL will be based on an average of the available data from the most recent four quarters. An MCL violation for systems on annual or less frequent monitoring that have been increased to quarterly monitoring as outlined in Table 9A, is determined after four quarterly samples are taken. | |
| | | Transient noncommunity | Not applicable. | |

| Contaminants | MCL | Type of water system | Determination of MCL violation |
|---|------------|----------------------|--|
| | (mg/L) | | |
| Specific Organic Chemicals | | Community, NTNC and | If the results of a monitoring sample analysis exceed the MCL, the |
| Alachlor | 0.002 | Transient | supplier of water shall collect one to three more samples from the same |
| Aldicarb | 0.003 | [N]noncommunity | sampling point, as soon as practical, but within 30 days. An MCL |
| Aldicarb sulfone | 0.002 | | violation occurs when at least one of the confirming samples is positive |
| Aldicarb sulfoxide | 0.004 | | and the average of the initial sample and all confirming samples exceed |
| Atrazine ⁴ | 0.003 | | the MCL. |
| Benzo(a)pyrene | 0.0002 | | |
| Carbofuran | 0.04 | | |
| Chlordane | 0.002 | | |
| Di(2-ethylhexyl)phthalate | 0.006 | | |
| Dibromochloropropane (DBCP) | 0.0002 | | |
| 2,4-D | 0.05 | | |
| 1,4-Dioxane | 0.0010 | | |
| Dinoseb | 0.007 | | |
| Diquat | 0.02 | | |
| Endrin | 0.002 | | |
| Ethylene dibromide (EDB) | 0.00005 | | |
| Heptachlor | 0.0004 | | |
| Heptachlor epoxide | 0.0002 | | |
| Hexachlorobenzene | 0.001 | | |
| Lindane | 0.0002 | | |
| Methoxychlor | 0.04 | | |
| Methyl-tertiary-buty-ether(MTBE) | 0.010 | | |
| Pentachlorophenol | 0.001 | | |
| Perfluorodecanoic acid (PFDA) ⁶ | 0.0000100 | | |
| Perfluoroheptanoic acid (PFHpA) ⁶ | 0.0000100 | | |
| Perfluorohexanesulfonic acid (PFHxS) ⁶ | 0.0000100 | | |
| Perfluorononanoic acid (PFNA) ⁶ | 0.0000100 | | |
| Perfluorooctanesulfonic acid (PFOS) ⁶ | 0.0000100 | | |
| Perfluorooctanoic acid (PFOA) ⁶ | 0.0000100 | | |
| Polychlorinated biphenyls (PCBs) ⁵ | 0.0005 | | |
| Propylene glycol | 1.0 | | |
| Simazine | 0.004 | | |
| Toxaphene | 0.003 | | |
| 2,4,5-TP (Silvex) | 0.01 | | |
| 2,3,7,8-TCDD (dioxin) | 0.00000003 | | |
| Vinyl chloride | 0.002 | | |

A sample is considered positive when the quantity reported by the State approved laboratory is greater than or equal to the method detection limit.

- ² For systems monitoring yearly or less frequently, the sample results for each monitoring location is considered the LRAA for that monitoring location. Systems required to conduct monitoring at a frequency that is less than quarterly shall monitor in the calendar month identified in the monitoring plan developed under section 5-1.51(c). Compliance calculations shall be made beginning with the first compliance sample taken after the compliance date.
- 3 Systems that are demonstrating compliance with the avoidance criteria in section 5-1.30(c), shall comply with the TTHM and HAA5 LRAA MCLs; however the LRAA MCLs are not considered for avoidance purposes. For avoidance purposes, TTHMs and HAA5s are based on a running annual average of analyses from all monitoring locations.
- Syngenta Method AG–625, "Atrazine in Drinking Water by Immunoassay," February 2001, available from Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. Telephone: 336–632–6000, may not be used for the analysis of atrazine in any system where chlorine dioxide is used for drinking water treatment. In samples from all other systems, any result for atrazine generated by Method AG–625 that is greater than one-half the maximum contaminant level (MCL) (in other words, greater than 0.0015mg/L or 1.5 μg/L) must be confirmed using another approved method for this contaminant and should use additional volume of the original sample collected for compliance monitoring. In instances where a result from Method AG–625 triggers such confirmatory testing, the confirmatory result is to be used to determine compliance
- ⁵ If PCBs (as one of seven Aroclors) are detected in any sample analyzed using USEPA Method 505 or 508, the system shall reanalyze the sample using USEPA Method 508A to quantitate PCBs (as decachlorobiphenyl). Compliance with the PCB MCL shall be determined based upon the quantitative results of analyses using Method 508A.
- 6 Monitoring, reporting and public notification requirements are effective April 1, 2023. The supplier of water shall comply with the MCL requirements by January 1, 2025.
- A sample is considered positive when the quantity reported by the State approved laboratory is greater than or equal to the method detection limit for any of the PFAS6 analytes.
- 8 When averaging PFAS6 samples, each compound must be confirmed when performing the PFAS6 compliance calculation. Only results greater than or equal to the method detection limit can be used when calculating averages for each individual compound.

A new Table 3B is added to section 5-1.52 as follows

Table 3B. Emerging Contaminants – Notification Level Determination (Effective Date April 1, 2023)

| Contaminant ¹ | Abbreviation | Notification | Notification Level Determination |
|---|--------------|--------------|---|
| | | Level (mg/L) | |
| List 1 | | , 8 | |
| Perfluorododecanoic acid | PFDoA | 0.0000300 | If the sum of the concentration of these compounds in a monitoring |
| Perfluoroundecanoic acid | PFUnA | | sample is equal to or exceeds 0.0000300 mg/L, the supplier of water shall |
| 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid | 11Cl- | | collect one to three more samples from the same sampling point, as soon |
| | PF3OUdS | | as practical, but within 30 days. Public notification is required when at |
| 9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid | 9Cl- | | least one of the confirming samples is positive ² and the average of the |
| | PF3ONS | | initial sample and all confirming samples is at or above a notification |
| Hexafluoropropylene oxide dimer acid | HFPO-DA | | level. ^{3,4} |
| | (GenX) | | |
| Perfluoroheptanesulfonic acid | PFHpS | | |
| Perfluorobutanesulfonic acid | PFBS | 0.0001000 | If the sum of the concentration of these compounds in a monitoring |
| Perfluorohexanoic acid | PFHxA | | sample is equal to or exceeds 0.0001000 mg/L, the supplier of water shall |
| 4,8-Dioxa-3H-perfluorononanoic acid | ADONA | | collect one to three more samples from the same sampling point, as soon |
| 1H,1H, 2H, 2H-Perfluorohexane sulfonic acid | 4:2FTS | | as practical, but within 30 days. Public notification is required when at |
| 1H,1H, 2H, 2H-Perfluorooctane sulfonic acid | 6:2FTS | | least one of the confirming samples is positive ² and the average of the |
| 1H,1H, 2H, 2H-Perfluorodecane sulfonic acid | 8:2FTS | | initial sample and all confirming samples is at or above a notification |
| Nonafluoro-3,6-dioxaheptanoic acid | NFDHA | | level. ³ |
| Perfluorobutanoic acid | PFBA | | |
| Perfluoro (2-ethoxyethane) sulfonic acid | PFEESA | | |
| Perfluoro-4-methoxybutanoic acid | PFMBA | | |
| Perfluoro-3-methoxypropanoic acid | PFMPA | | |
| Perfluoropentanoic acid | PFPeA | | |

| Perfluoropentanesulfonic | PFPeS | |
|--------------------------|-------|--|

- 1 Sample collection shall begin during the 3-year monitoring period starting April 1, 2023. Samples collected to satisfy the requirements of 40 CFR 141.140 shall satisfy the requirements of this Subpart, provided samples are collected in accordance with Appendix 5-C of this Subpart.
- A sample is considered positive when the quantity reported by the State approved laboratory is greater than or equal to the minimum reporting level established in 40 CFR 141.140 for any analyte on List 1.
- When averaging emerging contaminant samples, each compound must be confirmed when performing the emerging contaminant notification level calculation. Only results greater than or equal to the minimum reporting level established in 40 CFR 141.140 may be used when calculating averages for each individual compound.
- 4 Notification is required if the average concentration of HFPO-DA (GenX) is equal to or exceeds 0.000010 mg/L.

Section 5-1.52, Table 9C is repealed and replaced with a new Table 9C to read as follows:

Table 9C. Additional Organic Chemicals – Minimum Monitoring Requirements

| Conta | minant | Type of water system | Initial requirement | Continuing requirement where detected ^{1,2,3,4} | Continuing requirement where not detected ¹ |
|---|---------------------------|----------------------------|---|--|---|
| Synthetic Organic Compoun | ds | • | | | |
| Alachlor | Endothall | Community and | Quarterly sample per | Quarterly | One sample every |
| Aldicarb | Endrin | Nontransient | source, for one year ^{1,5} | | eighteen months per |
| Aldicarb sulfone | Glyphosate | noncommunity | | | source ^{6,7,8} |
| Aldicarb sulfoxide | Heptachlor | serving 3,300 or | | | |
| Aldrin | Heptachlor epoxide | more persons. | | | |
| Atrazine | Hexachlorobenzene | | | | |
| Benzo(a)pyrene | Hexachlorocyclopentadiene | | | | |
| Butachlor | 3-Hydroxycarbofuran | | | | |
| Carbaryl | Lindane | | | | |
| Carbofuran | Methomyl | | | | |
| Chlordane | Methoxychlor | Community and | Quarterly samples per | Quarterly | Once per entry point |
| Dalapon | Metribuzin | Nontransient | entry point for one | | every three years ^{6,7,8} |
| Di(2-ethylhexyl) adipate | Oxamyl (vydate) | noncommunity | year ^{6,7,8} | | |
| Di(2-ethylhexyl) phthalate | Pentachlorophenol | serving fewer than | | | |
| Dibromochloropropane | Picloram | 3,300 persons. | | | |
| Dicamba | Polychlorinated byphenyls | | | | |
| 2,4-D | Propachlor | | | | |
| Dieldrin | Simazine | | | | |
| Dinoseb | 2,3,7,8-TCDD (Dioxin) | | | | |
| 1,4-Dioxane | 2,4,5-TP (Silvex) | <u>Transient</u> | State discretion ⁹ | State discretion ⁹ | State discretion ⁹ |
| Diquat | Toxaphene | noncommuity | | | |
| Perfluoroalkyl substances ¹⁰ | | excluding NTNC | | | |
| Perfluorodecanoic acid (PFI | | Community and nontransient | Quarterly samples per source for one year ^{1,8,10} | Quarterly | One sample every eighteen months per |
| Perfluoroheptanoic acid (PF) | | noncommunity | | | source ^{6,7,8} |
| Perfluorohexanesulfonic acid | , | serving 3,300 or | | | |
| Perfluorononanoic acid (PFN | NA) | more persons | | | |

| Perfluorooctanesulfonic acid (PFOS) | Community and | Quarterly samples per | Quarterly | Once per entry point |
|-------------------------------------|--------------------|---------------------------------------|-------------------------------|------------------------------------|
| Perfluorooctanoic acid (PFOA) | Nontransient | source for one year ^{1,8,10} | | every three years ^{6,7,8} |
| | noncommunity | | | |
| | serving fewer than | | | |
| | 3,300 persons | | | |
| | Community | State discretion | State discretion ⁹ | State discretion ⁹ |
| | serving fewer than | | | |
| | 15 service | | | |
| | connections or 25 | | | |
| | persons | | | |
| | Transient | State discretion ⁹ | State discretion ⁹ | State discretion ⁹ |
| | noncommunity | | | |

- The location for sampling of each ground water source of supply shall be representative of each source between the individual well and at or before the first service connection and before mixing with other sources, unless otherwise specified by the State to be at the entry point. Public water systems which take water from a surface water body or watercourse shall sample at points in the distribution system representative of each source or at entry point or points to the distribution system after any water treatment plant.
- The State may decrease the quarterly monitoring requirement to annually provided that system is reliably and consistently below the MCL based on a minimum of two quarterly samples from a ground water source and four quarterly samples from a surface water source. Systems which monitor annually must monitor during the quarter that previously yielded the highest analytical result. Systems serving fewer than 3,300 persons and which have three consecutive annual samples without detection may apply to the State for a waiver in accordance with footnote 6.
- 3 If a contaminant is detected, repeat analysis must include all analytes contained in the approved analytical method for the detected contaminant.
- Detected as used in the table shall be defined as reported by the State approved laboratory to be greater than or equal to the method detection limit.
- The State may allow a system to postpone monitoring for a maximum of two years, if an approved laboratory is not reasonably available to do a required analysis within the scheduled monitoring period.
- The State may waive the monitoring requirement for a public water system that submits information every three years to demonstrate that a contaminant or contaminants was not used, transported, stored or disposed within the watershed or zone of influence of the system.
- The State may reduce the monitoring requirement for a public water system that submits information every three years to demonstrate that the public water system is invulnerable to contamination. If previous use of the contaminant is unknown or it has been used previously, then the following factors shall be used to determine whether a waiver is granted.

 a. Previous analytical results.
 - b. The proximity of the system to a potential point or nonpoint source of contamination. Point sources include spills and leaks of chemicals at or near a water treatment facility or at manufacturing, distribution, or storage facilities, or from hazardous and municipal waste landfills and other waste handling or treatment facilities. Nonpoint sources include the use of pesticides to control insect and weed pests on agricultural areas, forest lands, home and gardens, and other land application uses.
 - c. The environmental persistence and transport of the pesticide, PCBs, PFAS6 or 1,4-dioxane.
 - d. How well the water source is protected against contamination due to such factors as depth of the well and the type of soil and the integrity of the well casing.
 - e. Elevated nitrate levels at the water supply source.
 - f. Use of PCBs in equipment used in production, storage or distribution of water.
- 8 The State may allow systems to composite samples in accordance with the conditions in Appendix 5-C of this Title.
- State discretion shall mean requiring monitoring when the State has reason to believe the MCL has been violated, the potential exists for an MCL violation, emerging contaminants are at or above the notification level or the contaminant may present a risk to public health.
- All samples must be analyzed using USEPA method 533: Determination of Per- and Polyfluoroalklyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry or USEPA method 537.1: Determination of Selected Per- and Polyfluoroalklyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS). All compounds analyzed shall be reported to the State along with all pertinent information from the laboratory performing the analysis. Failure to report all compounds in the approved analytical method is a monitoring and reporting violation. All PFAS results are subject to the Department's review. Invalidated results shall not be used in determining compliance with the MCLs. If a sample is invalidated, the supplier of water shall collect and analyze a replacement sample.

A new Table 9E is added to section 5-1.52 as follows:

Table 9E. Emerging Contaminants – Minimum monitoring requirements

| Contaminant ¹ | Abbreviation | Type of Water System | Initial Requirement ³ | Continuing requirement at or above Notification Level ⁴ |
|---|----------------|---|--|---|
| List 1 (Effective date April 1, 2023) | | | | |
| Perfluorododecanoic acid | PFDoA | Community water | One sample per entry | One sample per entry |
| Perfluoroundecanoic acid | PFUnA | system serving 25 or | point. ² | point per year. |
| 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid | 11Cl-PF3OUdS | more persons. | | |
| 9-Chlorohexadecafluoro-3-oxanonane-1-sulfonic acid | 9Cl-PF3ONS | | | |
| Hexafluoropropylene oxide dimer acid | HFPO-DA (GenX) | | | |
| Perfluoroheptanesulfonic acid | PFHpS | Community water system serving fewer than 25 persons. | One sample per entry point. ⁵ | One sample per entry point per year. ⁵ |
| Perfluorobutanesulfonic acid | PFBS | | | |
| Perfluorohexanoic acid | PFHxA | | | |
| 4,8-Dioxa-3H-perfluorononanoic acid | ADONA | | | |
| 1H,1H, 2H, 2H-Perfluorohexane sulfonic acid | 4:2FTS | | | |
| 1H,1H, 2H, 2H-Perfluorooctane sulfonic acid | 6:2FTS | | | |
| 1H,1H, 2H, 2H-Perfluorodecane sulfonic acid | 8:2FTS | Nontransient | One sample per entry | One sample per entry |
| Nonafluoro-3,6-dioxaheptanoic acid | NFDHA | noncommunity water | point. | point per year. |
| Perfluorobutanoic acid | PFBA | systems. | | |
| Perfluoro (2-ethoxyethane) sulfonic acid | PFEESA | | | |
| Perfluoro-4-methoxybutanoic acid | PFMBA | | | |
| Perfluoro-3-methoxypropanoic acid | PFMPA | | | |
| Perfluoropentanoic acid | PFPeA | | | |
| Perfluoropentanesulfonic | PFPeS | | | |

- 1 Every covered public water system shall monitor drinking water for the presence of emerging contaminants within three years of the List effective date.
- 2 Public water systems that are required to monitor in accordance with 40 CFR sections 141.40-141.42 (UCMR) shall submit all sample results to the Department.
- 3 The supplier of water shall notify the Department within 24-hours of receiving confirmed sample results at or above the NL.
- 4 If sampling confirms that contaminants are present at or above the notification level during initial monitoring, subsequent confirmation samples are not needed during required continuing monitoring.
- 5 Results for PFAS6 must also be reported, and compliance determination made in accordance with table 3A.

Section 5-1.52 Table 13 has been amended to read as follows:

Table 13 – REQUIRED NOTIFICATIONS

| Contaminant/Situation (Subpart 5-1 citations | Single sample exceeds | MCL/MRDL/TT ¹ Violation and other | Failure to meet monitoring requirements and/or failure to |
|--|---|---|---|
| ` . | MCL/MRDL ¹ | notification requirements | use applicable testing procedure |
| Public Health Hazard (Section 5-1.1(bz)) ² | Not applicable | State Tier 1 | State Tier 1 |
| Escherichia coli (E. coli) in distribution system (Section 5-1.52, Tables 6, 11 and 11B) | State ³ Not applicable, or Tier 1 ⁴ | State Tier 1 | State Tier 3, or Tier 1 ⁵ |
| Total coliform in distribution system (Section 5-1.52, Tables 6, 11 and 11B) | Not applicable | State ⁸ Tier 2, or Tier 1 ⁹ | State Tier 3, or Tier 2 as directed by State |
| Entry Point Turbidity monthly average (Section 5-1.52, Tables 4 and 10) | State ¹⁰ | State Tier 2 | State Tier 3 |
| Entry Point Turbidity two-day average (Section 5-1.52, Tables 4 and 10) | State | State Tier 2, or Tier 1 ¹¹ | State Tier 3 |
| Raw Water Turbidity (Subdivision 5-1.30(d) and Section 5-1.52, Table 10A) | State | State Tier 2, or Tier 1 ¹¹ | State Tier 3 |
| Filtered Water Turbidity Single exceedance of the maximum allowable Turbidity level (Section 5-1.52, Tables 4A and 10A) | State | State Tier 2, or Tier 1 ¹¹ | State Tier 3 |
| Filtered Water Turbidity Treatment Technique violation (Section 5-1.52, Tables 4A and 10A) | Not applicable | State Tier 2 | State Tier 3 |
| Distribution Point Turbidity (Section 5-1.52, Tables 5, 10 and 10A) | Not applicable | State Tier 2 | State Tier 3 |
| Treatment Technique violations other than turbidity12,13 (Sections 5-1.12, 5-1.30, 5-1.32, 5-1.81, and 5-1.83 and Subdivision 5-1.71(d)) | Not applicable | State Tier 2, or Tier 1 ^{2,13} | State Tier 3 ¹³ , or Tier 2 ¹² |
| Free chlorine residual less than 0.2 mg/L at the entry point ¹⁴ (Subdivision 5-1.30(d)) | Not applicable | State | Not applicable |
| Free chlorine residual less than required minimum for a ground water system or ground water source required to provide 4-log virus treatment15 (Subdivision 5-1.30(a)) | Not applicable | State Tier 2, or Tier 1 ⁹ | Tier 2 |
| Inorganic chemicals and physical characteristics listed in Tables 8A and 8B (Section 5-1.52, Tables 1, 8A, and 8B) | State | State Tier 2 | State Tier 3 |
| Chloride, iron, manganese, silver, sulfate, and zinc (Section 5-1.52, Tables 1 and 8D) | Not applicable | State Tier 3 | State Tier 3 |
| Sodium (Section 5-1.52, Tables 1 and 8D) | State if the level exceeds 20 mg/L | Tier 2 if the level exceeds 270 mg/L | Tier 3 |
| Nitrate, Nitrite, Total Nitrate and Nitrite (Section 5-1.52, Tables 2 and 8C) | State | State Tier 1 | State Tier 1, or Tier 3 ¹⁶ |
| Lead and Copper (Sections 5-1.40 to 1.48) | Not applicable | State | State |

| | | Tier 2 | Tier <u>3</u> |
|---|--------------------|----------------------|--------------------------|
| Organic Chemicals [Group 1 and 2] (Section 5-1.52, Table 9C) | State | State | State |
| | | Tier 2 | Tier 3 |
| Principal Organic Contaminants Unspecified Organic Contaminants | State | State | State |
| Total POCs and UOCs | | Tier 2 | Tier 3 |
| (Section 5-1.52, Tables 3, 9B and 9D) | | | |
| Radiological Contaminants (Section 5-1.52, Tables 7 and 12) | State | State | State |
| | | Tier 2 | Tier 3 |
| Monitoring and Control of Disinfection Byproduct Precursors | Not applicable | State | State |
| (Sections 5-1.60 to 5-1.64) | | Tier 2 | Tier 3 |
| Disinfectant residuals Chlorine and Chloramine (Section 5-1.52, | State | State | State |
| Tables 3A and 15A) | | Tier 2 | Tier 3 |
| Disinfectant residual Chlorine dioxide at entry point (Section 5-1.52, | State | State | State |
| Tables 3A, 15 and 15A) | | Tier 2 | Tier 3, or Tier 2^{17} |
| Disinfectant residual Chlorine dioxide in distribution system (Section | State | State | State |
| 5-1.52, Tables 3A, 15 and 15A) | | Tier 1 ¹⁸ | Tier 1 ¹⁸ |
| Disinfection byproducts Trihalomethanes Haloacetic acids (Section 5- | Not applicable | State | State |
| 1.52, Tables 3 and 9A) and Bromate and Chlorite (Section 5-1.52, | | Tier 2 | Tier 3 |
| Tables 1 and 8B) | | | |
| Acrylamide and Epichlorohydrin (Subdivision 5-1.51(m)) | Not applicable | State | Not applicable |
| | | Tier 2 | |
| Operation under a variance, exemption or deferral (Sections 5-1.90 to | Not applicable | Tier 3 | Not applicable |
| 5-1.96 and section 5-1.51(p)) | | | |
| Violation of conditions of a variance, exemption or deferral (Sections | Not applicable | State | Not applicable |
| 5-1.90 to 5-1.96 and section 5-1.51(p)) | | Tier 2 | |
| Disruption of water service of four hours or more (Subdivision 5-1.23(b)) | Not applicable | State ¹⁹ | Not applicable |
| Emerging contaminants confirmed at or above the notification level | State ⁸ | State | <u>State</u> |
| | | Other ²⁰ | <u>Tier 3</u> |

MCL – maximum contaminant level, MRDL – maximum residual disinfectant level, TT-treatment technique

² Community systems must describe in their annual water supply statement (see section 5-1.72(e) and (f)) any Public Health Hazard that is determined to be a violation, and any uncorrected significant deficiency, and must indicate whether corrective action has been completed. This notice must be repeated every year until the annual report documents that corrective action has been completed in accordance with section 5-1.22 of this Subpart.

³ State notification must be made by the supplier of water within 24 hours of learning of an E. Coli positive sample

⁴ Public notification normally does not have to be issued for an *E. Coli* positive sample prior to the results of repeat samples. However, there may be situations where the State determines that a Tier 1 notification is necessary to protect public health. The supplier of water must provide the Tier 1 notification no later than 24 hours after learning of the State's determination.

Failure to test for *E. Coli* requires a Tier 1 notification if testing is not performed after any repeat sample tests positive for coliform. All other *E. coli* monitoring and testing procedure violations require Tier 3 notification.

At a ground water system, Tier 1 notification is required after initial detection of E. coli or other fecal indicator in raw source water, if the system does not provide 4-log virus treatment and process compliance monitoring. Confirmation of E. coli or other fecal indicator in the source water requires Tier 1 notification. Failure to take confirmatory samples may be a public health hazard requiring Tier 1 notification.

Notice of the fecal indicator positive raw water sample must be made in the annual water supply statement (see section 5-1.72(e)), until the annual report documents that corrective action has been completed.

⁸ State notification must be made by the supplier of water within 24 hours of learning of the violation or emerging contaminants at or above the notification level.

- ⁹ Tier 2 notification is normally required; however, there may be situations where the State determines that a Tier 1 notification is necessary to protect the public health. The supplier of water must provide the Tier 1 notification no later than 24 hours after learning of the State's determination.
- If the daily entry point analysis exceeds one NTU, a repeat sample must be taken as soon as practicable, and preferably within one hour. If the repeat sample exceeds one NTU, the supplier of water must make state notification.
- Systems must consult with the State within 24 hours after learning of the violation. Based on this consultation, the State may subsequently decide to elevate the violation from a Tier 2 to a Tier 1 notification. If consultation does not take place within the 24-hour period, the water system must distribute a Tier 1 notification no later than 48 hours after the system learns of the violation.
- These violations include the following: failure to comply with the treatment technique or monitoring requirements in section 5-1.30(a), (b), (c), and (g) of this Subpart; failure to comply with the avoidance criteria in section 5-1.30(c) of this Subpart; failure to cover a finished water storage facility or treat its discharge required in section 5-1.32 of this Subpart; failure to report to the state information required in section 5-1.72(c)(3) of this Subpart; failure to maintain records required in section 5-1.72(d)(7) of this Subpart; and failure to meet the treatment and bin classification requirements associated with Cryptosporidium in section 5-1.83 of this Subpart. Failure to collect three or more samples for Cryptosporidium analysis as required in section 5-1.81 of this Subpart is a Tier 2 violation requiring public notification. Failure to perform any other monitoring and testing procedure as required in section 5-1.81 of this Subpart is a Tier 3 violation.
- Any significant deficiency that is not corrected, or where correction has not begun according to a State-approved corrective action plan within 120 days, or as directed by the State, is a TTV and must be addressed in accordance with section 5-1.12. If the deficiency is a public health hazard, the deficiency must be addressed as directed by the State and Tier 1 notification is required.
- Applies to systems that have surface water or groundwater directly influenced by surface water as a source and use chlorine. The system must make State notification whether the residual was restored to at least 0.2 mg/L within four hours.
- 15 Required minimum chlorine residual at point that demonstrates adequate CT for disinfected water from ground water sources at first customer.
- Failure to take a confirmation sample within 24 hours for nitrate or nitrite after an initial sample exceeds the MCL requires a Tier 1 notification. Other monitoring violations for nitrate or nitrite require a Tier 3 notification.
- Failure to monitor for chlorine dioxide at the entrance to the distribution system the day after exceeding the MRDL at the entrance to the distribution system requires a Tier 2 notification. Other monitoring violations for chlorine dioxide at the entrance to the distribution system require a Tier 3 notification.
- 18 If any daily sample taken at the entrance to the distribution system exceeds the MRDL for chlorine dioxide and one or more samples taken in the distribution system the next day exceed the MRDL, Tier 1 notification is required. Failure to take the required samples in the distribution system the day after the MRDL is exceeded at the entry point also triggers Tier 1 notification.
- 19 Tier 1 notification is required if the situation meets the definition of a public health hazard.
- Whenever one or more emerging contaminants is confirmed to be present in drinking water at concentrations at or above a notification level, the supplier of water for community and nontransient noncommunity water systems must provide public notification to owners of real property no later than ninety days after the system learns of samples at or above the notification level in accordance with paragraph 5-1.78(f) of this Subpart.

* * *

Section 5-1.70 is amended as follows:

5-1.70 Applicability. Sections 5-1.70 through 5-1.79 of this Subpart shall be applicable to all public water systems, provided the systems serve 15 or more service connections or serve 25 or more persons. Subdivisions 5-1.71 (c) and (d), subdivision 5-1.72 (c), [and] paragraph 5-1.78(a) (4), paragraph 5-1.78(b) (3), and subdivision 5-1.78 (f) of this [Part]Subpart apply to all public water systems.

Subdivision (f) of section 5-1.72 is amended to read as follows:

(f) The report shall contain such information as is required in this subdivision and any additional information required by the State, except that paragraph [(7)](8) and subparagraphs [(13)](14)(vii) through (xi) of this subdivision shall not apply to systems serving fewer than 1,000 service connections. The information required to be included in the report is described below.

* * *

- (5) Definitions for emerging contaminant and notification level. Each report must include the definitions set forth using the following language:
- (i) Emerging Contaminant (EC). Any physical, chemical, microbiological or radiological substance listed as an emerging contaminant pursuant to 10 NYCRR Part 5, Subpart 5-1, Section 5-1.52 Table 3B that does not have a MCL listed in accordance with 10 NYCRR Part 5, Subpart 5-1, Section 5-1.52 Table 3.
- (ii) Notification Level (NL). The concentration level of an emerging contaminant in drinking water that the Commissioner has determined, based on available scientific information, warrants

public notification and may require actions, which may include enhanced monitoring and activities to reduce exposure.

[(5)] (6) Information on detected contaminants from sampling used to determine compliance. For the purpose of this subdivision (except Cryptosporidium, Giardia and radon monitoring), detected means: at or above the contaminant's method detection limit (MDL), as defined in section 5-1.1[(bl)](bm) of this Subpart, or as prescribed by the State. Any contaminants specified in sections 5-1.41 (lead and copper) and 5-1.51 of this Subpart and section 5-1.52 tables 8A, 8B, 8C, 8D, 9A, 9B, 9C, 9D, 9E, 10, 10A, 11, 11A, 11B, 12, 16 and 17 of this Subpart that are detected during compliance monitoring shall be displayed in one table or in several adjacent tables. Additionally, the report shall include detected monitoring results for samples collected and analyzed by the State and/or detected monitoring results of additional samples required by the State. If a system is allowed to monitor for specific contaminants less often than once a year, the table shall include the date and results of the most recent sampling and the report shall include a brief statement indicating that the data presented in the report are from the most recent testing done in accordance with the regulations. No data older than five years need be included. For the contaminants listed in section 5-1.52 tables 8A, 8B, 8C, 8D, 9A, 9B, 9C, 9D, 10, 10A, 11, 11B, 12, 16 and 17 of this Subpart the table(s) shall contain:

* * *

Existing paragraphs (6) - (17) of subdivision 5-1.72(f) are renumbered to paragraphs (7) - (18) and new paragraph (19) is added to read as follows:

(19) Any contaminants listed in section 5-1.52 Table 3B of this Subpart that are detected during monitoring shall be displayed in one table or in several adjacent tables. Additionally, the report

shall include detected monitoring results for samples collected and analyzed by the State and/or detected monitoring results of additional samples required by the State. The table shall include the date and results of the most recent sampling and the report shall include a brief statement indicating that the data presented in the report are from the most recent testing done in accordance with the regulations. For the contaminants listed in section 5-1.52 Table 3B of this Subpart, the table(s) shall contain:

(i) the notification level for that contaminant expressed as a number equal to or greater than 1.0;(ii) the highest contaminant level detected and the range of detected levels.

Subparagraph 5-1.72(g)(1)(v) is amended to read as follows:

(v) If a supplement is prepared in accordance with paragraph (f)[(7)](8) of this section, the report must contain a statement that describes that the analytical results for source water samples not used to determine compliance are contained in a supplement and that the supplement is available to the customer on request. The supplement shall also be:

Paragraph 5-1.72(h)(5) is amended to read as follows:

(5) A community water system that sells water to another community water system, must deliver the applicable information required in paragraphs (f)(1), [(5)](6)-[(10)](11) and [(13)](14) of this section to the buyer system:

Subdivision 5-1.74(c) is amended to read as follows:

(c)The owner of a water system shall ensure <u>that all analyses performed by the [approved]</u> environmental laboratory [performing the analyses sends laboratory results to the department]

<u>certified in accordance with Subpart 55-2 of this title, are sent</u> to the <u>State</u> [department] electronically in a manner prescribed by the department.

Subdivisions (a) and (b) of section 5-1.77 are amended to read as follows:

- (a) The supplier of water shall make State notification within 24 hours of learning of the existence or potential existence of a public health hazard, analytical results that are equal to or exceed a notification level, or within 48 hours for any other violation or situation that may pose a risk to public health. Section 5-1.52 Table 13 of this Subpart lists violations and situations that require State notification.
- (b) The information provided in a State notification shall include, but not be limited to, the following:
- (1) a description of the violation, notification level or situation, including the contaminant(s) of concern, and (as applicable) the contaminant level;
- (2) when the violation, notification level or situation occurred;
- (3) what the system is doing to correct the violation, notification level or situation; and
- (4) <u>as applicable</u>, when the water system expects to return to compliance.

Subdivision 5-1.78(a) has been amended to read as follows:

(a) General public notification requirements. Each owner or operator of a public water system must provide public notification for public health hazards, and for all MCL, MRDL, treatment technique, monitoring and testing procedure violations, emerging contaminants at or above the notification level and for other situations posing a risk to public health. Public notification requirements are divided into three tiers to take into account the seriousness of the violation or

situation and any potential adverse health effects that may be involved. The form, manner, frequency, and other requirements for each tier and notification requirements for emerging contaminants at or above the notification level are described in subdivisions (c)-[(e)](h) of this section. Section 5-1.52 table 13 of this Subpart lists the required public notification (Tier 1, Tier 2,[or] Tier 3 or notification requirements for emerging contaminants) for specific violations and other situations posing a risk to public health.

Subdivision (b) of section 5-1.78 is amended to read as follows:

(b) Content, presentation, and standard language requirements for all public notifications.

* * *

- (3) When a public water system confirms one or more emerging contaminants is present in drinking water at or above the notification level, the public notice must contain the following elements:
- (i) a description of emerging contaminants and notification levels, including the contaminants of concern, and the contaminant level;
- (ii) when the samples were collected;
- (iii) available health effects information as provided by the Department;
- (iv) any actions required by the Department, which may include enhanced monitoring and activities to reduce exposure;
- (v) the phone number of the water system owner, operator, or designee of the public water system as a source of additional information concerning the notice; and
- (vi) the phone number of the county or district health department which has jurisdiction over the water system.

[(3)](4) Notice presentation. Each public notice required by this section:

* * *

[(4)](5) Standard Language.

* * *

A new subdivision (f) is added to section 5-1.78 and existing subdivisions (f) - (h) are amended to read as follows:

- (f) Notification requirements for emerging contaminants
- (1) Whenever one or more emerging contaminants is confirmed to be present in drinking water at concentrations at or above a notification level, the supplier of water for community and nontransient noncommunity water systems must provide public notification to owners of real property no later than ninety days after the system learns of samples at or above the notification level.
- (2) The supplier of water may use a single public notice for multiple violations, emerging contaminants confirmed to be at or above the notification level or situations that require public notification, as long as the timing requirements of paragraph (1) of this subdivision are met.

 Community water systems may use the Annual Water Supply Statement (report) (see section 5-1.72(e)-(h) of this Subpart) to provide public notice about emerging contaminants confirmed to be at or above the notification level as long as the requirements of paragraph (1) are met.
- (3) The supplier of water must provide public notices in a form and manner reasonably expected to reach all persons served by the water system.
- (i) Community water systems must provide notice by mail or other delivery method(s) approved by the Department to each customer receiving a bill, and to other service connections to which

water is delivered by the public water system; and by any other method reasonably expected to reach other persons served by the system.

(ii) Unless directed otherwise by the State in writing, noncommunity water systems must provide notice by posting the notice in conspicuous locations, and by any other method(s) reasonably expected to reach other persons served by the system if they would not normally be reached by posting.

[(f)](g) Notice to new billing units or new customers. Community water systems must give a copy of the most recent public notice for any continuing violation, the existence of a variance or exemption, emerging contaminants at or above the notification level or other ongoing situations requiring a public notice to all new billing units or new customers prior to or at the time service begins.

[(g)](h) Information on unregulated contaminants.

* * *

[(h)](i) Notice by the State on behalf of the public water system.

* * *

Subdivision (d) of section 5-1.91 is amended to read as follows:

(d) The technologies listed in this section are the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for organic chemicals listed in section 5-1.52 table 3 of this Subpart:

| Contaminant | В | Best Available Technologies | | | | |
|--------------------|------------------|-----------------------------|--------|--|--|--|
| Alachlor | PTA ¹ | GAC^2 | OX^3 | | | |
| Aldicarb | | X | | | | |
| Aldicarb sulfone | | X | | | | |
| Aldicarb sulfoxide | | X | | | | |
| Atrazine | | X | | | | |
| Benzene | X | X | | | | |

| Benzo(a)pyrene | | X | |
|--|---|----------|---|
| Carbofuran | | X | |
| Carbon tetrachloride | X | X | |
| Chlordane | Λ | X | |
| Dalapon | | X | |
| Di(2-ethylhexyl)adipate | X | X | |
| | Λ | X | |
| Di(2-ethylhexyl)phthalate Dibromochloropropane | X | X | |
| 1,1-Dichloroethylene | X | X | |
| | X | X | |
| para-Dichlorobenzene o-Dichlorobenzene | X | X | |
| 1,2-Dichloroethane | X | X | |
| | | | |
| cis-1,2-Dichloroethylene | X | X | |
| trans-1,2-Dichloroethylene | X | X | |
| Dichloromethane | X | | |
| 1,2-Dichloropropane | X | X | |
| Dinsoeb | | X | |
| 1,4-Dioxane | | | X |
| Endothal | | X | |
| Endrin | | X | |
| Ethylbenzene | X | X | |
| Ethylene dibromide | X | X | |
| Glyphosate | | | X |
| Heptachlor | | X | |
| Heptachlor epoxide | | X | |
| Hexachlorobenzene | | X | |
| Hexachlorocyclopentadiene | X | X | |
| Lindane | | X | |
| Methoxychlor | | X | |
| Monochlorobenzene | X | X | |
| Oxamyl (Vydate) | | X | |
| PCBs | | X | |
| Pentachlorophenol | | X | |
| PFAS6 | | <u>X</u> | |
| Picloram | | X | |
| Simazine | | X | |
| Styrene | X | X | |
| 2,3,7,8 -TCDD (Dioxin) | | X | |
| Tetrachloroethylene | X | X | |
| Toluene | X | X | |
| Toxaphene | | X | |
| 2,4,5 -TP | | X | |
| 1,2,4 -Trichlorobenzene | X | X | |
| 1,1,1 -Trichloroethane | X | X | |
| 1,1,2 -Trichloroethane | X | X | |
| Trichloroethylene | X | X | |
| Vinyl chloride | X | | |
| Xylenes (total) | X | X | |
| TTHM, HAA5, Bromate, Chlorite ⁴ | | | |
| 1 11111, 111 11 15, Diolinuo, Cinolino | | 1 | |

Packed Tower Aeration

² Granular Activated Carbon

³ Oxidation (Chlorination or Ozonation) and Advanced Oxidation Process (AOP)

For surface water systems or ground water systems influenced by surface water, GAC10, as defined in section 5-1.1 of this Subpart, is the BAT for compliance with the TTHM and HAA5 MCL as a Running Annual Average (RAA). The other BAT for RAA compliance is

enhanced coagulation for TTHM and HAA5 precursor removal, as described in section 5-1.60 of this Subpart. For compliance with the MCLs for TTHM and HAA5 as LRAAs, the following are the BATs: enhanced coagulation or enhanced softening, plus GAC10; GAC20, as defined in section 5-1.1 of this Subpart;

or nanofiltration with a molecular weight cutoff less than or equal to 100 Daltons. Refer to section 5-1.65 of this Subpart for BATs for TTHM, HAA5, Bromate, and Chlorite.

Section 5-1.100 is renumbered to section 5-1.110 and new sections 5-1.100 through 5-1.102 are added, to read as follows:

§ 5-1.100 Applicability. The provisions of this section and sections 5-1.101 and 5-1.102 of this Subpart shall become effective on April 1, 2023 and apply to any public water system that serves at least five service connections used by year-round residents or that regularly serves at least twenty-five year-round residents; or a public water system that regularly serves at least twenty-five of the same people, four hours or more per day, for four or more days per week, for twenty-six or more weeks per year.

§ 5-1.101 Monitoring requirements for emerging contaminants.

- (a) The minimum monitoring requirements for emerging contaminants are listed in section 5-1.52 table 9E of this Subpart. Samples collected in accordance with 40 CFR sections 141.40-141.42 may be used to satisfy the requirements of this subdivision, notwithstanding the requirements of subdivision (c) of this section.
- (b) Unless the Department notifies the supplier of water in writing that samples shall be collected at an alternate location, all samples shall be collected in accordance with section 5-1.52 table 9E of this Subpart.
- (c) Every test conducted in accordance with section 5-1.52 table 9E of this Subpart shall be conducted by an environmental laboratory approved pursuant to Subpart 55-2 of this Title.

Laboratories shall submit such results electronically to the Department, in accordance with subdivision 5-1.74(c) of this Subpart.

(d) The Department may collect and analyze water samples from any public water system for emerging contaminants at any time, either by its own personnel or by contract with others.

§ 5-1.102 Notification Levels

- (a) The notification levels are located in 5-1.52 table 3B of this Subpart. Whenever one or more emerging contaminants is confirmed to be present in drinking water at concentrations at or above a notification level established pursuant to this Subpart, the supplier of water shall take the following actions:
- (1) The water supplier shall notify the State electronically within twenty-four hours in a manner acceptable to the Department.
- (2) the water supplier shall issue public notification in accordance with subdivision 5-1.78(f) of this Subpart.
- (3) The State may directly notify such owners of real property if it is determined that the public's interest would be best served by such notification, or if the State determines that the covered public water system is not acting or cannot act in a timely manner.
- (b) Notwithstanding anything contrary to this Subpart, the Commissioner may, by declaration, add any physical, chemical, microbiological or radiological substance to the list of emerging contaminants in section 5-1.52 Table 3B of this Subpart, establish a notification level, and require monitoring for such substance, if the Commissioner determines that: (i) such substance poses or has the potential to pose a significant hazard to human health when present in drinking water; (ii) such substance was recently detected in a public water system and has the potential to

be present in other public water systems; and (iii) it appears to be prejudicial to the interests of the people to delay action by preparing and filing regulations. The Commissioner shall, however, promulgate regulations adding such new emerging contaminant or establishing such notification level within one year of such declaration. Such declaration shall clearly state where and the date by which such monitoring must occur. After the Commissioner promulgates regulations adding such emerging contaminant, such regulations shall supersede the declaration issued pursuant to this subdivision.

(c) the Commissioner may require that the covered public water system take such actions as may be appropriate to reduce exposure to emerging contaminants. If the Commissioner determines that the concentration of the emerging contaminant constitutes an actual or potential threat to public health in accordance with subdivision 5-1.1(cc) of this Subpart, based on the best available scientific information, the Commissioner shall consult with the Commissioner of the Department of Environmental Conservation regarding any further action that may be appropriate, including but not limited to actions pursuant to title twelve of article twenty-seven of the Environmental Conservation Law.

The title of subdivision (B) of section (II) of Appendix 5-C is amended to read as follows: B. Water Sample Compositing Requirements for Pesticides, Dioxin, PCBs, [PFOA, PFOS,] Perand Polyfluoroalkyl Substances and 1,4-Dioxane.

SUMMARY OF REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 201(1)(l) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include the regulation of the sanitary aspects of public water systems (PWS). Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. Section 1112 establishes the authority to require monitoring for emerging contaminants and establish notification levels.

Legislative Objective:

The legislative objective of section 1112 of the PHL is to ensure that the Department promulgates regulations for emerging contaminants and establishes notification levels for those contaminants. This amendment will update the SSC per the recommendations of the Drinking Water Quality Council, by establishing MCLs for four (4) additional perfluoroalkyl substances, modifying reporting requirements, requiring monitoring for emerging contaminants and establishing notification levels.

Needs and Benefits:

Emerging Contaminants Monitoring Requirements (ECMR): Public Health Law Section 1112 (PHL 1112) requires the Department to adopt ECMR. The effective date of the monitoring requirements will be April 1, 2023.

Notification Levels (NL): PHL § 1112 requires that NL be established for twenty-three PFAS designated as emerging contaminants. The first category is a sum of 6 compounds to 0.0000300 mg/L (30 ppt) with a 10 ppt notification level for hexafluoropropylene oxide-dimer acid (HFPO-DA/GenX) and the second category is a sum of 13 compounds to 0.000100 mg/L (100 ppt). Decisions on each PFAS chemical's notification category were made based on an evaluation of liver toxicity effect levels, human half-lives, established reference doses, and chemical structure similarities. The 30 ppt notification levels applies to the sum of six (6) PFAS compounds and the 100 ppt NL applies to the sum 13 PFAS compounds. Confirmed sample results that are at or above either NL will prioritize evaluations of the public water system, allow for exposure reduction recommendations based on those evaluations, and provide advanced communication to the community served by the water system.

Maximum Contaminant Levels (MCL): The Department proposes MCLs of 10 ppt each for perfluorohexanesulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA). A combined MCL of 30 ppt is proposed for the sum of PFOA, PFOS, PFHxS, PFHpA, PFNA and PFDA (PFAS6). The Department estimates a 1.46 percent increase in MCL violations if MCLs for PFHxS, PFHpA, PFNA, and PFDA are promulgated at 10 ppt each.

Costs

Compliance Costs

ECMR: PHL § 1112 applies to both community water systems (CWS) and nontransient noncommunity water systems (NTNC). The cost of analysis is estimated to be between \$350

and \$700 per sample. The cost to the average water system, based on 1.7 entry points per system, is between \$595 and \$1,190.

NL: The Department estimates a notification cost of \$5, including labor, fees and postage, per service connection that needs to be notified. Four (4) water systems are expected to distribute public notification for the first category and 26 water systems are expected to exceed the NL for the second category.

MCL: There are approximately 3,000 PWS that will be required to routinely monitor for PFNA, PFDA, PFHxS and PFHpA. Initial monitoring for PFAS6 compounds must be completed by December 31, 2023. Each PWS will be required to comply with the MCL by January 1, 2025. This proposal modifies the analytical requirements by mandating reporting all compounds in EPA 537.1 or EPA 533. The Department estimates that the cost of the full analytical method will be between \$350 and \$700 per sample. The number of samples required is based on number of sources, and compliance monitoring results. Less sampling is required when no contaminants are detected.

Costs to Private Regulated Parties

ECMR: The ECMR apply to CWS) and NTNC water systems, including private water systems. It is estimated that a significant percentage of the approximately 2,200 PWS that serve less than 1,000 people are privately owned. The total estimated cost to these PWS is \$1,309,000 and \$2,618,000. There are approximately 550 PWS that serve fewer than 25 people or five service connections that will be required to comply. The total cost to these water systems is anticipated to be \$327,250-\$654,500. These exact costs are dependent on variables such as the

number of sources and/or entry points, the source water type the level of contaminants detected and are therefore difficult to estimate. The costs are dependent the number of sources and/or entry points, the source water type and the level of contaminants detected.

NL: The cost of notices is estimated to be \$5 per connection.

MCL: Monitoring and treatment costs for each privately-owned PWS is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The cost for a single sample for emerging contaminants is between \$350-\$700 per sample using either USEPAUSEPA method 533 or 537.1, including field reagent blank costs. Compliance monitoring for PFNA, PFHxS, PFDA and PFHpS can be conducted using either USEPA method 533 or 537.1.

Privately-owned water systems with MCL violations will be required to take actions to come into compliance, which may require the installation of treatment. The U.S. Environmental Protection Agency (USEPA) has developed a cost estimating tool for different PFAS treatment options. Total annualized costs using this costing tool include capital costs for the purchase of treatment system components (amortized over an approximately 20-year period) and annual operation and maintenance costs. The cost estimating tool approximates that total annualized costs for systems serving 501 to 3,330 persons could range from \$87,700 to \$134,000, systems serving 3,301 to 10,000 persons could range from \$335,000 to \$489,500, systems serving 10,001 to 50,000 persons could range from \$1,016,000 to \$1,476,900, systems serving 50,001 to 100,000 persons could range from \$2,281,900 to \$3,316,800, and systems serving more than 100,000 persons could range from \$7,255,600 to \$10,640,000 based on 2020 dollars and the use of granular activated carbon (GAC) treatment. The approximate total annualized cost for GAC

treatment for these very small systems could range from \$19,800 to \$33,300, and the approximate costs for providing point-of-use units could range from \$1,700 to \$33,800

Cost to State Government:

ECMR: Approximately 250 state operated facilities will be required to comply. The cost of monitoring is anticipated to be between \$350 and \$750 per entry point. The cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190 per water system for a total financial impact to the State of between \$148,750 and \$295,500.

The Department will incur costs to implement the ECMR. The cost to the Department will range from \$682,000 for salary, fringe and information technology for regulatory implementation and enforcement only. The estimated cost is \$9,000,000 for a program that includes monitoring assistance for small and disadvantaged communities that serve fewer than 3,300 people.

NL: The Department estimates that the cost per notice will be \$5 per connection.

MCL: State agencies that operate a PWS will be required to comply with the proposed amendments. There are approximately 250 State-owned or operated facilities.

Costs will include monitoring and treatment in the event of a MCL exceedance. These potential costs will be the same as the costs to private regulated parties.

The proposed regulation will also create administrative costs to the Department as well as costs to the NYS Department of Environmental Conservation (NYSDEC).

Cost to Local Government:

The regulations will apply to local governments which own or operate a PWS.

ECMR: There are approximately 1,500 PWS that are owned or operated by local governments. The cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190 per water system. As a result, the total cost to local government for monitoring is expected to be between \$892,500 and \$1,785,000. Water systems with more entry points will have a proportionally higher cost.

NL: There are approximately 1,500 PWS that are owned or operated by local governments. It is expected that 13 notifications will be required. The Department estimates a cost of \$5 per connection.

MCL: The regulations will apply to local governments. There are approximately 1,500 PWS that are owned or operated by local governments. Costs will include monitoring for PFHxS, PFHpA, PFNA, PFDA and/or PFAS6, and treatment in the event of a MCL violation.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight.

Local Government Mandates:

Local governments will be required to comply with this regulation as noted above.

Paperwork:

ECMR and NL: The ECMR and NL are new monitoring and regulatory programs with associated paperwork, tracking and enforcement.

MCL: The additional monitoring, reporting, recordkeeping and paperwork needed for PFAS6 is expected to be minimal. The reporting and recordkeeping requirements will increase if MCLs are exceeded and/or treatment is required.

Duplication:

The ECMR is duplicative with the federal Unregulated Contaminant Monitoring Rule (UCMR) for each PWS that serves 3,300 or more people. For NL and MCL, there will be no duplication.

Alternatives:

Three alternatives to MCLs were considered: 1. maintain the existing MCL of 0.05 mg/L that applies to all organic chemicals when no chemical specific MCL exists for PFNA, PFHxS, PFHpA and PFDA; 2. wait for the US USEPA to issue a federal MCL; or 3. promulgate an MCL for PFNA, PFHxS, PFHpA and PFDA at 10 ppt each. Based on deliberations of the DWQC and the additional toxicological analysis conducted by the Department it was determined that the current MCL of 0.05 mg/L is not protective of public health for these four specific chemicals. Waiting for the USEPA to set a new MCL was impractical due to the prevalence and concerns surrounding these compounds combined with the timeframes required under the Safe Drinking Water Act.

The 10 ppt standard, while health protective, will allow for a total concentration of upwards of 60 ppt, which is not sufficiently health protective. Therefore, the Department determined that adoption of the MCLs as recommended by DWQC for PFNA, PFHxS, PFHpA

and PFDA, as well as establishing PFAS6 MCL is in the best interest of protecting the public health.

Federal Standards:

The ECMR proposal is similar to UCMR5 but expands the scope by extending applicability to PWS that serve fewer than 3,300 persons. There are no federal standards for NL and MCL.

Compliance Schedule:

Each PWS will begin monitoring for emerging contaminants beginning April 1, 2023. A PWS may monitor in accordance with the schedule established by USEPA for UCMR5. The effective date for NLs is April 1, 2023. Public notification is required for a PWS that detects or has detected emerging contaminants at or above the NL. For MCL, all water systems must begin monitoring for PFAS6 and report all compounds in the analytical method beginning April 1, 2023. If the MCL is exceeded or compounds are detected at or above a NL, public notification is required. Compliance with the MCL is required by January 1, 2025.

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REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the proposed regulations is set forth in Public Health Law (PHL) Sections 201, 225 and 1112. Section 201(1)(1) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include the supervision and regulation of the sanitary aspects of public water system (PWS). Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. Further, section 225(5)(a) of the PHL allows the SSC to deal with any matter affecting the security of life or health, or the preservation or improvement of public health, in New York State and allows the Department to establish Maximum Contaminant Levels (MCL). Section 1112 establishes the authority to require monitoring for emerging contaminants and establish notification levels.

Legislative Objective:

The legislative objective of sections 201 and 225 of the PHL is to ensure that the Department and PHHPC, in conjunction with the Commissioner of Health, protect public health by adopting drinking water sanitary standards. The legislative objective of section 1112 of the PHL is to ensure that the Department promulgates regulations defining the monitoring requirements for emerging contaminants and establishes notification levels for those contaminants. In accordance with those objectives, this regulation amends the SSC by revising Part 5 to enhance current protections governing PWS. Furthermore, this amendment will update the SSC in accordance with the recommendations of the Drinking Water Quality Council

(DWQC), by establishing MCLs for four (4) additional perfluoroalkyl substances and modifying reporting requirements, requiring monitoring for the emerging contaminants listed in the PHL and establishing notification levels.

Needs and Benefits:

PHL § 1112 specifically lists 23 per- and polyfluoroalkyl substances (PFAS) as emerging contaminants, for which the Department must adopt monitoring and public notification requirements for every covered public water system. PFAS are a group of synthetic organic chemicals that have been manufactured or used throughout the United States in a wide range of consumer products and industrial applications. They have been used in non-stick cookware, water-repellent clothing, stain-resistant fabrics and carpets, cosmetics, firefighting foams, electroplating, and products that resist grease, water, and oil.

The DWQC, established pursuant to PHL § 1113, is charged with making recommendations to the Department on which compounds should be listed as emerging contaminants and their corresponding notification levels. After discussion and deliberation spanning several meetings, the DWQC voted to accept the Department's recommendation to proceed with regulations adopting the first list of emerging contaminants with two notification level categories; adopt MCLs of 10 ppt for PFHxS, PFHpA, PFNA and PFDA; and have the Department evaluate the feasibility of an MCL that is the sum of six (6) PFAS compounds. PHL § 1112 directs that, through regulation, any substance can be removed from the list of emerging contaminants upon adopting a maximum contaminant level for such substance. Available toxicology information and occurrence data support the Department's recommendation to

exclude PFHxS, PFHpA, PFNA and PFDA from the first emerging contaminants list in favor of substance specific MCLs.

Emerging Contaminants Monitoring Requirements:

In 2021, PHL § 1112 was amended to include the first list of emerging contaminants and required that the commissioner publish regulations to adopt the following compounds as emerging contaminants within 180 days: perfluorononanoic acid (PFNA); perfluorohexanesulfonic acid (PFHxS); perfluoroheptanoic acid (PFHpA); perfluorobutanesulfonic acid (PFBS); hexafluoropropylene oxide dimer acid (HFPO-DA); Perfluorodecanoic acid (PFDA); Perfluorododecanoic acid (PFDoA); Perfluorohexanoic acid (PFHxA); Perfluoroundecanoic acid (PFUnA); 11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS); 9-chlorohexadecafluoro-3-oxanonane-1-sulfonic acid (9Cl-PF3ONS); 4,8-dioxa-3H-perfluorononanoic acid (ADONA); Nonafluoro-3,6-dioxaheptanoic acid (NFDHA); Perfluorobutanoic acid (PFBA); 1H, 1H, 2H, 2HPerfluorodecane sulfonic acid (8:2FTS); Perfluoro(2-ethoxyethane)sulfonic acid (PFEESA); Perfluoroheptanesulfonic acid (PFHpS); 1H,1H, 2H, 2H-Perfluorohexane sulfonic acid (4:2FTS); Perfluoro-3methoxypropanoic acid (PFMPA); Perfluoro-4-methoxybutanoic acid (PFMBA); 1H,1H, 2H, 2H-Perfluorooctane sulfonic acid (6:2FTS); and Perfluoropentanoic acid (PFPeA); Perfluoropentanesulfonic acid (PFPeS).

The Department is amending 10 NYCRR Part 5 to establish monitoring requirements for the emerging contaminants listed above, except for PFHxS, PFHpA, PFNA and PFDA. As described above, an MCL will be established for these compounds, and monitoring will be conducted in accordance with the MCL. Per PHL § 1112, establishing an MCL will remove these compounds from the emerging contaminant list.

Notification Levels for Emerging Contaminants:

In 2021, PHL § 1112 was amended to require the Commissioner to promulgate regulations establishing notification levels for any listed emerging contaminant. The PHL requires notification levels be equal to or lower than any federal lifetime health advisory level established pursuant to the federal Safe Drinking Water Act (42 U.S.C. § 300g-1), if available. For the current compounds listed as emerging contaminants, there are no federal lifetime health advisory levels.

Based on a review of available scientific literature, the Department presented two categories of notification levels to the DWQC on May 2, 2022. The first category is the prioritized PFAS notification level category and is a sum of six chemicals to 0.0000300 mg/L (30 ppt) with a 10 ppt notification level for hexafluoropropylene oxide-dimer acid (HFPO-DA/GenX) and the second category is a sum of 13 compounds to 0.000100 mg/L (100 ppt). The remaining PFAS notification level category is the sum of 13 chemicals to 0.000100 mg/L (100 ppt). These chemicals are listed in Table 1.

Table 1 – Summary of Notification Level Categories

| Prioritized PFAS Notification Level Category | Remaining PFAS Notification Level Category | | |
|--|--|-----------------|--|
| Notification Level = 30 ppt | Notification Level = 100 ppt | | |
| Sum of 6 Chemicals | Sum of 13 Chemicals | | |
| PFHpS | PFBA | 4:2FTS | |
| PFUnA | PFBS | 6:2FTS | |
| PFDoA | PFPeA | 8:2FTS | |
| GenX* | PFPeS | NFDHA | |
| 9Cl-PF3ONS | PFHxA | PFEESA | |
| 11Cl-PF3OUdS | ADONA | PFMPA | |
| | | PFMBA | |
| * Notification is required if HFPO-DA (GenX) is ed | ual to or exceeds 0.000010 | mg/L or 10 ppt. | |

New York State currently has MCLs for perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) at 0.0000100 milligrams-per-liter (mg/L) or 10 parts-per-trillion (ppt) each. Monitoring for PFOA and PFOS has been conducted since 2020-2021 for the 3,000 PWS required to monitor. When the MCL for PFOA or PFOS is exceeded, the existing regulation requires the water system to collect between one and three follow up samples to confirm the levels of the compound in drinking water. The confirmation samples are required to include all analytes reported in the approved analytical method. Similarly, when either PFOS or PFOA are detected above the method detection limit, regulations require that subsequent quarterly monitoring includes all analytes contained in the approved analytical method. As such, the Department has a robust dataset on the occurrence of additional PFAS compounds, based on analytical data reported by approximately 1,000 PWS.

Based on an evaluation of the existing monitoring data, it was determined that the six compounds in the prioritized PFAS notification level category occurred at levels between 2.1 and 10 ppt in 13 PWS; 10.1-20 ppt in four (4) PWS; 20.1-30 ppt in one (1) PWS; and 50.1-75 ppt in one (1) PWS. The thirteen compounds in the remaining PFAS notification level category occurred at levels between 2.1-10 ppt in 286 PWS; 10.1-20 in 89 PWS; 20.1-30 ppt in 32 PWS; 30.1-40 ppt in 17 PWS; 40.1-50 ppt in 7 PWS; 50.1-75 ppt in 12 PWS; 75.1-100 ppt in 5 PWS; and >100 ppt in 13 PWS. As such 0.12% of PWS or four (4) PWS would be required to provide

public notification due to the presence of compounds at or above the notification level in the first category and 2.45% of PWS or 87 PWS would be required to provide public notification due to presence of compounds at or above the notification level in in the second category.

During a public meeting of the DWQC on May 2, 2022, the Department presented detailed technical information on the toxicology of emerging contaminants, as well as on the general methods used to derive health-based drinking water concentrations that are protective against noncancer health effects. These presentations included key citations to the extensive, publicly available scientific literature upon which the Department relied.

Notification levels rather than chemical specific MCLs are implemented for these 19 emerging PFAS because the available toxicity information for most of these chemicals does not inform derivation of chemical-specific health-based drinking water values, which is an important step in the MCL derivation process. There are also limited state-specific occurrence data for most of the 19 PFAS. Implementing notification levels for these emerging PFAS will provide occurrence data to inform future prioritization of chemical-specific drinking water standards and will identify drinking water systems for possible exposure reduction measures. Notification levels will also provide advance communication to the community served by the water system if such a level is exceeded.

The Department presented an approach to the DWQC that separates the 19 emerging PFAS into two notification level categories. The notification level categories are based on differences in the available toxicity¹ and human half-life information for the 19 emerging PFAS. One category is designated for emerging PFAS having toxicity and half-life information indicating the need for prioritization and notification at a lower water concentration. The second

¹ Studies evaluating the carcinogenicity of most of the 19 emerging PFAS are not available. Therefore, noncancer toxicity information was used for this notification level approach.

category is designated for the remaining emerging PFAS, for which the currently available toxicity and half-life information is either insufficient or does not indicate a need for including in the group of prioritized PFAS chemicals.

The Department identified chemicals for the prioritized lower notification level category based on four criteria:

- A low liver toxicity effect level observed in laboratory animal studies
- A long-estimated half-life in humans
- A low reference dose established by one or more authoritative bodies
- A chemical structure similar to chemicals with low toxicity effect levels, long human half-lives, or low reference doses.

If the available information for the emerging PFAS satisfied any of these criteria, the Department included the chemical in the prioritized notification level category. The Department used the liver toxicity effect level because it provides a consistent means of comparison across several of the 19 emerging PFAS, and is a well-established, sensitive endpoint for this group of chemicals. Liver toxicity was consistently observed in two comparative rat toxicity studies of seven short-and long-chain PFAS conducted by the National Toxicology Program (NTP 2018a,b). The NTP reported that liver toxicity was induced at lower dose levels of long-chain PFAS (PFHxS, PFOA, PFOS, PFNA, and PFDA) compared to the short-chain PFAS (PFBS and PFHxA). Chemicals with lower effect levels are considered more toxic than those with higher effect levels, and therefore PFAS with relatively low effect levels for liver toxicity were prioritized for the lower notification level category.

The human half-life is a measure of how long a chemical remains in the body. Longchain PFAS have been shown to have substantially longer half-lives in humans when compared to short-chain PFAS (ATSDR 2021). Longer human half-lives among PFAS are generally associated with greater toxicity, and therefore provide a basis for prioritizing emerging PFAS for the lower notification level category.

The reference dose is an estimate of the daily oral lifetime human exposure to a chemical that is not expected to result in adverse noncancer health effects. Reference doses are set at exposure levels much lower than those known or estimated to cause health effects. A low reference dose indicates a higher degree of toxicity for a chemical than one with a higher reference dose. Reference doses for several of the emerging PFAS have been derived by authoritative bodies, and therefore the Department prioritized emerging PFAS that have a relatively low reference dose (indicating a greater degree of toxicity) for the lower notification level category.

If data on effect levels and human half-life were not available or insufficient, and if a reference dose was not available, similarities in chemical structure to other PFAS having more information on these parameters were also used as a basis for selecting the notification level category for the chemical.

Of the 19 emerging PFAS that were considered for the notification level approach, six met the criteria to be prioritized for the lower notification level. The available toxicity, half-life, and reference dose information for each of these six chemicals is provided in Table 2.

Table 2. Toxicity, Human Half-life, and Reference Dose Information for Six Emerging PFAS Prioritized for the Lower Notification Level Category

| Emerging PFAS | Liver Toxicity Effect Level (mg/kg/day) | Estimated Human Half-Life | Reference Dose (ng/kg/day) |
|--------------------|---|--|----------------------------------|
| PFHpS ^a | - | 1.46 – 4.7 years (Xu et al. 2020; Li et al. 2019) | - |
| PFUnA | 0.3 (Takahashi et al. 2014) | 4.5 – 12 years (Zhang et al. 2013, as cited in ATSDR 2021) | - |
| PFDoA ^b | 0.5 (Kato et al. 2015) | - | - |

| | 0.5 | 81 hours | 3 |
|----------------|------------------------------|---------------------------------|-----------|
| Gen-X c | (Dupont 2010, as cited in US | (US USEPA 2021a using data from | (US USEPA |
| | USEPA 2021a) | Clark 2021) | 2021a) |
| 9Cl-PF3ONS | 0.04 | 15.3 years | |
| 9CI-PF3UNS | (Zhang et al. 2018) | (Shi et al. 2016) | - |
| 11Cl-PF3OUdS d | | > 15.3 years | |
| 11CI-PF3OUdS a | - | (Shi et al. 2016) | - |

^a Toxicity studies are limited for PFHpS and a liver toxicity effect level is not available. The estimated PFHpS human half-life is long (measured in multiple years), and PFHpS is structurally similar to fully fluorinated, straight-chain perfluoro sulfonic acids that have low effect levels and long human half-lives (e.g., PFHxS, PFOS). PFHpS differs from PFHxS and PFOS by only one carbon atom in the fully fluorinated carbon chain. Therefore, PFHpS is included in the prioritized, lower notification level category.

The remaining 13 emerging PFAS are placed in a second notification level category. For these chemicals, the available information suggests higher effect levels, (higher doses of the chemical are required to cause an adverse health effect) and shorter human half-lives (the chemical is removed from the body faster) than are reported for chemicals in the prioritized notification level category. Additionally, the established reference doses for three of these 13 PFAS (PFBA, PFBS, PFHxA) are much higher than reference doses of the long-chain identified for the chemical-specific MCL approach (reference doses were all below 5 ng/kg/day for PFHxS, PFHpA, PFNA, and PFDA), as well the reference doses for the currently regulated PFAS (PFOA and PFOS). These considerations support grouping the 13-remaining emerging PFAS in a second and higher notification level category. Toxicity, half-life, and reference dose information for the remaining 13 emerging PFAS is summarized in Table 3.

Table 3. Toxicity, Human Half-life, and Reference Dose Information for the Remaining 13 Emerging PFAS for the Second Notification Level Category

| Emerging PFAS | Liver Toxicity Effect | Estimated Human | Reference Dose |
|---------------|-------------------------------|---|--------------------------|
| | Level (mg/kg/day) | Half-Life | (ng/kg/day) |
| PFBA | 30 (Butenhoff et al. 2012) | 3 days (Change et al. 2008, as cited in ATSDR 2021) | 1000 (US USEPA 2021b) |

^b Human half-life estimates for PFDoA are not available. The liver toxicity effect level is similar to PFUnA, which is a structurally similar long-chain PFAS with a long estimated human half-life. Therefore, PFDoA is included in the prioritized, lower notification level category.

^c Gen-X has a short estimated human half-life, but a low effect level for liver toxicity. The Gen-X reference dose is consistent with established reference doses for PFAS having a greater degree of relative toxicity (reference doses for PFOA, PFOS, PFHxS, PFHpA, PFNA, and PFDA are all lower than 5 ng/kg/day). Therefore, Gen-X is included in the prioritized, lower notification level category.

^d Toxicity studies are limited for 11Cl-PF3OUdS, and a liver toxicity effect level is not available. One study suggests that the 11Cl-PF3OUdS human half-life is expected to be longer than the structurally similar 9Cl-PF3ONS. 11Cl-PF3OUdS differs from 9Cl-PF3ONS only in that it has two additional fully fluorinated carbons in the carbon chain. Therefore, 11Cl-PF3OUdS is included in the prioritized, lower notification level category.

| PFBS 62.6 | | | 44 days | | |
|--|----------------------|---------------------|------------------------|------------------|--|
| PFPeA - (NTP 2019a) cited in US USEPA 2021c) 2021c) - (14 days (Xu et al. 2020) - (Xu et al. 2020) PFPeS a - (Xu et al. 2020; Li et al. 2019) PFHxA 125 (NTP 2019b) 11.5 days (Nilsson et al. 2013, as cited in US USEPA 2022) ADONA 30 (Gordon et al 2011) 16 - 31 days (EFSA 2011) - (VS USEPA 2021c) | DEDC | 62.6 | (Xu et al. 2020, as | 300 | |
| PFPeA - (Xu et al. 2020) - (Xu et al. 2020) PFPeS a - (Xu et al. 2020; Li et al. 2019) PFHxA 125 (NTP 2019b) 11.5 days (Nilsson et al. 2013, as cited in US USEPA 2022) 2022) ADONA 30 (Gordon et al 2011) 16 - 31 days (EFSA 2011) - | TTDS | (NTP 2019a) | cited in US USEPA | (US USEPA 2021c) | |
| PFPeA - (Xu et al. 2020) - 223 – 365 days PFPeS a - (Xu et al. 2020; Li et al. 2019) - 11.5 days PFHxA 125 (NTP 2019b) 11.5 days (Nilsson et al. 2013, as cited in US USEPA 2022) 2022) ADONA 30 | | | 2021c) | | |
| PFPeS a PFHxA PFHxA 125 (NTP 2019b) ADONA (Gordon et al 2011) (Xu et al. 2020) 223 – 365 days (Xu et al. 2020; Li et al. 2019) 11.5 days (Nilsson et al. 2013, as cited in US USEPA 2022) 2022) (US USEPA 2022) | DED ₀ A | | < 14 days | | |
| PFPeS a - (Xu et al. 2020; Li et al. 2019) PFHxA 125 (NTP 2019b) (Nilsson et al. 2013, as cited in US USEPA 2022) ADONA 30 (Gordon et al 2011) (EFSA 2011) - (US USEPA 2011) | PrpeA | - | (Xu et al. 2020) | - | |
| ADONA Continue | | | | | |
| PFHxA 125 (NTP 2019b) ADONA 125 (NIlsson et al. 2013, as cited in US USEPA 2022) 30 (Gordon et al 2011) 11.5 days (Nilsson et al. 2013, as cited in US USEPA 2022) 16 – 31 days (EFSA 2011) | PFPeS ^a | - | (Xu et al. 2020; Li et | - | |
| PFHxA 125 (NTP 2019b) (Nilsson et al. 2013, as cited in US USEPA 2022) 2022) ADONA 30 (Gordon et al 2011) (Gordon et al 2011) (Nilsson et al. 2013, as cited in US USEPA 2022) (US USEPA 2022) (US USEPA 2022) | | | al. 2019) | | |
| ADONA (NTP 2019b) cited in US USEPA (US USEPA 2022) 30 | | | 11.5 days | | |
| ADONA (NTP 2019b) Cited in US USEPA 2022) 30 | PFHxA | 125 | | 500 | |
| ADONA 30 16 – 31 days (Gordon et al 2011) (EFSA 2011) - | | (NTP 2019b) | cited in US USEPA | (US USEPA 2022) | |
| ADONA (Gordon et al 2011) (EFSA 2011) | | | 2022) | | |
| (Gordon et al 2011) (EFSA 2011) | ADONA | 30 | 16 – 31 days | | |
| 4.2 EXEC b | | (Gordon et al 2011) | (EFSA 2011) | _ | |
| 4:2 F15° | 4:2 FTS ^b | - | - | - | |
| 6:2 FTS b 5 | 6.2 ETC b | 5 | | | |
| (Sheng et al 2017) | 0.2 F13 | (Sheng et al 2017) | _ | - | |
| 8:2 FTS ^b | 8:2 FTS ^b | | - | - | |
| NFDHA ° | NFDHA ^c | <u>-</u> | - | - | |
| PFEESA ° | PFEESA ^c | | - | - | |
| PFMPA ^c | PFMPA ^c | - | - | - | |
| PFMBA ^c | PFMBA ^c | - | - | - | |

^a The human half-life data for PFPeS suggest a half-life approaching one year, rather than multiple years as for the emerging PFAS prioritized for a lower notification level (Table 1). Therefore, PFPeS has been identified for the second, higher notification level category.

The prioritized notification level category is set at a drinking water concentration of 30 ppt, which applies to the combined concentration of the emerging PFAS identified for this category with a 10 ppt notification level for hexafluoropropylene oxide-dimer acid (HFPO-DA/GenX). Six PFAS were designated for the 30 ppt category based on chemical-specific information that suggest these chemicals have a higher degree of toxicity when compared to other chemicals in the group of 19 emerging PFAS. These six prioritized chemicals have low liver toxicity effect levels, long human half-lives, or low reference doses, or they are structurally

^b Of the three fluorotelomer sulfonates identified as emerging PFAS (4:2, 6:2, and 8:2 FTS), only 6:2 FTS has comparative toxicity information. The liver toxicity effect level is higher than effect levels observed for the prioritized notification level category (Table 1). Human half-life data were not available for 6:2 FTS, however, the European Chemical Agency (ECHA 2020) noted that urinary excretion times in rats suggest a half-life of 20-24 hours. Rat half-life data suggest that short-chain PFAS have half-lives in the range of 2 – 13 hours, whereas long-chain PFAS have rat half-lives on the order of weeks to months (ATSDR 2021). A comparison of the rat half-life information suggests that the half-life of 6:2 FTS is comparable with that of other short-chain PFAS that have been identified for the second, higher notification level category. The 4:2 and 8:2 FTS are included in this second notification level category based on their structural similarity with the 6:2 FTS.

^c Comparative information was not identified for NFDHA, PFEESA, PFMPA, and PFMBA. These PFAS contain shorter fluorinated carbon chains (≤ 4 carbons) than chemicals that have been prioritized for the lower notification level category (Table 1). Therefore, these PFAS have been included in the second, higher notification level category.

similar to other emerging PFAS with known toxicity. These parameters suggest that notification is needed at a lower water concentration.

The notification level of 30 ppt was also evaluated in the context of available drinking water standards and guidelines established by other states for chemicals in this prioritized notification level category, which are generally set a health-protective levels that are much lower than levels known to cause health effects. Of the six emerging PFAS in this group, Gen-X is the only chemical with established drinking water standards and guidelines. The range of these values is 21-370 ppt (Table 4). The notification level of 30 ppt is at the low end of this range.

Table 4. State Drinking Water Standards and Guidelines Established for Gen-X

| State Agency | Year Established | Drinking Water Standard or Guideline (ppt) |
|--|---------------------|--|
| Ohio Environmental Protection Agency | 2022 | 21 |
| Michigan Department of Environment, Great Lakes, | 2020 | 370 |
| and Energy | | |
| North Carolina Department of Health and Human | 2017 | 140 |
| Services | | |

Finally, the notification level of 30 ppt was evaluated in the context of analytical detection limits. The total concentration of six chemicals would be used to determine if the notification level is exceeded, and analytical methods used to measure these chemicals in drinking water have limitations and variations in the concentration of the chemical that can be reliably reported. The notification level value cannot be set below the level that is reliably reported by the analytical method. The analytical method must be able to reliably report each of the six prioritized emerging PFAS at 5 ppt. Based on analytical methods developed by US USEPA (US USEPA 2019b, 2020b), a notification level of 30 ppt for the total concentration of six PFAS should retain confidence in the analytical results.

The remaining 13 PFAS have been placed in a second category with a notification level of 100 ppt for the total concentration of the PFAS in the group. The notification level of 100 ppt was selected by evaluating drinking water standards and guidelines established by other states for chemicals in this category, with consideration of analytical detection limits. Drinking water standards and guidelines have been established for PFBA, PFBS, and PFHxA, and the values range from 100 to 560,000 ppt (Table 5). The notification level of 100 ppt is the low end of this range. Further, a level of 100 ppt is indicative of a significant source of contamination at which notification is needed for the community served by the water system.

Table 5. State Drinking Water Standards and Guidelines Established for PFBA, PFBS, and PFHxA

| State Agency | Year(s) Established | Drinkin | g Water Stan Guideline (ppt) | dard or |
|---|------------------------|---------|------------------------------------|---------|
| | | PFBA | PFBS | PFHxA |
| Minnesota Department of Health | 2018-2022 | 7000 | 100 | 200 |
| California Water Boards | 2022 | | 500 | |
| Illinois Environmental Protection Agency | 2021 | | 2,100 | 560,000 |
| Michigan Department of Environment, Great Lakes, and Energy | 2020 | | 420 | 400,000 |
| Ohio Environmental Protection Agency | 2019 | | 2,100 | |

The notification level of 100 ppt was evaluated in the context of analytical detection limits. As was discussed above for the prioritized notification level, the total concentration of chemicals in the category would be used to determine if the notification level is exceeded. For the 100 ppt notification category, the analytical method must be able to reliably report each of the 13 emerging PFAS at 8 ppt. Based on analytical methods developed by US USEPA (US USEPA 2019b, 2020b), a notification level of 100 ppt for the total concentration of these 13 PFAS should retain confidence in the analytical results.

The Department is proposing to amend 10 NYCRR Part 5 to establish a notification level of 30 ppt for the sum of PFHps, PFUnA, PFDoA, GenX, 9Cl PF3ONS and 11ClPF3OUdS; and a

notification level of 100 ppt for the sum of PFBA, PFBS, PFPeA, PFPeS, PFHxA, ADONA 4:2FTS, 6:2FTS, 8:2FTS, NFDHA, PFEESA, PFMPA and PFMBA. The notification levels will apply to all public water systems regulated by the Department and will reduce lifetime exposure through drinking water for the general population.

Maximum Contaminant Levels:

New York State currently has MCLs for perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) at 0.0000100 milligrams-per-liter (mg/L) or 10 parts-per-trillion (ppt) each. Monitoring for PFOA and PFOS has been conducted since 2020-2021 for the 3,000 PWS required to monitor. When the MCL for PFOA or PFOS is exceeded, the existing regulation requires the water system to collect between one and three follow up samples to confirm the levels of the compound in drinking water. The confirmation samples are required to include all analytes reported in the approved analytical method. Similarly, when either PFOS or PFOA are detected above the method detection limit, regulations require that subsequent quarterly monitoring includes all analytes contained in the approved analytical method. As such, the Department has a robust dataset on the occurrence of additional PFAS compounds, based on analytical data reported by approximately 1,000 PWS.

Based on the evaluation of existing monitoring data, it was determined that PFDA has been detected in two (2) PWS greater than 10 ppt. Twelve (12) PWS have reported PFDA at concentrations less than 10 ppt. PFHpA has been detected in 39 PWS greater than 10 ppt. A total of 206 PWS have reported PFHpA at concentrations less than 10 ppt. PFHxS has been detected in 29 PWS greater than 10 ppt. A total of 146 PWS have reported PFHxS at concentrations less than 10 ppt. PFNA has been detected in 30 PWS greater than 10 ppt. A total of 56 PWS have

reported PFNA at concentrations less than 10 ppt. A total of 139 PWS have total concentrations of PFAS6 greater than 30 ppt. As such, approximately 7% of water systems would be required to undertake corrective action as a result of promulgating individual MCL of 10 ppt. Some systems were found to exceed multiple compounds listed above. Many PWS in this category already exceed the MCL for PFOA and/or PFOS or have an enforcement deferral for these compounds and are working towards or have achieved corrective action that is expected to also address these compounds. Based on this occurrence data, the Department estimates an overall 1.46 percent increase in the number MCL violations for PFAS if MCLs for PFHxS, PFHpA, PFNA, and PFDA are promulgated at 10 ppt each. Therefore, it is anticipated that 44 water systems will exceed the proposed MCL for these compounds requiring corrective actions not already triggered due to exceedances of other PFAS compounds.

During public meetings of the DWQC on March 10, 2022, and May 2, 2022, the Department presented detailed technical information on the toxicology of PFHxS, PFHpA, PFNA, and PFDA, as well as on the general methods used to derive health-based drinking water concentrations that are protective against noncancer health effects. These presentations included key citations to the extensive, publicly available scientific literature upon which the Department relied.

The toxicity of PFOA, PFOS, PFHxS, PFHpA, PFNA, and PFDA has been reviewed and summarized by several authoritative state, national, and international bodies (US USEPA 2016a,b, 2021a,b,c, 2022; ATSDR 2021; EFSA 2011, 2018, 2020; NTP 2016, 2018a,b; NJ DEP 2015, 2019a,b, MA DEP 2019, CA OEHHA 2022). These reviews identify important studies on the health effects associated with exposure to these chemicals, including studies on cancer and non-cancer, developmental, and reproductive effects observed in humans and animals.

Human studies show associations between increased PFOA exposure and an increased risk for several health effects. These include effects on the liver, kidney, immune system, thyroid gland, cholesterol levels, pre-eclampsia (a complication of pregnancy that includes high blood pressure), and kidney and testicular cancer (C8 Science Panel 2017; Darrow et al. 2013; Steenland et al. 2012; Steenland et al. 2013; Winquist and Steenland 2014; Barry et al. 2013; Costa 2009; Darrow et al. 2016; Shearer et al. 2021). Human studies also show associations between increased PFOS exposure and an increased risk for several health effects, including increases in total cholesterol in serum (i.e., the fluid portion of blood that contains components not used in clotting), triglycerides, and uric acid, as well as effects on the immune system, reproduction and development (Olsen et al. 2003; Steenland et al. 2009; Gleason et al. 2015; Grandjean et al. 2012; Grandjean et al. 2017; Fei et al. 2012; Verner et al. 2015).

Exposure to PFOA or PFOS has been shown to cause several types of adverse health effects in numerous studies of laboratory animals. PFOA caused cancer of the liver, pancreas, and testis in male rats exposed for their lifetimes (Butenhoff et al. 2012a; NTP 2020). Non-cancer health effects caused by PFOA exposure in animals include liver toxicity, developmental toxicity, and immune system toxicity (Macon et al. 2011; Loveless et al. 2006; Lau et al. 2006; DeWitt et al. 2015). PFOS caused liver and thyroid cancer in rats exposed for their lifetimes (Butenhoff et al. 2012b). PFOS also causes several non-cancer health effects in animals, including adverse effects on the immune system, reduced offspring body weight, and effects on the developing nervous system (Dong et al. 2009; Luebker et al. 2005; Butenhoff et al. 2009).

Studies in humans show associations between exposures to PFHxS, PFHpA, PFNA and PFDA and an increased risk for several health effects. These include effects on serum lipids, cardiovascular function, liver enzymes, the immune system, the reproductive system, and thyroid

hormone levels (ATSDR 2021, CA OEHHA 2022, Cakmak et al. 2022, Guo et al. 2021, Kvalem et al. 2020, Shen et al. 2022, Wang et al. 2021). Human studies have also identified associations between exposures to PFHxS, PFHpA, PFNA and PFDA and an increased risk for breast cancer (Velarde et al. 2022, Wielsøe et al. 2017, Feng et al. 2022), and exposures to PFHxS and PFDA have been associated with an increased prostate cancer risk among those with hereditary risk (Hardell et al. 2014).

PFHxS, PFHpA, PFNA and PFDA cause several types of adverse health effects in studies of laboratory animals exposed to these chemicals. Each of the chemicals causes liver and reproductive toxicity in animals (ATSDR 2021, NTP 2018a,b, Han et al. 2020, Li et al. 2021). PFHxS, PFNA, and PFDA also cause thyroid and developmental toxicity, and PFNA and PFDA cause immune toxicity (ATSDR 2021, NTP 2018a,b). Animal studies that evaluate the carcinogenicity of PFHxS, PFHpA, PFNA and PFDA are not available.

The Department evaluated the toxicity of the six PFAS (PFOA, PFOS, PFHxS, PFHpA, PFNA, and PFDA). Based on similarities in chemical structure, common health endpoints and available data on modes of action, the health effects from these six PFAS are expected to be additive when present in mixtures. This is consistent with the basis for the drinking water health advisory for the sum of PFOA and PFOS derived by the US USEPA (US USEPA 2016c), and the approaches used for multiple PFAS by Massachusetts (MA DEP 2019), Vermont (VT DOH 2018), Connecticut (CT DPH 2020), Rhode Island (RI 2021), Maine (ME DHHS 2021), and Oregon (Oregon Health Authority).

The Department also evaluated the level of 30 ppt in the context of analytical detection limits. The total concentration of six chemicals would be used to determine if the summed MCL is exceeded, and analytical methods used to measure these chemicals in drinking water have

limitations and variations in the concentration of the chemical that can be reliably reported. The MCL cannot be set below the level that is reliably reported by the analytical method. The analytical method must be able to reliably report each of the six PFAS at 5 ppt. Based on analytical methods developed by US USEPA (US USEPA 2019b, 2020b), a level of 30 ppt for the total concentration of six PFAS should retain confidence in the analytical results.

Based on analysis of available toxicological data, the Department determined that summing six PFAS compounds to 30 ppt addresses the additive toxicity of the chemicals in situations where they are present as mixtures, and is also operationally feasible. It is expected that approximately 2.14% of PWS will either exceed the proposed MCL of 10 ppt for PFHxS, PFHpA, PFNA and PFDA or the PFAS6 MCL, for a total of 64 PWS.

The toxicity of PFHxS, PFHpA, PFNA and PFDA has been discussed above. The results of the human and animal studies on PFHxS, PFHpA, PFNA and PFDA and their structural similarity to PFOA and PFOS provide an overall weight of evidence that indicates human exposure to these chemicals at currently observed environmental levels can increase the risk for health effects, and that public health actions to minimize such exposures are needed.

The general methods presented by Department staff to the DWQC for deriving health-based drinking water concentrations that are protective against noncancer health effects have been regularly used by the United States Environmental Protection Agency (US USEPA) and other health agencies since the 1980s (US USEPA 2000, US USEPA 2020a, US USEPA 1984, MDH 2008).

The methods include:

- Identifying an exposure level or point of departure that represents the most sensitive noncancer health effect caused by the contaminant in the most sensitive species;
- 2. Deriving a reference dose (a lifetime exposure at which noncancer health effects are unlikely) by dividing the point of departure by uncertainty factors that compensate for limitations in the quality and quantity of scientific information on the chemical and provide a margin of protection against the most sensitive health effects;
- 3. Dividing the reference dose by a water consumption rate to obtain a drinking water exposure equivalence level; and
- 4. Multiplying the drinking water equivalence level by a relative source contribution that adjusts for the percentage of exposure to the contaminant from drinking water compared to other sources (e.g., food, soil).

On March 10, 2022, Department staff presented reference doses and health-based drinking water concentrations for PFHxS, PFHpA, PFNA, and PFDA to the DWQC.

The Department presented a PFHxS reference dose derived by the New Hampshire

Department of Environmental Services (NH DES 2019), based on a study by Chang et al. (2018)

that reported decreased litter size in mice exposed to PFHxS before mating and throughout

gestation. The Department presented this reference dose because it was based on an effect that

occurred at the lowest dose identified in a high-quality animal study. New Hampshire

Department of Environmental Services derived this reference dose from a benchmark serum

level (13,900 ng/mL), which was converted to a human equivalent dose of 1,200 ng/kg/day using

a chemical specific clearance value of 0.086 mL/kg/day. This human equivalent dose was

divided by a total uncertainty factor of 300 to account for human variability (10), interspecies differences (3), duration of exposure (3), and database deficiencies (3) to obtain a reference dose of 4.0 ng/kg/day (NH DES 2019).

The Department presented a PFNA reference dose derived by the Michigan Science Advisory Workgroup (MI SAW 2019), based on a study by Das et al. (2015) that reported decreased body weight and developmental delays in offspring of mice exposed during gestational days 1-17. The Department presented this reference dose because it is based on a sensitive effect during a vulnerable life stage identified in a high-quality animal study. The Michigan Science Advisory Workgroup derived this reference dose from a serum concentration corresponding to a no-observed adverse effect level for decreased body weight gain and delayed eye opening, preputial separation, and vaginal opening in offspring of exposed mice (6,800 ng/mL). The Michigan Science Advisory Workgroup converted this serum concentration to a human equivalent dose of 665 ng/kg/day using a chemical specific clearance value of 0.098 mL/kg/day. This human equivalent dose was divided by a total uncertainty factor of 300 to account for human variability (10), interspecies differences (3), and database deficiencies (10) to obtain a reference dose of 2.2 ng/kg/day (MI SAW 2019).

Reference doses for PFHpA and PFDA are not available. For these PFAS, the Department presented reference doses based on PFAS with similar chemical structures, consistent with approaches used by Massachusetts, Maine, Rhode Island, Vermont, and Connecticut (MA DEP 2019, ME DHHS 2021, RI 2021, VT DOH 2018, CT DPH 2020).

In the absence of sufficient information to derive a PFHpA reference dose, the Department proposed using the reference dose for PFOA to obtain a health-based water value for this chemical. PFHpA is structurally similar to PFOA, and has a relatively long human half-life

of 1.1-1.5 years (Zhang et al. 2013), similar to 2 to 3.5 years for PFOA (Bartell et al. 2010, Olsen et al. 2007). These considerations suggest that it would have similar potency to PFOA. A PFOA reference dose of 1.5 ng/kg/day derived by the Department and presented to the DWQC on October 17, 2018 (NYS DOH 2018), was used as the basis for health-based drinking water values for PFHpA. This reference dose is based on increased liver weight in the offspring of mice exposed to PFOA during pregnancy (Macon et al., 2011). The measured serum level corresponding to a lowest-observed effect level (4,980 ng/mL) was converted to a human equivalent dose of 460 ng/kg/day using a chemical specific clearance value of 0.092 mL/kg/day. The human equivalent dose was divided by a total uncertainty factor of 300 to account for sensitive humans (10), interspecies differences (3), the use of a LOEL (3) and database deficiencies (3) to obtain a final reference dose of 1.5 ng/kg/day.

In the absence of sufficient information to derive a PFDA reference dose, the Department proposed using the reference dose for PFNA to obtain a health-based water value for this chemical. PFDA is structurally similar to PFNA and has a relatively long half-life of 4 to 12 years (Zhang et al. 2013), as does PFNA (2.5 to 4.4 years) (Zhang et al. 2013). In addition, a comparative toxicity study conducted by The National Toxicology Program (NTP 2018b) reported that PFDA induced liver and thyroid toxicity in laboratory animals at exposure levels comparable to PFNA, which suggests that PFDA and PFNA have similar toxic potency. Thus, the previously summarized reference dose for PFNA was used to calculate health-based values for PFDA.

To obtain the corresponding drinking water equivalence levels for PFHxS, PFHpA, PFNA and PFDA, the reference doses were divided by water consumption rates of 0.035, 0.047 and 0.143 liters per kilogram body weight per day for adults, lactating women, and infants,

respectively (US USEPA 2019a). The drinking water equivalence levels for each chemical are presented in Table 6.

The drinking water equivalence levels, which represent the reference doses expressed as water concentrations for different members of the population, were then multiplied by a relative source contribution of 0.5. The relative source contribution accounts for the percentage of contaminant exposure from drinking water compared to other sources when setting drinking water standards and guidelines based on noncancer toxicological endpoints.

The US USEPA drinking water program applies a default relative source contribution factor of 0.2 to the reference dose in the absence of chemical-specific information (US USEPA 2020a). This default allows 20% of the reference dose to be applied to drinking water exposure sources and 80% of the reference dose to be reserved for other environmental exposure sources. However, data from the National Health and Nutrition Examination Survey (CDC 2021) provide a source of chemical-specific information on the individual levels of PFHxS, PFHpA, PFNA and PFDA in the blood of the general US population. These blood levels for the general US population are much lower than the serum levels corresponding to each of the four reference doses for PFHxS, PFHpA, PFNA, and PFDA. This suggests that environmental background exposures (e.g., exposures other than drinking water) to these four PFAS account for a smaller portion of the reference dose than the US USEPA default relative source contribution allocates. Thus, the chemical-specific information for PFHxS, PFHpA, PFNA and PFDA supports using a relative source contribution of 0.5. This value is higher than the default of 0.2, but below the 0.8 ceiling recommended by the US USEPA to account for possible unknown sources of exposure to these chemicals (US USEPA 2020a). The Minnesota Department of Health (MDH 2020a,b,c) the Michigan Science Advisory Workgroup (MI SAW 2019), New Jersey Department of

Environmental Protection (NJ DEP 2015), New Hampshire Department of Environmental Services (NH DES 2019), and Washington State Department of Health (WA DOH 2019), have also used a relative source contribution of 0.5 in developing health-based drinking water concentrations for PFAS.

The resulting health-based water concentrations presented in Table 6, ranged from 14 to 57 ppt for PFHxS, 5 to 21 ppt for PFHpA, and 8 to 31 ppt for both PFNA and PFDA. From these health-based water concentrations, the Department provided information to the Drinking Water Quality Council indicating that a chemical-specific maximum contaminant level of 10 ppt each for PFHxS, PFHpA, PFNA and PFDA would be sufficiently protective of human health. The Department also presented information indicating that a level of 10 ppt would be analytically achievable for laboratories and would retain confidence in the analytical result. On May 2, 2022, the Drinking Water Quality Council recommended maximum contaminant levels of 10 ppt each for PFHxS, PFHpA, PFNA, and PFDA.

Table 6 Health-Based Drinking Water Values for PFHxS, PFHpA, PFNA and PFDA

| Chemical | Reference Dose (ng/kg/day) | Drinking Water Ingestion Rates (L/kg/day) | Drinking Water Equivalency Level (ppt) | Relative Source Contribution | Health-Based Drinking Water Value (ppt) |
|----------|----------------------------------|---|--|------------------------------------|---|
| PFHxS | 4.0 | | 28-114 | | 14-57 |
| PFHpA | 1.5 | 0.143 (infants) 0.047 (lactating | 10-43 | 0.5 | 5-21 |
| PFNA | 2.2 | women) 0.035 (adults | 15-63 | 0.5 | 8-31 |
| PFDA | 2.2 | , | 15-63 | | 8-31 |

The Department evaluated the margin of protection against health effects provided by the recommended maximum contaminant level by comparing the exposure at 10 ppt each of PFHxS, PFNA and PFDA for infants (the population that would receive the largest contaminant dose per body weight at 10 ppt) to the human equivalent doses corresponding to the lowest

exposure that causes health effects in animal studies. The margins of protection are provided in Table 7 and ranged from 300 to 850, meaning that exposures at the proposed maximum contaminant levels would be 300 to 850 times lower than PFHxS, PFHpA, PFNA and PFDA exposures estimated to cause health effects in humans.

Table 7 Margins of Protection at 10 ppt of PFHxS, PFHpA, PFNA and PFDA

| Chemical | Effect | Effect Level (human equivalent dose, ng/kg/day) | Drinking Water Dose at 10 ppt (infant, ng/kg/day) | Margin of Protection |
|----------|--|---|---|----------------------|
| PFHxS | Reduced litter size in mice exposed before mating and throughout gestation (Chang et al. 2018, NH DES 2019) | 1200 | 1.4 | 857 |
| PFHpA | Increased relative liver weight in offspring of mice exposed to PFOA on gestational days 1-17 (Macon et al. 2011) | 460 | 1.4 | 329 |
| PFNA | Increased relative liver weight in pregnant mice exposed to PFNA (Das et al. 2015, NJ DEP 2015) | 431 | 1.4 | 308 |
| PFDA | Increased relative liver weight in pregnant mice exposed to PFNA (Das et al. 2015, NJ DEP 2015) | 431 | 1.4 | 308 |

The Department concluded that the margins of protection provided by the proposed maximum contaminant level are sufficiently protective of public health. The proposed maximum contaminant levels are also consistent with long-standing US USEPA practice for development of drinking water standards, specifically, that health-based concentrations, or maximum contaminant level goals for contaminants be set at levels where no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety, and that the maximum contaminant levels be set as close to the maximum contaminant level goals as feasible (US USEPA 2020a).

The Department is amending 10 NYCRR Part 5 to establish individual MCLs for PFHxS, PFHpA, PFNA and PFDA, as well as a combined MCL for PFAS6. The Department is proposing an MCL of 0.0000100 mg/L (10 ppt) for PFHxS, PFHpA, PFNA and PFDA as individual contaminants, and 0.0000300 mg/L (30 ppt) for PFAS6. These MCLs will apply to all public water systems regulated by the Department and provide a sufficient margin of protection against adverse health effects in the most sensitive populations, including fetuses during pregnancy, breastfed infants, and infants bottle fed with formula reconstituted using tap water. In addition, the MCLs provide a sufficient margin of protection for lifetime exposure through drinking water for the general population.

References

ATSDR (Agency for Toxic Substances and Disease Registry). 2021. Toxicological Profile for Perfluoroalkyls. Atlanta, GA: Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, Public Health Service. May 2021. https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

Barry V, Winquist A, Steenland K. 2013. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environmental Health Perspectives*; 121:1313-1318.

Bartell SM, Calafat AM, Lyu C, Kato K, Ryan PB, Steenland K. 2010. Rate of decline in serum PFOA concentrations after granular activated carbon filtration at two public water systems in Ohio and West Virginia. *Environmental Health Perspectives*; 118(2):222-8.

Butenhoff JL, Ehresman DJ, Chang S-C, Parker GA, Stump DG. 2009. Gestational and lactational exposure to potassium perfluorooctanesulfonate (K+PFOS) in rats: Developmental neurotoxicity. *Reproductive Toxicology*; 27:319-330.

Butenhoff JL, Kennedy Jr GL, Chang S-C, Olsen GW. 2012a. Chronic dietary toxicity and carcinogenicity study with ammonium perfluorooctanoate in Sprague-Dawley rats. *Toxicology*; 298:1-13.

Butenhoff JL, Chang S-C, Olsen GW, Thomford PJ. 2012b. Chronic dietary toxicity and carcinogenicity study with potassium perfluorooctanesulfonate in Sprague Dawley rats. *Toxicology*; 293:1-15.

C8 Science Panel. 2017. The Science Panel Website. http://www.c8sciencepanel.org/index.html.

CA OEHHA (California Office of Environmental Health Hazard Assessment). 2022. Notification Level Recommendation for Perflourohexane Sulfonic Acid in Drinking Water. Accessed 5/12/2022 https://oehha.ca.gov/media/downloads/water/document/pfhxsnl031722.pdf

Cakmak S, Lukina A, Karthikeyan S, Atlas E, Dales R. 2022. The association between blood PFAS concentrations and clinical biochemical measures of organ function and metabolism in participants of the Canadian Health Measures Survey (CHMS). *Sci. Total Environ.*; 827:153900.

CDC (Centers for Disease Control and Prevention). 2021. Fourth National Report on Human Exposure to Environmental Chemicals Vol. 1 (Updated Tables, March 2021). https://www.cdc.gov/exposurereport/index.html

Chang S, Butenhoff JL, Parker GA, Coder PS, Zitzow JD, Krisko RM, Bjork JA, Wallace KB, Seed JG. 2018. Reproductive and developmental toxicity of potassium perfluorohexanesulfonate in CD-1 mice. *Reprod. Toxicol.*; 78:150-168.

Clark, Dawn (The Chemours Company). 2021, March 17. Letter to USEPA, Office of Pollution Prevention and Toxics regarding propanoic acid, 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-CAS RN 13252-13-6 (also known as HFPO-DA). https://heronet.USEPA.gov/heronet/index.cfm/reference/details/reference_id/8631852.

Costa G. 2009. Thirty years of medical surveillance in perfluoctanoic acid production workers. *Journal of Occupational and Envtl Medicine*; 51:364-372.

CT DPH (Connecticut Department of Public Health). 2020. Accessed 5/12/2022 https://www.ctwater.com/water-quality/what-are-pfas

Darrow L, Stein CR, Steenland K. 2013. Serum perfluorooctanoic acid and perfluorooctane sulfonate concentrations in relation to birth outcomes in the mid-Ohio valley, 2005-2010. *Environ. Health Perspectives*; 121:1207-1213.

Darrow L, Groth AC, Winquist A, Shin H-M, Bartell SM, Steenland K. 2016. Modeled perfluorooctanoic acid (PFOA) exposure and liver function in a mid-Ohio Valley community. *Environ. Health Perspectives*; 124:1227–1233.

Das KP, Grey BE, Rosen MB, Wood CR, Tatum-Gibbs KR, Zehr RD, Strynar MJ, Lindstrom AB, Lau C. 2015. Developmental toxicity of perfluorononanoic acid in mice. *Reprod Toxicol*; 51:133-144.

DeWitt JC, Williams WC, Creech NJ, Luebke RW. 2015. Suppression of antigen-specific antibody responses in mice exposed to perfluorooctanoic acid: Role of PPARα and T- and B-cell targeting. *Journal of Immunotoxicology*; 13:38-45.

Dong G-H, Zhang Y-H, Zheng L, Liu W, Jin Y-H, He Q-C. 2009. Chronic effects of perfluorooctane sulfonate exposure on immunotoxicity in adult male C57BL/6 mice. *Archives of Toxicology*; 83:805–815.

DuPont-18405-1307: E.I. du Pont de Nemours and Company. 2010. H-28548: Subchronic Toxicity 90-Day Gavage Study in Mice. OECD Test Guideline 408. Study conducted by E.I. du Pont de Nemours and Company (Study Completion Date: February 19, 2010), Newark, DE.

ECHA (European Chemical Agency). 2020. Registration Dossier for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonic acid (CAS No. 27619-27-2). Published in accordance with the Registration, Evaluation, Authorisation and Restriction of Chemicals (i.e., REACH) legislation. https://echa.europa.eu/registration-dossier/-/registered-dossier/24637/7/6/2

EFSA (European Food Safety Authority). 2011. Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids on the safety evaluation of the substance, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt, CAS No. 958445-44-8, for use in food contact materials. EFSA Journal.

EFSA (European Food Safety Authority). 2018. Panel on Contaminants in the Food Chain, Scientific Opinion: Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food. EFSA Journal; 16:5194.

EFSA (European Food Safety Authority). 2020. Scientific Opinion of the Panel on Contaminants in the Food Chain: Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal. https://doi.org/10.2903/j.efsa.2020.6223

Fei C, Weinberg CR, Olsen J. 2012. Commentary: Perfluorinated chemicals and time to pregnancy: A link based on reverse causation? *Epidemiology*; 23:264-266.

Feng Y, Bai Y, Lu Y, Chen M, Fu M, Guan X, Cao Q, Yuan F, Jie J, Li M, Meng H, Wang C, Hong S, Zhou Y, Zhang X, He M, Guo H. 2022. Plasma perfluoroalkyl substance exposure and incidence risk of breast cancer: A case-cohort study in the Dongfeng-Tongji cohort. *Environ Pollut*; 306:119345.

Gleason JA, Post GB, Fagliano JA. 2015. Associations of perfluorinated chemical serum concentrations and biomarkers of liver function and uric acid in the US population (NHANES), 2007-2010. *Envtl. Research*; 136:8-14.

Gordon SC. 2011. Toxicological evaluation of ammonium 4,8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing. *Regul Toxicol Pharmacol*. 2011 Feb;59(1):64-80.

Grandjean P, Andersen EW, Budtz-Jørgensen E, Nielsen F, Mølbak K, Weihe P, Heilmann C. 2012. Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *Journal of the Am. Med. Assn*; 307:391-397.

Grandjean P, Heilmann C, Weihe P, Flemming N, Mogensen UB, Budtz-Jørgensen E. 2017. Serum vaccine antibody concentrations in adolescents exposed to perfluorinated compounds. *Envtl. Health Perspectives*; 125:077018.

Guo J, Zhang J, Wang Z, Zhang L, Qi X, Zhang Y, Chang X, Wu C, Zhou Z. 2021. Umbilical cord serum perfluoroalkyl substance mixtures in relation to thyroid function of newborns: Findings from Sheyang Mini Birth Cohort Study. *Chemosphere*; 273:129664.

Han J-S, Jang S, Son H-Y, Kim Y-B, Kim Y, Noh J-H, Kim M-J, Lee B-S. 2020. Subacute dermal toxicity of perfluoroalkyl carboxylic acids: comparison with different carbon-chain lengths in human skin

equivalents and systemic effects of perfluoroheptanoic acid in Sprague Dawley rats. *Archives of Toxicology*; 94:523-539.

Hardell E, Kärrman A, van Bavel B, Bao J, Carlberg M, Hardell L. 2014. Case-control study on perfluorinated alkyl acids (PFAAs) and the risk of prostate cancer. *Environ Int.*; 63:35-9.

Kato H, Fujii S, Takahashi M, Matsumoto M, Hirata-Koizumi M, Ono A, Hirose A. 2015. Repeated dose and reproductive/developmental toxicity of perfluorodecanoic acid in rats. *Environ Toxicol*. 30(11):1244

Kvalem HE, Nygaard UC, Lødrup Carlsen KC, Carlsen KH, Haug LS, Granum B. 2020 Perfluoroalkyl substances, airways infections, allergy and asthma related health outcomes - implications of gender, exposure period and study design. *Environ Int.*; 134:105259.

Lau C, Thibodeaux JR, Hanson RG, Narotsky MG, Rogers JM, Lindstrom AB, Strynar MJ. 2006. Effects of perfluorooctanoic acid exposure during pregnancy in the mouse. *Toxicological Sciences*; 90:510-518.

Li Y, Xu Y, Scott K, Lindh C, Jakobsson K, Fletcher T. 2019. Half-lives of PFOA, PFPeS, PFHxS, PFHpS and PFOS after end of exposure to contaminated drinking water. *Environmental Epidemiology*; 3:237.

Li Z, Li C, Wen Z, Yan H, Zou C, Li Y, Tian L, Lei Z, Li H, Wang Y, Zhong Y, G R-S. 2021. Perfluoroheptanoic acid induces Leydig cell hyperplasia but inhibits spermatogenesis in rats after pubertal exposure. *Toxicology*. 448(2021): 152633

Loveless S, Finlay C, Everds NE, Frame SR, Gillies PJ, O'Connor JC, Powley CR, Kennedy GL. 2006. Comparative responses of rats and mice exposed to linear/branched, linear, or branched ammonium perfluorooctanoate (APFO). *Toxicology*; 220:203–217.

Luebker DJ, Case MT, York RG, Moore JA, Hansen KJ, Butenhoff JL. 2005. Two-generation reproduction and cross-foster studies of perfluorooctanesulfonate (PFOS) in rats. *Toxicology*; 2015:126-148.

MA DEP (Massachusetts Department of Environmental Protection). 2019. Technical Support Document: Per- and Polyfluoroalkyl Substances (PFAS): An Updated Subgroup Approach to Groundwater and Drinking Water Values. Accessed 5/10/2022 https://www.mass.gov/doc/per-and-polyfluoroalkyl-substances-pfas-an-updated-subgroup-approach-to-groundwater-and/download

Macon MB, Villanueva LR, Tatum-Gibbs K, Zehr RD, Strynar MJ, Stanko JP, White SS, Helfant L, and Fenton SE. 2011. Prenatal perfluorooctanoic acid exposure in CD-1 mice: Low dose developmental effects and internal dosimetry. *Toxicological Sciences*; 121(1):134–145.

MDH (Minnesota Department of Health). 2008. Statement of Need and Reasonableness (SONAR) in the Matter of Proposed Rules Relating to Health Risk Limits of Groundwater. Accessed 5/12/2022 https://www.leg.mn.gov/archive/sonar/SONAR-03733.pdf#page=2.

MDH (Minnesota Department of Health). 2020a. Toxicological Summary for: Perfluorooctanoate. Accessed 5/16/2022

https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfoa.pdf

MDH (Minnesota Department of Health). 2020b. Toxicological Summary for: Perfluorooctane sulfonate. Accessed 5/16/2022

https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfos.pdf

MDH (Minnesota Department of Health). 2020c. Toxicological Summary for: Perfluorohexane sulfonate. Accessed 5/16/2022

https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfhxs.pdf

ME DHHS (Maine Department of Human Health Services). 2021 http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0064&item=3&snum=130

MI SAW (Michigan Science Advisory Workgroup). 2019. Health-Based Drinking Water Value Recommendations for PFAS in Michigan. Accessed 5/12/2022 https://www.michigan.gov/pfasresponse/media/Project/Websites/PFAS-Response/Documents/MPART/Reports/2019-Health-Based-Drinking-Water-Value-Recommendations-PFAS-MI.pdf

NH DES (New Hampshire Department of Environmental Services). 2019. Technical Background Report for the June 2019 Proposed Maximum Contaminant Levels (MCLs) and Ambient Groundwater Quality Standards (AGQSs) for Perfluorooctane sulfonic Acid (PFOS), Perfluorooctanoic Acid (PFOA), Perfluorononanoic Acid (PFNA), and Perfluorohexane sulfonic Acid (PFHxS). Accessed 5/10/2022 https://www4.des.state.nh.us/nh-pfas-investigation/wp-content/uploads/June-PFAS-MCL-Technical-Support-Document-FINAL.pdf

NJ DEP (New Jersey Department of Environmental Protection) & New Jersey Drinking Water Quality Institute Health Effects Subcommittee. 2015. Health-Based Maximum Contaminant Level Support Document: Perfluorononanoic Acid (PFNA). Accessed 5/12/2022 https://www.nj.gov/dep/watersupply/pdf/pfna-health-effects.pdf

NJ DEP (New Jersey Department of Environmental Protection). 2019a. Technical Support Document: Interim Specific Ground Water Criterion for Perfluorooctanoic Acid (PFOA, C8). https://www.nj.gov/dep/dsr/supportdocs/PFOA_TSD.pdf.

NJ DEP (New Jersey Department of Environmental Protection). 2019b. Technical Support Document: Interim Specific Ground Water Criterion for Perfluorooctane Sulfonate (PFOS). https://www.nj.gov/dep/dsr/supportdocs/PFOS TSD.pdf.

NTP (National Toxicology Program). 2016. Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) and Perfluorooctane Sulfonate (PFOS). Research Triangle Park, NC: National Toxicology Program https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf

NTP (National Toxicology Program). 2018a. TOX-96: 1-Perfluorobutanesulfonic acid (375-73-5), Potassium perfluorohexanesulfonate (3871-99-6), Perfluorooctane sulfonate (1763-23-1), WY-14643 (50892-23-4). Chemical Effects in Biological Systems (CEBS). Research Triangle Park, NC (USA): National Toxicology Program (NTP). Accessed 2022-03-08 https://cebs.niehs.nih.gov/cebs/publication/TOX-96

NTP (National Toxicology Program). 2018b. TOX-97: Perfluorohexanoic acid (307-24-4), Perfluorooctanoic acid (335-67-1), Perfluorononanoic acid (375-95-1), Perfluorodecanoic acid (335-76-2), WY-14643 (50892-23-4). Chemical Effects in Biological Systems (CEBS). Research Triangle Park,

NC (USA): National Toxicology Program (NTP). Accessed 2022-03-08. https://cebs.niehs.nih.gov/cebs/publication/TOX-97NTP

NTP (National Toxicology Program). 2020. NTP technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid (CASRN 335-67-1) administered in feed to Sprague Dawley (Hsd:Sprague Dawley SD) rats. https://doi.org/10.22427/NTP-TR-598.

NYS DOH (New York State Department of Health) October 17, 2018 https://www.health.ny.gov/environmental/water/drinking/dwqc/

Olsen GW, Burris JM, Burlew MM, Mandel JH. 2003. Epidemiologic assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) concentrations and medical surveillance examinations. *Journal of Occupational and Envtl. Medicine*; 45:260-270.

Olsen GW, Burris JM, Ehresman DJ, Froehlich JW, Seacat AM, Butenhoff JL, Zobel LR. 2007. Half-life of serum elimination of perfluorooctanesulfonate, perfluorohexanesulfonate, and perfluorooctanoate in retired fluorochemical production workers. *Environ Health Perspect*; 115(9):1298-305.

Oregon Health Authority. Per – and Polyfluoroalkyl Substances (PFAS) PFAS Drinking Water Health Advisory Levels. Accessed 5/12/2022

 $\frac{https://www.oregon.gov/oha/PH/HEALTHYENVIRONMENTS/DRINKINGWATER/OPERATIONS/Pages/PFAS.aspx}{}$

RI (Rhode Island) 2021. PFAS in Drinking Water, Groundwater and Surface Waters. http://webserver.rilin.state.ri.us/BillText21/SenateText21/S0107.pdf

Shearer JJ, Callahan CL, Calafat AM, Huang W-Y, Jones RR, Sabbisetti VS, Freedman ND, Sampson JN, Silverman DT, Purdue MP, Hofmann JN. 2021. Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma. *Journal of the Natl. Cancer Inst.*; 113(5):580-587.

Shen M, Xiao Y, Huang Y, Jing D, Su J, Luo D, Duan Y, Xiao S, Li J, Chen X. 2022. Perfluoroalkyl substances are linked to incident chronic spontaneous urticaria: A nested case-control study. *Chemosphere*; 287(Pt 3):132358.

Sheng N, Zhou X, Zheng 1 F, Pan Y, Guo X, Guo Y, Sun Y. 2017. Comparative hepatotoxicity of 6:2 fluorotelomer carboxylic acid and 6:2 fluorotelomer sulfonic acid, two fluorinated alternatives to longchain-perfluoroalkyl acids, on adult male mice. *Arch Toxicol*; 91(8):2909–2919.

Shi Y, Vestergren R, Xu L, Zhou Z, Li C, Liang Y, Cai Y. 2016. Human Exposure and Elimination Kinetics of Chlorinated Polyfluoroalkyl Ether Sulfonic Acids (Cl-PFESAs). *Environ. Sci. Technol.*; 50(5):2396-2404.

Steenland K, Tinker S, Frisbee S, Ducatman A, Vaccarino V. 2009. Association of perfluorooctanoic acid and perfluorooctane sulfonate with serum lipids among adults living near a chemical plant. *Am. Journal of Epidemiology*; 170:1268-1278.

Steenland K, Woskie S. 2012. Cohort mortality study of workers exposed to perfluorooctanoic acid. *Am. Journal of Epidemiology*; 176:909-917.

Steenland K, Zhao L, Winquist A, Parks C. 2013. Ulcerative colitis and perfluorooctanoic acid (PFOA) in a highly exposed population of community residents and workers in the mid-Ohio valley. *Envtl. Health Perspectives*; 121: 900-905.

Takahashi M, Ishida S, Hirata-Koizumi M, Ono A, Hirose A. 2014. Repeated dose and reproductive/developmental toxicity of perfluoroundecanoic acid in rats. *The Journal of Toxicological Sciences*; 39(1):97-108.

US USEPA (United States Environmental Protection Agency). 1984. National Primary Drinking Water Regulations: Volatile Synthetic Organic Chemicals, 49 Fed Reg 24330-24355.

US USEPA (United States Environmental Protection Agency). 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health USEPA-822-B-00-004, https://www.USEPA.gov/sites/production/files/2018-10/documents/methodology-wqcprotection-hh-2000.pdf

US USEPA (United States Environmental Protection Agency). 2016a. Health Effects Support Document for Perfluorooctanoic Acid (PFOA), USEPA 822-R-16-003. https://www.USEPA.gov/sites/production/files/2016-05/documents/pfoa hesd final 508.pdf.

US USEPA (United States Environmental Protection Agency). 2016b. Health Effects Support Document for Perfluorooctane Sulfonate (PFOS), USEPA 822-R-16-002. https://www.USEPA.gov/sites/production/files/2016-05/documents/pfos hesd final 508.pdf.

US USEPA (United States Environmental Protection Agency). 2016c. Fact Sheet: PFOA and PFOS Drinking Water Health Advisories. Accessed 5/17/2022 https://www.USEPA.gov/sites/default/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf

US USEPA (United States Environmental Protection Agency). 2019a. Update for Chapter 3 of the Exposure Factors Handbook: Ingestion of Water and Other Select Liquids. Accessed 5/17/2022 https://www.USEPA.gov/sites/default/files/2019-02/documents/efh - chapter 3 update.pdf

US USEPA (United States Environmental Protection Agency). 2019b. Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry. USEPA Document Number 815-B-19-020. December 2019. https://www.USEPA.gov/dwanalyticalmethods/method-533-determination-and-polyfluoroalkyl-substances-drinking-water-isotope

US USEPA (United States Environmental Protection Agency). 2020a. USEPA Regulates Drinking Water Contaminants https://www.USEPA.gov/sdwa/how-USEPA-regulates-drinking-water-contaminants US USEPA (United States Environmental Protection Agency). 2020b. UCMR5 Laboratory Approval Manual. Version 1.0. USEPA Document Number 815-B-20-007. December 2020. https://www.USEPA.gov/dwucmr/laboratory-approval-program-unregulated-contaminant-monitoring-rule-ucmr-5

US USEPA (United States Environmental Protection Agency). 2021a. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3): Also Known as "GenX Chemicals." USEPA Document Number 822R-21-010. October 2021.

US USEPA (United States Environmental Protection Agency). 2021b. IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Salts (Public Comment and External Review Draft, 2021). U.S. Environmental Protection Agency, Washington, DC, USEPA/635/R-20/424, 2021.

US USEPA (United States Environmental Protection Agency). 2021c. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). USEPA Document Number USEPA/600/R-20/345F. April 2021.

US USEPA (United States Environmental Protection Agency). 2022. IRIS Toxicological Review of Perfluorohexanoic Acid (PFHxA) and Related Salts (Public Comment and External Review Draft). U.S. Environmental Protection Agency, Washington, DC. USEPA Document Number USEPA/635/R-21/312. February 2022.

Velarde MC, Chan AFO, Sajo MEJV, Zakharevich I, Melamed J, Uy GLB, Teves JMY, Corachea AJM, Valparaiso AP, Macalindong SS, Cabaluna ND, Dofitas RB, Giudice LC, Gerona RR. 2022. Elevated levels of perfluoroalkyl substances in breast cancer patients within the Greater Manila Area. *Chemosphere*; 286(Pt 1):131545.

Verner M-A, Loccisano AE, Morken N-H, Yoon M, Wu H, McDougall R, Maisonet M, Marcus M, Kishi R, Miyashita C, Chen M-H, Hsieh W-S, Andersen ME, Clewell 3rd HJ, Longnecker MP. 2015. Associations of perfluoroalkyl substances (PFAS) with lower birth weight: An evaluation of potential confounding by glomerular filtration rate using a physiologically based pharmacokinetic model (PBPK). *Envtl. Health Perspectives*; 123:1317-1324.

VT DOH (Vermont Department of Health). 2018. Drinking Water Health Advisory for Five PFAS (per-and polyfluorinated alkyl substances). Accessed 5/12/2022 https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_DW_PFAS_HealthAdvisory.pdf

WA DOH (Washington Department of Health). 2019. Draft Recommended State Action Levels for Perand Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods and Supporting Information. Accessed 10/13/2021 at:

https://www.doh.wa.gov/Portals/1/Documents/4200/PFASToxicologicalAssessment.pdf

Wang B, Fu J, Gao K, Liu Q, Zhuang L, Zhang G, Long M, Na J, Ren M, Wang A, Liang R, Shen G, Li Z, Lu Q. 2021. Early pregnancy loss: Do Per- and polyfluoroalkyl substances matter? *Environ Int.*; 157:106837.

Wielsøe M, Kern P, Bonefeld-Jørgensen EC. 2017. Serum levels of environmental pollutants is a risk factor for breast cancer in Inuit: a case control study. *Environ Health*.; 16(1):56.

Winquist and Steenland. 2014. Perfluorooctanoic acid exposure and thyroid disease in community and worker cohorts. *Epidemiology*; 25:255-264.

Xu Y, Fletcher T, Pineda D, Lindh CH, Nilsson C, Glynn A, Vogs C, Norstrom K, Lilja K, Jakobsson K, Li Y. 2020. Serum half-lives for short- and long-chain perfluoroalkyl acids after ceasing exposure from drinking water contaminated by firefighting foam. *Environmental Health Perspectives*; 128(7):077004-1.

Zhang Y, Beesoon S, Zhu L, Martin JW. 2013. Biomonitoring of perfluoroalkyl acids in human urine and estimates of biological half-life. *Environ Sci Technol*; 47(18):10619-10627.

Zhang H, Zhou NS, Cui R, Cui Q, Guo H, Guo Y, Sun Y, Dai J. 2018. Subchronic Hepatotoxicity Effects of 6:2 Chlorinated Polyfluorinated Ether Sulfonate (6:2 Cl-PFESA), a Novel Perfluorooctanesulfonate (PFOS) Alternative, on Adult Male Mice. *Environ. Sci. Technol.*; 52(21):12809.

Costs:

Compliance Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity

The proposed regulation will require compliance with emerging contaminant monitoring, emerging contaminant notification levels and monitoring and treatment associated with the proposed PFAS MCLs. An overview of cost information for each of these elements is presented below.

Emerging Contaminants Monitoring Requirements (ECMR):

PHL § 1112, and thus the ECMR, applies to each PWS that serves at least five service connections used by year-round residents or that regularly serves at least 25 year-round residents, defined in the SSC as a community water system (CWS); or a PWS that regularly serves at least twenty-five of the same people, four hours or more per day, for four or more days per week, for 26 or more weeks per year, defined in the SSC as a nontransient noncommunity water system (NTNC). The ECMR applies to approximately 3,550 PWS that may be either privately owned or publicly owned. The cost of the ECMR includes the cost of laboratory analysis for each PWS as well as the cost to the Department for administering the ECMR program.

The ECMR will be modeled after the Environmental Protection Agency's (USEPA) fifth Unregulated Contaminant Monitoring Rule, 40 CFR 141.40 (UCMR5), to allow samples collected under UCMR5 to be used to satisfy the requirements of the ECMR. Consistent with UCMR5, ECMR will require that one sample set be collected per entry point. It is estimated that approximately 3,550 PWS will be required to monitor at 5,247 locations. All PWS must use USEPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry to comply with this requirement. The cost of analysis for this method may vary based on the laboratory selected, and whether a field reagent blank is analyzed in accordance with the approved method. It is estimated to cost between \$350 and \$700 per sample. Estimated sampling costs are based on estimates prepared by USEPA and surveys of laboratories certified by the ELAP. This estimate does not include the cost of labor to collect and transport the sample. The cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190 per PWS; total costs will be proportional to the number of entry points. The number of entry points does not always correspond with system size, meaning, large water systems may have one entry point where small systems may have multiple. Table 8 provides a range of sampling costs based on the estimated number of samples that will be required.

Table 8: Impacts on the regulated community – Emerging Contaminants

Monitoring Requirements

| System Type | Number of water systems | Estimated number of samples | Low cost per sample (\$350) | High cost per sample (\$700) | | |
|---------------------------|-------------------------|-----------------------------------|-----------------------------|---------------------------------|--|--|
| Community Water Systems | 2,837 | 4,797 | 1,678,950 | 3,357,900 | | |
| Nontransient noncommunity | 713 | 1,084 | 379,400 | 758,800 | | |
| Total | | | \$2,058,350 | \$4,116,700 | | |

The UCMR5 requires each PWS serving more than 10,000 people to monitor at their own expense. For PWS serving between 3,300 and 10,000 people, amendments to the American Water Infrastructure Act (AWIA) Section 2021(a) required that USEPA collect monitoring data from all systems serving more than 3,300 people "subject to the availability of appropriations". Similarly, USEPA is required under the Safe Drinking Water Act (SDWA) Section 1445(a)(2)(C)(ii) to pay the "reasonable cost of such testing and laboratory analysis" for all applicable PWS serving 25 to 10,000 people. This means that if appropriations are made, the USEPA will pay the cost of analysis for each PWS that serves between 3,300 and 10,000 people as well as a small national subset of PWS serving 25 to 3,300 people.

The effective date of this ECMR program has been established to align with the UCMR5 to ensure that the cost of analysis is minimized by allowing a PWS to use the same samples under both programs. For the ECMR, pursuant to PHL § 1112, samples must be collected by a laboratory certified by the Department's Environmental Laboratory Approval Program (ELAP). Not all laboratories certified under UCMR5 are ELAP certified. There are no similar programs available currently for each PWS that serves 3,300 people or fewer. These water systems generally do not participate in UCMR5 and will be required to pay for their own monitoring under the ECMR.

The cost of continued compliance will depend on many factors, including the concentration of compounds detected during initial monitoring and whether any MCLs are exceeded. The cost per sample is expected to be the same for continued compliance as it is for initial monitoring.

Notification Levels (NL):

There are 3,549 PWS that will be required to monitor for emerging contaminants and must provide public notification when levels are confirmed to be at or above the notification level. The Department estimates that 0.12% or four (4) PWS that monitor for emerging contaminants will have monitoring results that are equal to or exceed the category 1 notification level of 30 ppt and 2.5% or 87 PWS will have monitoring results that are equal to or exceed the notification level of 100 ppt. The Department estimates a notification cost of \$5 per service connection unit including labor, fees and postage, however larger systems may pay a much lower per unit cost for notification. Similarly, a water system that can hand deliver notices may pay a lower per unit cost. Many PWS that will provide notification are currently providing public notification due to an MCL exceedance. The cost per water system will vary significantly depending on the size of the water system and the method of notification selected. Table 9 demonstrates the expected number of PWS that will exceed both the category 1 and category 2 notification levels.

Table 9 – Expected Number of Systems at or Above the Notification Level

| System Type | Number of water systems | Category 1 Notifications | Category 2 Notifications |
|---------------------------|-------------------------|-----------------------------|-----------------------------|
| Community Water Systems | 2,837 | 3 | 70 |
| Nontransient noncommunity | 713 | 1 | 17 |
| Total | | 4 | 87 |

Maximum Contaminant Levels (MCL):

Community Water Systems (CWS) and non-transient noncommunity (NTNC) water systems will begin monitoring for PFNA, PFDA, PFHxS, PFHpA beginning April 1 of 2023. There are approximately 3,000 PWS that will be required to routinely monitor for these

compounds. Water systems that have previously monitored for these compounds and have confirmed the data by collecting between one and three follow-up samples can use existing data to determine whether an MCL is exceeded. If a PWS has not monitored for these compounds previously or if the presence of these compounds has not been confirmed, the PWS will be required to collect samples in 2023. Each PWS will be required to comply with the MCL by completing a State approved corrective action by January 1, 2025. A PWS that is not in compliance by this date will be considered in violation of the MCL.

The proposed regulation also modifies the analytical and reporting requirements. Effective April 1, 2023, each PWS must use USEPA 537.1: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) or USEPA 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry. All compounds in the approved analytical method must be reported to the State by the laboratory conducting the analysis to ensure that the State can review quality assurance/quality control information and any case narrative prepared by the laboratory. This change in monitoring requirements will require any laboratory that subcontracts analytical services to provide documentation from the laboratory conducting the analysis in addition to any summary that is prepared. The Department estimates that the cost of the full analytical method using either USEPA 537.1 or USEPA 533 will be between \$350 and \$700 per sample. It is difficult to estimate the cost for each water system, since each water system has a different number of sources. In addition, the total number of samples from each source that a PWS must collect is unknown since the number of samples

required is based on compliance monitoring results, with less sampling required when no contaminants are detected versus when contaminants are detected above and below the MCL.

This proposal includes modifications which clarify requirements that initial monitoring for PFAS compounds are at the source for all water systems regardless of size. The proposal gives the State discretion to move the compliance point to entry point based on specific system operation or the presence of treatment for PFAS compounds. There are 6,312 active sources in the Safe Drinking Water Information System (SDWIS). Table 10 provides a range of sample costs by source water type, based on the minimum number of samples required.

Table 10: Analytical Costs of sampling for PFNA, PFDA, PFHxS, PFHpA and PFAS6 for 3,000 public water systems

| Source Type | Minimum Number of samples required | Number of sources | Cost per source type low (\$) | Cost per source type high (\$) |
|---------------|------------------------------------|-------------------|-------------------------------|--------------------------------|
| Surface Water | 4 | 306 | 428,400 | 856,800 |
| Ground Water | 2 | 5,888 | 4,121,600 | 8,243,200 |
| Spring | 2 | 111 | 77,700 | 155,400 |
| Other | 4 | 7 | 9,800 | 19,600 |
| Total | | 6,312 | \$4,637,500 | \$9,275,000 |

Costs to Private Regulated Parties:

There are approximately 7,200 privately owned PWS in NYS. Of these, an estimated 2,100 systems serve residential suburban areas, manufactured housing communities and apartment buildings, residential and non-residential health care facilities, industrial and commercial buildings, private schools and colleges, and other facilities. The remaining 5,100 privately owned PWS serve restaurants, convenient stores, motels, campsites and other transient systems.

Emerging Contaminants Monitoring Requirements (ECMR):

The ECMR apply to approximately 3,500 CWS and NTNC. Mobile home parks, homeowners' associations that operate their own PWS, daycares, private schools, office buildings and investor-owned utilities are the types of private parties regulated by the Department and will be required to monitor for emerging contaminants. The exact costs for monitoring for emerging contaminants for each PWS, including privately-owned PWS, cannot be determined due to several variables. Monitoring costs for a privately-owned PWS is dependent upon the system size, the number of affected entry points and the levels of each contaminant. The Department does not maintain ownership records for each PWS, but it is estimated that a significant percentage of the approximately 2,200 PWS that serve less than 1,000 people are privately owned. Pursuant to PHL § 1112 the proposed regulation requires sampling of water systems that serve as few as five service connections and serve fewer than 25 people. These very small systems are typically privately owned and represent primarily mobile home parks or a small group of residents with a common source of drinking water. There are approximately 550 very small PWS that will be required to comply with these requirements. The total cost to the 550 very small water systems is anticipated to be \$327,250-\$654,500 or between \$595 and \$1,190 per water system based on 1.7 entry points. The total estimated cost to water systems that serves less than 1,000 people is \$1,309,000 and \$2,618,000, or similarly between \$595 and \$1,190 per PWS based on an average of 1.7 entry points.

Notification Levels (NL):

The cost of notices is estimated to be \$5 per service connection, depending on the size of the PWS, which includes privately owned PWS.

Maximum Contaminant Levels (MCL):

The costs to private regulated parties include monitoring and notification costs for community water systems and nontransient noncommunity water systems; routine compliance monitoring for PFAS6, and treatment costs for each PWS that exceeds the MCLs.

Monitoring and treatment costs for each privately-owned PWS is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs to PWS, including privately-owned PWS, for monitoring and treatment for emerging contaminants as well as PFAS6 cannot be determined due to several variables. The cost for a single sample for emerging contaminants is between \$350-\$700 per sample using USEPA method 537.1 or 533, including the cost of field reagent blank.

It is estimated that 14% of water systems would exceed the PFAS6 MCL of 30 ppt; however, many of these PWS already exceed the MCL for PFOA and/or PFOS or have an enforcement deferral for these compounds and are working towards or have achieved corrective action that is expected to also address these compounds. It is expected that an additional 46 PWS or 1.56% will exceed the MCL of 30 ppt for PFAS6. It is expected that approximately 2.14% of PWS will either exceed the proposed MCL of 10 ppt for PFHxS, PFHpA, PFNA and PFDA or the PFAS6 MCL, for a total of 64 PWS. These PWS may be either publicly owned or private.

The USEPA has developed a Work Breakdown Structure (WBS) cost estimating tool for different PFAS treatment options. Depending on the treatment option selected and the size of the system, USEPA's WBS tool provides estimated annualized costs per system size as shown in Table 11.

Table 11 - Estimate Annualized Costs for Treatment

| Total Annual (Direct, indirect capital plu operation and recommend) | et and add-on s annual | Population Served ≤500 | Population Served 501 to 3,300 | Population Served 3,301 to 10,000 | Population Served 10,001 to 50,000 | Population Served 50,001 to 100,000 | Population Served 100,001 to 500,000 |
|---|---------------------------|---------------------------|--------------------------------------|---|---|--|---|
| Treatment Costs: Granular | Midpoint Estimate | \$25,000 | \$110,900 | \$412,200 | \$1,246,400 | \$2,799,400 | \$8,947,800 |
| Activated Carbon | Range | \$19,800 to \$30,300 | \$87,700 to \$134,000 | \$335,000 to \$489,500 | \$1,016,000 to \$1,476,900 | \$2,281,900 to \$3,316,800 | \$7,255,600 to \$10,640,000 |
| Treatment Costs: Ion | Midpoint Estimate | \$19,500 | \$74,000 | \$262,400 | \$869,700 | \$2,036,400 | \$7,339,100 |
| Exchange | Range | \$15,000 to \$24,000 | \$59,100 to \$88,900 | \$212,400 to \$312,300 | \$692,700 to \$1,046,600 | \$1,623,400 to \$2,449,300 | \$5,777,400 to \$8,900,800 |
| Treatment Costs: Point | Midpoint Estimate | \$17,800 | \$128,500 | \$449,600 | Not | Not | Not |
| of Use Reverse Osmosis | Range | \$1,700 to \$33,800 | \$33,800 to \$223,100 | \$223,100 to \$676,000 | applicable | applicable | applicable |

These estimated costs are based on 2020 dollars and incorporate a 3% discounting rate over approximately 20 years. Given recent supply-chain challenges for different components of these treatment systems and higher inflationary pressures, actual annualized estimates could be higher than the ranges presented by USEPA.

Each PWS will likely make rate adjustments to accommodate these additional capital and operational costs. Municipally owned PWSs may qualify for federal or state loans or grants to offset some of the capital investment for treatment system components or upgrades. Most privately owned water systems do not qualify for grants but are able to take advantage of loans.

Cost to the Department of Health:

Emerging Contaminants Monitoring Requirements:

The Department will incur costs to implement the ECMR. The Department's responsibilities will involve regulatory oversight, program implementation, enforcement and limited sampling assistance to the smallest water systems. Three employees will need to be hired at a cost of \$397,000 to the Department. This cost includes salary, fringe and indirect costs. The

Department will also need to procure equipment for data management at a cost of \$285,000. The total anticipated cost to the Department is \$682,000.

Notification Levels:

The Department will incur costs associated with tracking public notices and completing enforcement if notices are not delivered. The cost of these services is included in the \$397,000 cost for personnel detailed above.

Maximum Contaminant Levels:

The proposed regulation will also create administrative costs to the Department and local health departments related to implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the PWS; review and approval of engineering plans (i.e., treatment plans); and activities associated with enforcement and public notification. The cost to the State for these services is included in the \$397,000 cost for personnel detailed above. The cost to local health departments that provide environmental health services on behalf of the Department will vary significantly, depending on the number of PWS in a county and how many of the PWS exceed the MCL.

Additionally, the Department and NYS Department of Environmental Conservation (NYSDEC) will incur costs associated with the investigation, remediation, and long-term monitoring associated with the release of these contaminants.

Although the proposed regulations do not apply to private wells, costs will be incurred by NYSDEC, as the lead agency for investigating, remediating, and monitoring of contaminated

sites, as the MCLs will be used by the NYSDEC as guidance to determine whether a private well in NYS is contaminated by PFHxS, PFHpA, PFNA, PFDA and/or PFAS6. There are an estimated 800,000 private water supply wells in NYS. At this time, it is not possible to estimate the number of private wells that might be affected by contamination and therefore costs to NYSDEC cannot be determined.

Cost to State and Local Government:

The regulations will apply to local governments—including towns, villages, counties, cities, and authorities or area wide improvement districts—which own or operate a PWS subject to this regulation. There are approximately 1,500 PWS that are owned or operated by local governments.

In addition, State agencies that operate a PWS will be required to comply with the proposed amendments. There are approximately 250 State-owned or operated facilities with a PWS. Examples of such facilities are State-owned schools, office buildings, correctional facilities, Thruway service areas, and any other State-owned structure or property.

Emerging Contaminants Monitoring Requirements:

The cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190 per water system. As a result, the total cost to State and local government is expected to be between \$1,041,250 and \$2,082,500. Alignment with the Federal UCMR5 will decrease the overall cost burden to local government, by reducing duplication of effort. Local governments with water systems that serve 3,300 and fewer people will be required to pay for monitoring as well as a PWS that serves between 3,300 and 10,000 that either do not have USEPA funded

samples analyzed by a ELAP certified laboratory or if USEPA is unable to support the analytical costs associated with UCMR5 for a PWS that serve between 3,300 and 10,000 people.

Notification Levels:

Department estimates a notification cost of \$5 per service connection unit including labor, fees and postage; however, larger systems may pay a much lower per unit cost for notification. Similarly, a water system that can hand deliver notices may pay a lower per unit cost. The cost per water system will vary significantly depending on the size of the water system and the method of notification selected.

Maximum Contaminant Levels:

The costs to state and local government owned PWS include monitoring and notification costs for CWS and NTNC water systems; routine compliance monitoring for PFAS6, and treatment costs for each PWS that exceeds the MCLs. There are approximately 1,500 PWS owned by local government and 250 PWS owned by State government.

Monitoring and treatment costs for each PWS owned by local government is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs for monitoring and treatment for emerging contaminants as well as PFAS6 for the PWS, including a PWS owned by local government, cannot be determined due to several variables. The cost for a single sample is between \$350-\$700 per sample using USEPA Method 537.1 or 533, including the cost of field reagent blank.

It is estimated that 14% of water systems would exceed the PFAS6 MCL of 30 ppt; however, many of these PWS already exceed the MCL for PFOA and/or PFOS or have an

enforcement deferral for these compounds and are working towards or have achieved corrective action that is expected to also address these compounds. It is expected that an additional 27 PWS owned by state or local government or 1.56% is expected to exceed the MCL of 30 ppt for PFAS6. It is expected that approximately 2.14% of PWS will either exceed the proposed MCL of 10 ppt for PFHxS, PFHpA, PFNA and PFDA or the PFAS6 MCL, for a total of 37 PWS owned by State or local government.

The USEPA has developed a Work Breakdown Structure (WBS) cost estimating tool for different PFAS treatment options. Depending on the treatment option selected and the size of the system, USEPA's WBS tool provides estimated annualized costs per system size as shown in Table 11.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the PWS; review and approval of plans (i.e., treatment plans); and activities associated with enforcement and public notification of MCL exceedances.

Each PWS owned by local government will likely make rate adjustments to accommodate these additional capital and operational costs. Municipally owned PWSs may qualify for federal or state loans or grants to offset some of the capital investment for treatment system components or upgrades. Most PWS owned by State government, such as correctional facilities or schools, do not have ratepayers.

Local Government Mandates:

Local governments that own or operate a PWS will be required to comply with this regulation as noted above for ECMR, notification levels and MCLs. There will be no impacts to local governments that do not own or maintain a PWS.

Paperwork:

Emerging Contaminants Monitoring Requirements (ECMR) and Notification Levels (NL):

The ECMR creates a new monitoring and regulatory program with associated paperwork, tracking and enforcement. Each PWS will be required to monitor for emerging contaminants and submit these results to the Department. They will be required to perform additional calculations to determine if they are in violation of any MCL as well as report any compounds at or above the notification level to the Department within 24 hours. The Department will be required to track water system compliance with these new regulations, and initiate enforcement when a water system fails to meet its regulatory obligations. This will require careful record keeping ensuring successful enforcement and ultimate compliance with the regulatory requirements.

Maximum Contaminant Levels:

The additional monitoring, reporting, recordkeeping and paperwork needed for PFAS6 is expected to be minimal because operators of a PWS are currently required to keep such records for existing MCLs, and these regulations add four additional chemicals. The reporting and recordkeeping requirements will increase if MCLs are exceeded and/or treatment is required.

Duplication:

Emerging Contaminants Monitoring Requirements:

The ECMR is duplicative with the UCMR5 requirements for a PWS that serves 3,300 or more people. To minimize duplication, the monitoring period in the proposed regulation has been aligned with the UCMR where possible, and samples collected under UCMR will count towards ECMR monitoring requirements when samples collected under UCMR are analyzed by an ELAP approved laboratory.

Notification Levels:

There will be no duplication of existing State or federal regulations.

Maximum Contaminant Levels:

There will be no duplication of existing State or federal regulations.

Alternatives:

Emerging Contaminants Monitoring Requirements:

The ECMR has been adopted into PHL § 1112, which requires the Commissioner to adopt regulations. No other alternatives were considered. The financial impact to a PWS that serves fewer than 3,300 people can be mitigated if the Department implements the program directly and assists small PWS with the cost of monitoring.

Notification Levels:

The NL program has been adopted into PHL § 1112, which requires the Commissioner to adopt regulations. The notification levels in the regulation were developed by the Department and recommended by the DWQC based on the best available scientific data. No other alternatives were considered.

Maximum Contaminant Levels:

Three alternatives to MCLs were considered:

- 1. maintain the existing MCL of 0.05 mg/L that applies to all unspecified organic chemicals when no chemical specific MCL exists for PFNA, PFHxS, PFHpA and PFDA;
- 2. wait for the US USEPA to issue a federal MCL; or
- 3. promulgate an MCL for PFNA, PFHxS, PFHpA and PFDA at 10 ppt each.

Based on deliberations of the DWQC and the additional toxicological analysis conducted by the Department it was determined that the current MCL of 0.05 mg/L, which is a generic standard for a broad class of organic chemicals, is not protective of public health for these four specific chemicals. Waiting for the USEPA to set a new MCL was impractical due to the prevalence and concerns surrounding PFNA, PFHxS, PFHpA and PFDA combined with the timeframes required under the Safe Drinking Water Act.

The 10 ppt standard, while health protective, will allow for a total concentration of upwards of 60 ppt, which is not sufficiently health protective.

The DWQC recommended that the Department review scientific data and propose a regulatory approach to sum PFOA, PFOS, PFDA, PFHxS, PFNA, and PFHpA. This has been called PFAS6. Based on a review of the occurrence of these compounds and available toxicological data, the Department proposes MCLs of 10 ppt each for perfluorohexanesulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA). Based on available health effects information, the Department also proposes a MCL of 30 ppt for the sum of PFOA, PFOS, PFHxS, PFHpA, PFNA and PFDA.

The Department determined that summing six PFAS compounds to 30 ppt addresses the additive toxicity of the chemicals in situations where they are present as mixtures and is also operationally feasible.

Federal Standards:

Emerging Contaminants Monitoring Requirements

This proposal is similar to UCMR5 in that it is a monitoring rule for unregulated contaminants in drinking water. This proposal expands the scope of UCMR5 by extending applicability to a PWS that serves fewer than 3,300 persons.

Notification Levels:

There are no federal standards for notification levels.

Maximum Contaminant Levels:

There are no federal MCLs for PFDA, PFHpA, PFHxS, PFNA or PFAS6.

Compliance Schedule:

Emerging Contaminants Monitoring Requirements (ECMR):

Each PWS will begin monitoring for emerging contaminants beginning April 1, 2023. A PWS may monitor in accordance with the schedule established by USEPA for UCMR. A PWS that is not required to participate in UCMR5 will have a monitoring schedule issued by the Department.

Notification Levels:

The effective date for NLs is April 1, 2023. Public notification is required for each PWS that detects emerging contaminants at or above the notification level on or after this date.

Maximum Contaminant Levels:

All water systems must begin monitoring for PFAS6 beginning April 1, 2023. A PWS that has conducted monitoring prior to April 1, 2023 for PFAS as a result of the MCLs for PFOA and PFOS may count this monitoring towards the this requirement as long as this monitoring meets all the requirements of this proposed regulation. For example, there must be at least two quarters of monitoring with all of the compounds in the analytical method reported; USEPA methods 537.1 or 533 must be used; and analysis must be performed by an ELAP approved laboratory. If the MCL is exceeded or compounds are detected at or above the notification level, public notification is required. The requirement to report all compounds in the approved analytical method will begin on April 1, 2023. Water systems must implement corrective action and be in compliance with the MCLs by January 1, 2025.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effects on Small Business and Local Governments:

Many of the public water systems (PWS) affected by the proposal are owned or operated by small businesses or local government. The Department does not maintain information on the number of the PWS owned by small businesses. There are approximately 1,500 PWS owned by local governments.

Emerging Contaminants Monitoring Requirements (ECMR): Small businesses will be affected. The cost of analysis is estimated to be between \$350 and \$700 per sample. The cost per average PWS, based on 1.7 entry points per system is between \$595 and \$1,190 per water system. The cost to local governments will be between \$892,500 and \$1,785,000. Costs will likely be absorbed by rate payers, tenants and business owners.

Notification Levels (NL): The Department estimates a notification cost of \$5 per service connection including labor, fees and postage. Costs will likely be absorbed by rate payers, tenants and business owners.

Maximum Contaminant Levels (MCL): Each PWS owned and operated by small businesses or local governments must comply with the MCLs and will incur the same impacts as other PWS. Costs will likely be absorbed by rate payers, tenants and business owners.

Reporting and Recordkeeping and Other Compliance Requirements:

Emerging Contaminants Monitoring Requirements and Notification Levels: The ECMR

creates a new regulatory program with paperwork, tracking and enforcement. A PWS owned and

operated by small businesses or local governments will incur the same costs as other PWS.

Maximum Contaminant Levels: The additional paperwork needed is expected to be

minimal because a PWS is required to keep such records for existing MCLs. The paperwork

requirements will increase if MCLs are exceeded and/or treatment is required. A PWS owned

and operated by small businesses or local governments will incur the same costs as other PWS.

Professional Services:

Emerging Contaminants Monitoring Requirements and Maximum Contaminant Levels:

Each PWS will require the services of a laboratory to analyze samples for emerging

contaminants. The laboratory must be approved for USEPA Method 533 by the Department

under its Environmental Laboratory Approval Program (ELAP). Sufficient laboratory capability

and capacity is anticipated to be available. If an MCL is exceeded, a professional will be required

to design changes to the PWS to meet the MCL. A PWS owned and operated by small businesses

or local governments will incur the same costs as other PWS.

Notification Levels: No professional services are required.

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Compliance Costs:

Emerging Contaminants Monitoring Requirements: PHL 1112, and thus the ECMR, applies to CWS and NTNC. The ECMR applies to approximately 3,550 PWS that may be either privately owned or publicly owned. The cost of the ECMR includes the cost of laboratory analysis for each PWS as well as the cost to the Department for administering the ECMR program. Local governments own or operate approximately 1,500 PWS. The remaining 2,050 are expected to be privately owned and could include small businesses. The Department does not track how many PWS are owned by small businesses.

The ECMR will be modeled after the Environmental Protection Agency's (USEPA) fifth Unregulated Contaminant Monitoring Rule, 40 CFR 141.40 (UCMR5), to allow samples collected under UCMR5 to be used to satisfy the requirements of the ECMR. It is estimated that approximately 3,550 PWS will be required to monitor. All PWS must use USEPA Method 533 to comply with this requirement. The cost of analysis for this method may vary based on the laboratory selected, and whether a field reagent blank is analyzed in accordance with the approved method. It is estimated to cost between \$350 and \$700 per sample. The cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190 per PWS; total costs will be proportional to the number of entry points.

The UCMR5 requires each PWS serving more than 10,000 people to monitor at their own expense. For PWS serving between 3,300 and 10,000 people, statutory amendments required that USEPA collect monitoring data from all systems serving more than 3,300 people "subject to the availability of appropriations". Similarly, USEPA is required under the Safe Drinking Water Act (SDWA) § 1445(a)(2)(C)(ii) to pay the "reasonable cost of such testing and laboratory analysis" for all applicable PWS serving 25 to 10,000 people. This means that if appropriations

are made, the USEPA will pay the cost of analysis for each PWS that serves between 3,300 and 10,000 people.

The effective date of this ECMR program has been established to align with the UCMR5 to minimize by allowing a PWS to use the same samples under both programs. For the ECMR, samples must be collected by a laboratory certified by ELAP. Not all laboratories certified under UCMR5 are ELAP certified. PWS serving 3,300 people or fewer generally do not participate in UCMR5 and will be required to pay for their own monitoring under the ECMR.

The cost of continued compliance will depend on the concentration of compounds detected during initial monitoring and whether any MCLs are exceeded.

Notification Levels: PHL § 1112, applies to CWS or NTNC or 3,550 PWS. There are 3,549 PWS that will be required to monitor for emerging contaminants and provide public notification when levels are confirmed to be at or above the notification level.

The Department estimates that 0.12% or four PWS that monitor for emerging contaminants will have results that are equal to or exceed the category 1 notification level of 30 ppt and 2.5% or 87 PWS will have results that are equal to or exceed the notification level of 100 ppt. These PWS may be operated by small business or local government. The Department estimates a notification cost of \$5 per service connection. The cost per water system will vary significantly depending on the size of the water system and the method of notification selected.

Maximum Contaminant Levels: The costs include monitoring and notification costs for CWS and NTNC; routine compliance monitoring for PFAS6, and treatment costs for each PWS that exceeds the MCLs. There are approximately 1,500 PWS owned by local government.

Monitoring and treatment costs is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The cost for a single sample is between \$350-\$700 per sample using USEPA method 537.1 or 533, including the cost of field reagent blank.

It is estimated that 14% of PWS would exceed the PFAS6 MCL of 30 ppt; however, many of these PWS already exceed the MCL for PFOA and/or PFOS or have an enforcement deferral for these compounds and are working towards or have achieved corrective action that is expected to also address these compounds. It is expected that an additional 1.56% will exceed the MCL of 30 ppt for PFAS6. It is expected that approximately 2.14% of PWS will either exceed the proposed MCL of 10 ppt for PFHxS, PFHpA, PFNA and PFDA or the PFAS6 MCL. These PWS may be owned by either a small business or local government. The Department does not track how many PWS are owned or operated by small business.

The USEPA has developed a cost estimating tool for different PFAS treatment options. Depending on the treatment option selected and the size of the system, USEPA's tool provides estimated annualized costs per system size as shown in Table 1.

Table 1 – Estimate Annualized Costs for Treatment

| Total Annualized Costs (Direct, indirect and add-on capital plus annual operation and maintenance) | | Population Served ≤500 | Population Served 501 to 3,300 | Population Served 3,301 to 10,000 | Population Served 10,001 to 50,000 | Population Served 50,001 to 100,000 | Population Served 100,001 to 500,000 |
|---|----------------------|---------------------------|--------------------------------------|---|---|--|---|
| Treatment Costs: Granular | Midpoint Estimate | \$25,000 | \$110,900 | \$412,200 | \$1,246,400 | \$2,799,400 | \$8,947,800 |
| Activated Carbon | Range | \$19,800 to \$30,300 | \$87,700 to \$134,000 | \$335,000 to \$489,500 | \$1,016,000 to \$1,476,900 | \$2,281,900 to \$3,316,800 | \$7,255,600 to \$10,640,000 |
| Treatment Costs: Ion | Midpoint Estimate | \$19,500 | \$74,000 | \$262,400 | \$869,700 | \$2,036,400 | \$7,339,100 |
| Exchange | Range | \$15,000 to \$24,000 | \$59,100 to \$88,900 | \$212,400 to \$312,300 | \$692,700 to \$1,046,600 | \$1,623,400 to \$2,449,300 | \$5,777,400 to \$8,900,800 |
| Treatment Costs: Point | Midpoint Estimate | \$17,800 | \$128,500 | \$449,600 | Not applicable | Not applicable | Not applicable |

|--|--|

These estimated costs are based on 2020 dollars and incorporate a 3% discounting rate over approximately 20 years. Given recent supply-chain challenges and inflationary pressures, actual annualized estimates could be higher than the ranges presented by USEPA.

Each PWS will likely make rate adjustments to accommodate these additional capital and operational costs. Municipally owned PWSs may qualify for federal or state loans or grants to offset some of the capital investment costs. Most privately owned PWS do not qualify for grant but may receive loans. Municipally owned PWS may need to comply with cross-cutters such as Davis-Bacon Act of 1931/ NY Prevailing Wage Rates, American Iron and Steel and/or Buy American Build American Requirements and federal equivalency requirements for environmental assessment when receiving federal assistance, such as funding from the Drinking Water State Revolving Fund (DWSRF). Small businesses that do not pursue DWSRF funding may not need to comply with these cross cutters.

Economic and Technological Feasibility:

Emerging Contaminants Monitoring Requirements and Notification Levels: The proposed requirements are economically and technologically feasible for small businesses and local governments. Analytical methods exist for accurate sample analysis to detect the list of emerging contaminants.

Maximum Contaminant Levels: There are technologically feasible treatment solutions for all PFAS6 contaminants. Many small and rural PWS are currently pursuing treatment for PFOA and PFOS. The treatment technologies for PFAS6 are the same as PFOA and PFOS. Treatment

may present a greater challenge to smaller systems that typically have less resources including financial and technical expertise than larger systems.

Minimizing Adverse Impact:

Emerging Contaminants Monitoring Requirements: The Department is minimizing adverse impact by aligning monitoring requirements with the UCMR. This reduces the amount of duplicative sampling. The Department has the authority to provide monitoring assistance to a PWS, and directly implement the program should funding for both analysis and staffing become available. This option would decrease the financial burden of sampling on small businesses such as mobile home parks or daycares.

Notification Levels: Adverse impacts are expected to be minimal.

Maximum Contaminant Levels: The Department has included several provisions that minimize the impacts on regulated parties. Previous testing conducted using an ELAP approved method and laboratory may satisfy some or all of the initial monitoring requirements; and sampling frequency will decrease after the first year if the contaminants are not detected at a PWS.

New York State offers programs to support PWS with infrastructure investments including but not limited to treatment and development/connection to alternate sources of water. Programs include the DWSRF which provides market rate, low to no interest loans and grants available to many municipally and some privately-owned PWS based on need and financial hardship. In addition, the New York State Clean Water Infrastructure Act of 2017 invests \$2.5 billion in clean and drinking water infrastructure projects and water quality protection across the State. The New York State Water Infrastructure Improvement Act (WIIA) provides competitive

grants to help municipalities fund water quality infrastructure projects. The Infrastructure Investment and Jobs Act (IIJA) passed by Congress and signed by President Biden in 2021 includes funding specifically targeted towards emerging contaminants with a focus on per- and polyfluoroalkyl substances.

Small Business and Local Government Participation:

Small business and local governments were not specifically consulted on this proposal. The Department will send the notice of proposed rulemaking to American Water Works

Association, the New York Rural Water Association and the Association of Towns and

Conference of Mayors. Emerging contaminant monitoring and notification levels are

requirements of PHL § 1112. The NL categories and MCLs set forth in this proposed rule were

recommendations from the Drinking Water Quality Council (DWQC) which met numerous

times in a public forum and were also recorded and publicly available. During each DWQC

meeting, members of the public were allowed to comment, and comments were provided to the

Department outside of the meetings. Based on the information available it is not possible to

determine the number of small businesses that participated during the meetings or provided

comments. All comments provided by the public were made available to the DWQC for their

consideration.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Rural Areas:

These regulations apply to rural areas of the state, where approximately 6,400 small public water supplies (PWS) are located.

Emerging Contaminants Monitoring Requirements (ECMR): There are more PWS in rural areas than urban areas, and those PWS are typically smaller. This regulation applies to community water systems (CWS) which serve at least five service connections used by year-round residents or regularly serve at least 25 year-round residents as well as nontransient noncommunity water systems (NTNC) that regularly serve at least 25 of the same people, four hours or more per day, for four or more days per week, for 26 or more weeks per year. There are approximately 2,200 CWS and NTNC water systems that serve less than 1,000 persons and approximately 335 PWS that serve between 1,000 and 3,300 persons. Most of those water systems are in rural areas. Costs can be mitigated if the Department directly implements the program and provides monitoring assistance to small water supplies.

Notification Levels (NL): It is expected that NLs will impact rural areas in the same manner as the rest of the State.

Maximum Contaminant Levels (MCL): The cost of monitoring may impact rural areas of the State more than urban and suburban areas of the state since rural areas were less likely to detect PFOA and PFOS during 2020 and 2021. These water systems may have expected to be able to reduce monitoring to once every three years for only PFOA and PFOS. These regulations require sampling for the full analytical method and will require monitoring for up to four additional quarters depending on source water type.

Reporting, Recordkeeping and Other Compliance Requirements

Reporting and Recordkeeping:

The obligations imposed on rural area PWS are the same as for all owners or operators of PWS.

Professional Services:

ECMR: Each PWS impacted by the amended regulations will require the Environmental Laboratory Approval Program (ELAP) approved services in accord with USEPA method 533 to analyze samples for emerging contaminants. Sufficient laboratory capability and capacity is anticipated to be available. If an MCL is exceeded, a licensed professional will be required to design changes to the PWS to meet the MCL. A PWS in a rural area will incur the same costs as other PWS.

NL: Most rural area PWS will not need professional services to conduct public notification when a water system confirms the presence of emerging contaminants at or above the notification level.

MCL: If an MCL is exceeded, a licensed professional will be required to design changes to the PWS to meet the MCL.

Compliance Costs:

ECMR: Pursuant to PHL § 1112 the ECMR applies to each PWS that serves at least five service connections used by year-round residents or regularly serves at least 25 year-round residents, defined in the SSC as a community water system (CWS); or a PWS that regularly serves at least 25 of the same people, four hours or more per day, for four or more days per

week, for 26 or more weeks per year, defined in the SSC as a nontransient noncommunity water system (NTNC). The ECMR applies to approximately 3,550 PWS, many of which are located in rural areas. The cost of the ECMR includes the cost of laboratory analysis for each PWS as well as the cost to the Department for administering the ECMR program.

The ECMR will be modeled after the US Environmental Protection Agency's (USEPA) fifth Unregulated Contaminant Monitoring Rule, 40 CFR 141.40 (UCMR5), to allow samples collected under UCMR5 to be used to satisfy the requirements of the ECMR. Consistent with UCMR5, ECMR will require that one sample set be collected per entry point. It is estimated that approximately 3,550 PWS will be required to monitor at 5,247 locations. All PWS must use USEPA Method 533 to comply with this requirement. All PWS must use USEPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry to comply with this requirement. The cost of analysis for this method may vary based on the laboratory selected, and whether a field reagent blank is analyzed in accordance with the approved method. It is estimated to cost between \$350 and \$700 per sample. Estimated sampling costs are based on estimates prepared by USEPA and surveys of laboratories certified by the ELAP. This estimate does not include the cost of labor to collect and transport the sample. The expected cost per average water system, based on 1.7 entry points per system is between \$595 and \$1,190; total costs will be proportional to the number of entry points. Table 1 provides a range of sampling costs based on the estimated number of samples that will be required.

Table 1: Impacts on the regulated community – Emerging Contaminants

Monitoring Requirements

| System Type | Number of water systems | Estimated number of samples | Low cost per sample (\$350) | High cost per sample (\$700) |
|---------------------------|-------------------------|-----------------------------------|-----------------------------|---------------------------------|
| Community Water Systems | 2,837 | 4,797 | 1,678,950 | 3,357,900 |
| Nontransient noncommunity | 713 | 1,084 | 379,400 | 758,800 |

| Total | | \$2,058,350 | \$4,116,700 |
|--------|--|-------------|-------------|
| 1 Otal | | Ψ2,030,330 | 94,110,700 |

The UCMR5 requires each PWS serving more than 10,000 people to monitor at their own expense. For PWS serving between 3,300 and 10,000 people, amendments to the American Water Infrastructure Act (AWIA) Section 2021(a) required that USEPA collect monitoring data from all systems serving more than 3,300 people "subject to the availability of appropriations". For PWS serving between 3,300 and 10,000 people, amendments to the American Water Infrastructure Act (AWIA) Section 2021(a) required that USEPA collect monitoring data from all systems serving more than 3,300 people "subject to the availability of appropriations." Similarly, USEPA is required under the Safe Drinking Water Act (SDWA) Section 1445(a)(2)(C)(ii) to pay the "reasonable cost of such testing and laboratory analysis" for all applicable PWS serving 25 to 10,000 people. This means that if appropriations are made, the USEPA will pay the cost of analysis for each PWS that serves between 3,300 and 10,000 people as well as a small national subset of PWS serving 25 to 3,300 people.

The ECMR program effective date aligns with the UCMR5 to ensure that costs are minimized by allowing a PWS to use the same samples under both programs. For the ECMR, samples must be collected by a laboratory certified by the Department's Environmental Laboratory Approval Program (ELAP). Not all laboratories certified under UCMR5 are ELAP-certified. There are no similar programs available currently for each PWS that serves 3,300 people or fewer. These water systems generally do not participate in UCMR5 and will be required to pay for their own monitoring under the ECMR. Many of the PWS that serve 3,300 people or fewer are in rural areas, and most PWS that serve less than 1,000 people are in rural areas.

The cost of continued compliance will depend on many factors, including the concentration of compounds detected during initial monitoring and whether any MCLs are exceeded. The cost per sample is expected to be the same for continued compliance as it is for initial monitoring.

NL: The Department estimates that 0.12% of PWS that monitor for emerging contaminants will have monitoring results that are equal to or exceed the category 1 notification level of 30 ppt and 2.5% will have monitoring results that are equal to or exceed the notification level of 100 ppt. The Department estimates an average cost of \$5 per service connection to send out proper notifications, which includes labor, fees and postage; however, larger systems may pay a much lower per unit cost for notification. Similarly, a water system that can hand deliver notices may pay a lower per unit cost. The cost per water system will vary significantly depending on the size of the water system and the method of notification selected. Table 9 demonstrates the expected number of PWS that will exceed both the category 1 and category 2 notification levels.

MCL: The costs to PWS in rural areas include monitoring and notification costs for CWS and NTNC; routine compliance monitoring for PFAS6, and treatment costs for each PWS that exceeds the MCLs.

Monitoring and treatment costs for each rural PWS is dependent upon the system size, number of affected entry points/sources and the concentration of each contaminant. The cost for a single sample for emerging contaminants is between \$350-\$700 per sample using USEPA method 537.1 or 533, including the cost of field reagent blank. The cost of a single sample for

emerging contaminants is between \$350-\$700 using USEPA method 537.1 or 533, including the cost of field reagent blank.

It is estimated that 14% of water systems would exceed the PFAS6 MCL of 30 ppt; however, many of these PWS already exceed the MCL for PFOA and/or PFOS or have an enforcement deferral for these compounds and are working towards or have achieved corrective action that is expected to also address these compounds. It is expected that an additional 1.56% of PWS will exceed the MCL of 30 ppt for PFAS6. It is expected that approximately 2.14% of PWS will either exceed the proposed MCL of 10 ppt for PFHxS, PFHpA, PFNA and PFDA or the PFAS6 MCL.

The USEPA has developed a Work Breakdown Structure (WBS) cost estimating tool for different PFAS treatment options. Depending on the treatment option selected and the size of the system, USEPA's WBS tool provides estimated annualized costs per system size as shown in Table 2.

Table 2 - Estimate Annualized Costs for Treatment

| Total Annualized Costs (Direct, indirect and add-on capital plus annual operation and maintenance) | | Population Served ≤500 | Population Served 501 to 3,300 | Population Served 3,301 to 10,000 | Population Served 10,001 to 50,000 | Population Served 50,001 to 100,000 | Population Served 100,001 to 500,000 |
|---|----------------------|---------------------------|--------------------------------------|---|---|--|---|
| Treatment Costs: Granular | Midpoint Estimate | \$25,000 | \$110,900 | \$412,200 | \$1,246,400 | \$2,799,400 | \$8,947,800 |
| Activated Carbon | Range | \$19,800 to \$30,300 | \$87,700 to \$134,000 | \$335,000 to \$489,500 | \$1,016,000 to \$1,476,900 | \$2,281,900 to \$3,316,800 | \$7,255,600 to \$10,640,000 |
| Treatment Costs: Ion | Midpoint Estimate | \$19,500 | \$74,000 | \$262,400 | \$869,700 | \$2,036,400 | \$7,339,100 |
| Exchange | Range | \$15,000 to \$24,000 | \$59,100 to \$88,900 | \$212,400 to \$312,300 | \$692,700 to \$1,046,600 | \$1,623,400 to \$2,449,300 | \$5,777,400 to \$8,900,800 |
| Treatment Costs: Point | Midpoint Estimate | \$17,800 | \$128,500 | \$449,600 | Not | Not | Not |
| of Use Reverse Osmosis | Range | \$1,700 to \$33,800 | \$33,800 to \$223,100 | \$223,100 to \$676,000 | applicable | applicable | applicable |

These estimated costs are based on 2020 dollars and incorporate a 3% discounting rate over approximately 20 years. Given recent supply-chain challenges and higher inflationary pressures, actual annualized estimates could be higher than the ranges presented by USEPA.

Each PWS will likely make rate or rent adjustments to accommodate these additional capital and operational costs. Municipally owned PWSs may qualify for federal or state loans or grants to offset some of the capital investment for treatment system components or upgrades.

Most privately owned water systems do not qualify for grant but are able to take advantage of loans.

Economic and Technological Feasibility

ECMR: The ECMR is economically and technologically feasible for rural area PWS.

Analytical methods exist for accurate sample analysis to detect emerging contaminants.

NL: The NLs are economically and technologically feasible for rural area PWS. The cost of notices is estimated to be \$5 per service connection. This should be feasible for any water system that detects emerging contaminants at or above the notification level.

MCL: Many small and rural water systems are currently pursuing treatment for PFOA and PFOS using treatment technologies that can also abate PFAS6. Treatment may present a greater challenge to smaller systems that typically have less resources than larger systems.

Rural Area Participation:

The Department made presentations outlining the requirements of Public Health Law to rural operators at the New York Rural Water Association conference on May 24, 2022; the Southeastern NY Water Works Conference on June 9, 2022 and the American Water Works Association New York Conference on April 13, 2022. The proposal was discussed during the Drinking Water Quality Council meeting on May 2, 2022. This meeting was open to the public, was broadcast live on the internet, and is available on the Department's website.

JOB IMPACT STATEMENT

Nature of the Impact:

The Department expects there to be a positive impact on jobs and employment opportunities. A subset of public water system (PWS) owners will hire engineering/architectural firms or individuals to assist with regulatory compliance. Each PWS impacted by this amendment will require the professional services of a certified or approved laboratory to perform the analyses for PFAS6 and emerging contaminants, which may create a need for additional laboratory capability and capacity. A PWS that confirms levels of emerging contaminants at or above the notification level may need copy or printing services. Additionally, a subset of owners will require the services of a licensed professional engineer to design facilities to meet the MCLs through treatment, or to access an alternate source.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the proposed regulations.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the proposed regulations.

Minimizing Adverse Impact:

Not applicable.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Subpart 5-1 of 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:

Subparagraph 5-1.43(c)(2)(i) is amended to read as follows:

(i) Any water system that maintains the range of State-specified values for the water quality parameters reflecting optimal corrosion control treatment during three consecutive years of monitoring in accordance with paragraph (1) of this subdivision may reduce the frequency with which it collects the number of distribution system samples for applicable water quality parameters specified in paragraph (1) of this subdivision from every six months to annually. This sampling shall begin during the calendar year immediately following the end of the monitoring period in which the third consecutive year of six-month monitoring occurs. Any water system that maintains the range of State-specified values for the water quality parameters reflecting optimal corrosion control treatment during three consecutive years of annual monitoring under this paragraph may reduce the frequency with which it collects the number of distribution system samples for applicable water quality parameters specified in paragraph (1) of this subdivision from annually to every three years. This sampling begins no later than the third calendar year following the end of the monitoring period in which the third consecutive year of monitoring occurs.

Subparagraph 5-1.47(b)(2)(ii)(b)(1) is amended to read as follows:

(1) contact the State for [information regarding] a list of community based organizations serving target populations, even if they are not located within the water system's service area, and deliver education materials to all appropriate organizations along with an informational notice that encourages distribution to all the organization's potentially affected customers or community water system's users as determined in consultation with the State[;]. The water system must contact the State directly by phone or in person;

Repeal Table 6 of section 5-1.52 and replace with a new Table 6 to read as follows:

 $Table \ 6. \ Microbiological \ Contaminants \ Maximum \ Contaminant \ Level \ (MCL)/Treatment \ Technique \ Trigger \ (TTT)/Treatment \ Technique \ Violation \ (TTV) \ Determination^1$

| Contaminant/ Trigger/Violation | Sample Location | MCL or TTT or TTV | Performance Standard | Determination of MCL/TTV and TTT ¹⁰ |
|-----------------------------------|---------------------------------|----------------------------|-----------------------------------|---|
| Total coliform ² | Distribution Sample Sites | TTT ³ | No positive sample ^{4,5} | A Level 1 TTT occurs at systems collecting 40 or more samples per month when more than 5.0 percent of the samples are total coliform positive. ¹¹ |
| | | TTT ³ | | A Level 1 TTT occurs at systems collecting less than 40 samples per month when two or more samples are total coliform positive. ¹¹ |
| | | TTT ³ | | A Level 1 TTT occurs at any system that fails to collect every required repeat sample after any single total coliform positive sample. ¹¹ |
| | | TTT ⁶ | | A Level 2 TTT occurs at any system that has a second Level 1 trigger within a rolling 12-month period, unless the State has determined a likely reason that the samples that caused the first Level 1 TTT were total coliform positive and has established that the system has corrected the problem. ¹¹ |
| Escherichia coli (E. Coli) | | MCL/ TTT ^{4,6} | No positive sample ^{5,7} | An MCL violation and Level 2 TTT occurs when a total coliform sample is positive for <i>E. coli</i> and a repeat total coliform sample is positive. ¹³ |
| | | MCL/ TTT ^{4,6} | No positive sample ^{5,7} | An MCL violation and Level 2 TTT occurs when a total coliform sample is positive for total coliform but negative for <i>E. coli</i> and a repeat total coliform sample is positive for <i>E. coli</i> . ¹³ |
| | | MCL/ TTT ^{4,6} | | An MCL violation and Level 2 TTT occurs when a total coliform sample is positive for total coliform but negative for <i>E. coli</i> and a repeat total coliform positive sample is not analyzed for <i>E. coli</i> . 13 |

| | | MCL/ TTT ^{4,6} | | An MCL violation occurs when a system fails to collect every required repeat sample after any <i>E. coli</i> positive routine sample. |
|---|--|----------------------------|---|---|
| Fecal indicator: <i>E. coli</i> , and/or enterococci, and/or coliphage ⁸ | Untreated Water from a Ground Water Source | TTV | No fecal indicator in samples collected from raw source water from a ground water source. ^{9,10} | A TTV occurs when a raw water sample is positive for the fecal indicator contaminant and system does not provide and document, through process compliance monitoring, 4-log virus treatment during peak flow at first customer. If repeat sampling of the raw water is directed by the State and all additional samples are negative for fecal indicator, there is no TTV. 9,13 |
| Other trigger or violation | | TTV ⁴ | | A TTV occurs when a system exceeds a TTT and then fails to conduct the required assessment or corrective actions. 12 |
| | | TTV ⁴ | | A TTV occurs when a seasonal system fails to complete a State-approved start-up procedure prior to serving water to the public. ¹⁴ |

All samples collected in accordance with Table 11 footnotes 1 and 2 and Table 11B of this section and samples collected in accordance with subdivision 5-1.51(g) of this Subpart shall be included in determining compliance with the MCL, TTT, and/or TTV unless any of the samples have been invalidated by the State. In accordance with 40 CFR 141.852(a)(2) systems need only determine the presence or absence of total coliforms and *E. coli*; a determination of density is not required.

For total coliform (TC) samples collected from untreated surface water or GWUDI sources, the time from sample collection to initiation of analysis may not exceed 8 hours and the samples must be held below 10 degrees C during transit to the laboratory. For other TC samples, the time from collection to initiation of analysis may not exceed 30 hours. Systems are encouraged, but not required, to hold TC samples below 10 degrees C during transit.

- If the Total Coliform Fermentation Technique using standard methods 9221A or B is used, and if inverted tubes are used to detect gas production, the media should cover these tubes at least one half to two-thirds after the sample is added. Also, no requirement exists to run the completed phase on 10 percent of all TC-positive confirmed tubes. Additionally, lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between this medium and lauryl tryptose broth using the water normally tested, and this comparison demonstrates that the false-positive rate and false-negative rate for TC, using lactose broth, is less than 10 percent.
- If Membrane Filter Technique Standard Methods 9222A, B, and optionally C are used, MI agar also may be used. Verification of colonies is not required.
- If the Standard Methods Presence-Absence (P-A) Coliform Test, 9221D is used, six-times formulation strength may be used if the medium is filter-sterilized rather than autoclaved.
- If the Total Coliform Membrane Filter Technique, Standard Methods 9222 A, B, C is used, MI agar also may be used. Verification of colonies is not required.
- For any TC testing it is strongly recommended that laboratories evaluate the false-positive and negative rates for the method(s) they use for monitoring TC. Laboratories are also encouraged to establish false-positive and false-negative rates within their own laboratory and sample matrix (drinking water or source water) with the intent that if the method they choose has an unacceptable false-positive or negative rate, another method can be used. It is

Total coliform method additions or modifications to approved methods

suggested that laboratories perform these studies on a minimum of 5% of all TC-positive samples, except for those methods where verification/confirmation is already required. Methods for establishing false-positive and negative-rates may be based on lactose fermentation, the rapid test for β -galactosidase and cytochrome oxidase, multi-test identification systems, or equivalent confirmation tests. False-positive and false-negative information is often available in published studies and/or from the manufacturer(s).

- The system must complete a Level 1 assessment as soon as practical after exceeding a Level 1 TTT. The system must submit the completed Level 1 assessment form to the State within 30 days after the system learns that it has exceeded a trigger. Corrective actions shall be addressed in accordance with section 5-1.71(e) of this Subpart.
- ⁴ See Table 13 for public notification requirements
- ⁵ If any total coliform or *E. Coli* sample is positive, repeat samples must be collected in accordance with Table 11B of this section.
- A Level 2 assessment must be completed within 30 days after the system learns that it has exceeded a trigger. Corrective actions shall be addressed in accordance with section 5-1.71(e) of this Subpart.
- For notification purposes, an E. coli MCL violation in the distribution system is a public health hazard requiring Tier 1 notification. At a ground water system, Tier 1 notification is required after initial detection of *E. coli* or other fecal indicator in raw source water, if the system does not provide 4-log virus treatment and process compliance monitoring, even if not confirmed with additional sampling
- For any fecal indicator sample collected as described in section 5-1.52, Table 6, the time from sample collection to initiation of analysis may not exceed 30 hours. The system is encouraged but is not required to hold samples below 10 °C during transit.
- If raw water source sample is fecal indicator positive, the water system, in consultation with the State, may collect an additional 5 samples within 24 hours at each source that tested fecal indicator positive. If none of the additional samples are fecal indicator positive, then there is no TTV. Note that Tier 1 notification must be made after the initial raw water fecal indicator positive sample, even if it is not confirmed with additional sampling.
- ¹⁰ Failure to take every required routine or additional routine sample in a compliance period is a monitoring violation.
- Failure to analyze for *E. coli* following a total coliform positive routine sample is a monitoring violation.
- Failure to submit a monitoring report or completed assessment form after a system properly conducts monitoring or assessment in a timely manner is a reporting violation.
- Failure to notify the State following an *E. coli*-positive sample as required by 5-1.52 Table 13 and 5-1.77(a) of this Subpart in a timely manner is a reporting violation.
- Failure to submit certification of completion of State approved start-up procedure by a seasonal system is a reporting violation.

Footnote 4 of section 5-1.52 Table 11A is amended to read as follows:

⁴ Samples must be taken and analyzed every day the system serves water to the public and the turbidity of the raw water exceeds [1.49]<u>1</u> NTU. The samples count toward the weekly sampling requirement.

Section 5-1.80 is amended to read as follows:

The provisions of this section, and sections 5-1.81 through 5-1.83 of this Subpart apply to all public water systems, as defined in paragraph 5-1.1(cb) of this Subpart, supplied by a surface water source(s) or ground water source(s) directly influenced by surface water, provided the system serves 15 or more service connections or serves 25 or more persons. The requirements in this section for filtered systems apply to any system with a surface water or GWUDI source that is required to provide filtration, regardless of whether the system is currently operating a filtration system. All treatment must comply with the requirements of the Microbial Toolbox Components as described in 40 CFR 141.715 through 40 CFR 141.720. Any unfiltered systems that are in compliance with the filtration avoidance criteria in section 5-1.30(c) of this Subpart, are subject to the requirements in sections 5-1.80 through 5-1.83 of this Subpart pertaining to unfiltered systems. Wholesale system compliance with sections 5-1.81 through 5-1.83 of this Subpart is based on the population of the largest system in the combined distribution system. The above systems shall comply with the following requirements:

Subparagraph 5-1.81(a)(1)(iii)(c) is repealed and replaced with the following:

- (c) shall sample their source water for *Cryptosporidium* at least twice per month for 12 months, or at least monthly for 24 months, if, based on monitoring conducted under this subparagraph, they meet one of the following criteria:
- (1) For systems using lake/reservoir sources, the annual mean *E. coli* concentration is greater than 10 E. coli/100 mL;
- (2) For systems using flowing stream sources, the annual mean *E. coli* concentration is greater than 50 E. *coli*/100 mL; or
- (3) The system does not conduct *E. Coli* monitoring once every two weeks for 12 months.
- (4) Systems using ground water under the direct influence of surface water (GWUDI) must comply with the requirements of subclause (1) through (3) of this clause based on the *E. coli* level that applies to the nearest surface water body. If no surface water body is nearby, the system must comply based on the requirements that apply to systems using lake/reservoir sources.
- (5) the State may approve an alternative to the *E. coli* concentration specified in subclause (1) and subclause (2) of this clause to trigger *Cryptosporidium* monitoring. This approval by the State will be provided to the system in writing and will include the basis for the State's determination that the alternative trigger concentration will provide a more accurate identification of whether a system will exceed the Bin 1 *Cryptosporidium* level specified in section 5-1.83(a)(2) of this Subpart.

Subdivision 5-1.92(a) is amended to read as follows:

(a) The supplier of water may request, and the department may grant, one or more exemptions from any treatment technique requirement, except for <u>filtration and disinfection</u> of a surface water source <u>in accordance with 5-1.30(b)</u>, (c) and (g) of this <u>Subpart</u>, and/or any MCL, except for *Escherichia coli* (*E. coli*). Exemptions may be granted to any public water system based on a finding that:

* * *

(4) The supplier of water has not been granted a variance under section 5-1.90 of this Subpart.

NOTICE OF CONSENSUS RULEMAKING

Statutory Authority:

The Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, is authorized by section 225 of the Public Health Law to establish, and from time to time, amend and repeal sanitary regulations, known as the sanitary code of the State of New York.

Basis:

The proposed regulatory amendments are non-substantive and non-controversial. The amendment of 10 NYCRR Subpart 5-1 "Public Water Systems" of the State Sanitary code will correct typographic errors, update references and make minor technical revisions to conform the regulation with federal requirements to obtain primacy for the implementation and enforcement of federal drinking water regulations from U.S. Environmental Protection Agency.

JOB IMPACT STATEMENT

The Department of Health has determined that the proposed revisions will not have substantial adverse impact on jobs or employment opportunities. These correct mainly typographic errors and do not change the requirements water systems need to follow to implement the regulation.



of Health

Department Public Health and Health Planning Council

Project # 221248-C NYU Langone Hospital-Long Island

Hospital Program: County: Nassau

Construction Acknowledged: July 26, 2022 Purpose:

Executive Summary

Description

NYU Langone Hospital-Long Island (NYULH-LI) requests approval to certify an extension clinic to provide single specialty (gastroenterology) ambulatory surgery services on the 7th floor of 211 Station Drive, Mineola. The project will allow NYULH-LI to address capacity issues at the main hospital.

The hospital also has approval for an extension clinic on the 6th floor of the building to provide wound care services, which is currently under construction.

OPCHSM Recommendation Contingent Approval is recommended.

Need Summary

Currently, patients needing outpatient endoscopies at NYU Langone Hospital-Long Island have a three-month wait time. The applicant projects 3,373 visits in the first year and 3,655 in the third with Medicaid utilization of 16.4%.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

The total project cost of \$18,219,372 will be met through equity from hospital operations. The budget projects Year One net income of \$3,304,223 and \$4.511.830 by Year Three.

| Budget | Year One | Year Three |
|------------|------------------|------------------|
| | (2023) | <u>(2025)</u> |
| Revenues | \$11,977,013 | \$13,769,697 |
| Expenses | <u>8,672,790</u> | <u>9,257,867</u> |
| Net Income | \$3,304,223 | \$4,511,830 |

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

- 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. The submission of Design Development and State Hospital Code (SHC) Drawings, as described in BAER Drawing Submission Guidelines DSG-1.0 Required Schematic Design (SD) and Design Development (DD) Drawings, and 3.20 LSC Chapter 20, New Ambulatory Healthcare Public Use, for review and approval. [DAS]

Approval conditional upon:

- 1. This project must be completed by **June 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **June 1**, **2023**, and construction must be completed by **March 1**, **2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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 December 8, 2022

Need and Program Analysis

Proposal

NYU Langone Hospital-Long Island is seeking approval to certify an extension clinic to provide single specialty (gastroenterology) ambulatory surgery services on the 7th floor of 211 Station Drive, Mineola, NY 11501, in Nassau County.

Analysis

Currently, inpatients and outpatients receive their care in the same endoscopy suite which is located within the adjacent hospital. The wait for outpatient endoscopy procedures has been up to three months. This project will relieve pressure on the in-hospital endoscopy rooms by performing surgeries that meet appropriate criteria for the proposed extension clinic. The current hospital endoscopy suite has six procedure rooms. This extension clinic will have four procedure rooms for immediate use and two shelled procedure rooms for future growth. Approval of this project will allow more timely appointments leading to improved outcomes and patient satisfaction.

The primary service area is Nassau County, the secondary service area includes Suffolk and Queens Counties. According to Data USA, in 2019, 95.7% of the population in Nassau County has health coverage as follows.

| Employer Plans | 58.9% |
|-----------------|-------|
| Medicaid | 10.4% |
| Medicare | 13.7% |
| Non-Group Plans | 12.4% |
| Military or VA | 0.19% |

The applicant projects 3,373 visits in the first year and 3,655 in the third with Medicaid utilization of 16.4%. Staffing is expected to increase by 32.2 FTEs as a result of this project.

The table below shows the number of patient visits at relevant ambulatory surgery centers in Nassau County for the years 2019 through 2021.

| Facility Name | Specialty | Patient Visits | | |
|-------------------------------------|------------------|----------------|--------|--------|
| | | 2019 | 2020 | 2021 |
| Day OP of North Nassau ³ | Multi | 860 | 619 | 0 |
| East Hills Surgery Center | Multi | 3,001 | 3,964 | 4,886 |
| Endoscopy Center of LI | Gastroenterology | 8,547 | 6,874 | 8,696 |
| Garden City Surgi Center | Multi | 7,109 | 5,628 | 7,066 |
| LI Center for Digestive Health | Gastroenterology | 6,508 | 4,267 | 5,605 |
| Lynbrook Surgery Center 2 | Multi | 7,325 | 5,647 | 4,736 |
| Meadowbrook Endoscopy | Gastroenterology | 10,088 | 7,850 | 9,553 |
| New Hyde Park Endoscopy | Gastroenterology | 4,900 | 4,859 | 6,350 |
| Pro Health ASC, Inc ³ | Multi | 11,203 | 11,031 | 0 |
| ProHealth Day Op ASC 1,3 | Multi | 5,377 | 985 | 0 |
| Star Surgical Suites | Gastroenterology | N/A | N/A | 807 |
| (opened 10/20/20) | | | | |
| Syosset SurgiCenter | Multi | 709 | 3,886 | 4,993 |
| (opened 1/15/19) | | 05.00= | FF 040 | F0.000 |
| Totals | | 65,627 | 55,610 | 52,692 |

¹ 2020 SPARCS data is for a partial year

² 2021 SPARCS data is for a partial year

³ No SPARCS data found for 2021

Compliance with Applicable Codes, Rules, and Regulations

The medical staff will continue to ensure that the procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and expertise. The Facility's admissions policy includes anti-discrimination provisions regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures are performed in accordance with all applicable federal and state codes, rules, and regulations.

Conclusion

Approval of this project will result in improved care times and increased patient satisfaction for residents of Nassau, Queens, and Suffolk Counties needing gastroenterology surgery services through NYU Langone Hospital-LI. Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Analysis

Lease Rental Agreement

The applicant has submitted an executed lease rental agreement for the site that they are currently occupying, which is summarized below. The following lease includes space in the lobby and space on the fifth through the seventh floor.

| Premises | 81,500 square feet located at 211 Station Road, Mineola, New York. The lessee shall | | | |
|------------|--|--|--|--|
| | lease 2,000 square feet on the lobby, 26,500 square feet on the fifth floor, 26,500 | | | |
| | square feet on the sixth, and 26,500 square feet on the seventh floor. | | | |
| Lessor | Steel Station RD, LLC | | | |
| Lessee | NYU Langone Hospitals | | | |
| Term | 30-year term with two (2) options to extend the term of the lease for five years each. | | | |
| Rental | \$1,915,250. For the seventh floor alone, this comes to \$622,750. | | | |
| Provisions | The lessee shall be responsible for real estate taxes, maintenance, and utilities. | | | |

The applicant provided an affidavit indicating that there is no relationship between the lessor and the lessee.

Total Project Cost and Financing

The total project cost, which is for renovations and the acquisition of moveable equipment, is estimated at \$18,219,372 and will be financed from equity from operations.

| Renovation and Demolition | \$8,040,000 |
|----------------------------|--------------|
| Design Contingency | 88,259 |
| Construction Contingency | 804,000 |
| Planning Consultant Fees | 40,212 |
| Architect/Engineering Fees | 588,396 |
| Construction Manager Fees | 2,721,863 |
| Moveable Equipment | 3,996,127 |
| Telecommunications | 1,838,868 |
| CON Fee | 2,000 |
| Additional Processing Fee | 99,647 |
| Total Project Cost | \$18,219,372 |

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for the first and third years of the extension clinic, summarized below:

| | | Year One (2023) | | Year Three (2025) | |
|----------------------|------------|--------------------|------------|----------------------|--|
| | Per Visit | <u>Total</u> | Per Visit | <u>Total</u> | |
| <u>Revenues</u> | | | | | |
| Commercial MC | \$2,088 | \$446,751 | \$2,214 | \$513,619 | |
| Commercial FFS | \$6,036 | \$8,994,274 | \$6,403 | \$10,340,512 | |
| Medicare FFS | \$1,645 | \$1,232,036 | \$1,747 | \$1,416,443 | |
| Medicare MC | \$1,661 | \$594,636 | \$1,762 | \$683,639 | |
| Medicaid FFS | \$950 | \$12,350 | \$1,014 | \$14,198 | |
| Medicaid MC | \$1,178 | \$634,931 | \$1,248 | \$729,966 | |
| Private Pay | \$860 | \$4,299 | \$988 | \$4,942 | |
| Other | \$9,623 | <u>\$57,736</u> | \$11,063 | <u>\$66,378</u> | |
| Total Revenues | | \$11,977,013 | | \$13,769,697 | |
| <u>Expenses</u> | | | | | |
| Operating | \$2,386.61 | \$8,050,040 | \$2,362.55 | \$8,635,117 | |
| Capital | \$184.63 | 622,750 | 170.38 | 622,750 | |
| Total Expenses | \$2,571.24 | \$8,672,790 | \$2,532.93 | \$9,257,867 | |
| Net Income | | \$3,304,223 | | \$4,511,830 | |
| Utilization (Visits) | | 3,373 | | 3,655 | |
| Cost Per Visit | | \$2,571 | | \$2,533 | |

Utilization broken down by payor source during the first and third years is as follows:

| | Year One | Year Three |
|----------------|---------------|---------------|
| <u>Payor</u> | <u>(2023)</u> | <u>(2025)</u> |
| Commercial FFS | 6.34% | 6.35% |
| Commercial MC | 44.14% | 44.19% |
| Medicare FFS | 22.21% | 22.16% |
| Medicare MC | 10.61% | 10.62% |
| Medicaid FFS | 0.39% | 0.38% |
| Medicaid MC | 15.98% | 16.01% |
| Private Pay | 0.15% | 0.14% |
| Other | <u>0.18%</u> | <u>0.16%</u> |
| Total | 100.00% | 100.00% |

Capability and Feasibility

Total project costs of \$18,219,372 will be met with equity. BFA Attachment A is the August 31, 2020, and August 31, 2021, certified financial statements of NYU Langone Hospital, which indicate the availability of sufficient funds for the equity contribution.

The submitted budget indicates an excess of revenues over expenses of \$3,304,223 and \$4,511,830 during the first and third years, respectively. Revenues are based on current reimbursement methodologies for endoscopy services. The submitted budget appears reasonable.

As shown in BFA Attachment A, the entity had an average positive working capital position and an average positive net asset position for the years ending August 31, 2020, and August 31, 2021. The entity achieved an average excess of revenues over expenses of \$549,800,000 for the years ending August 31, 2020, and August 31, 2021.

Conclusion

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

Attachments

BFA Attachment A Financial Summary- August 31, 2020, and August 31, 2021, certified financial statements of NYU Langone Hospital.



of Health

Department Public Health and Health Planning Council

Project # 221191-B Maxillofacial Ambulatory Surgery Center, LLC

Program: **Diagnostic and Treatment Center** County: Suffolk **Establishment and Construction** Acknowledged: July 7, 2022 Purpose:

Executive Summary

Description

Maxillofacial Ambulatory Surgery Center, LLC, a New York limited liability company, is requesting approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) to be certified as a single-specialty freestanding ambulatory surgery center (FASC) for oral and maxillofacial surgical procedures. Currently, the facility is named Oral Maxillofacial S.C., LLC, which was formed to plan the development of the surgery center. Upon approval of this application, the LLC will amend its Articles of Organization to change its name to Maxillofacial Ambulatory Surgery Center, LLC. The facility will be located in leased space at 400 Townline Road, Hauppauge (Suffolk County).

| Proposed Operator | | | |
|------------------------------|------------------|--|--|
| Maxillofacial Ambulatory Sur | gery Center, LLC | | |
| Members % | | | |
| Lynn Pierri, DDS, MS | 9 5 % | | |
| Thomas DeNapoli | 5% | | |

Lynn Pierri DeNapoli uses her maiden name professionally. Dr. Pierri is Board Certified in Oral and Maxillofacial Surgery and will be the Center's Medical Director. The applicant expects to enter into a Transfer Agreement for backup and emergency services with St. Catherine of Siena Hospital, located 4.4 miles and 11 minutes travel time from the proposed Center.

All procedures projected are currently being performed in Lynn Pierri, DDS, MS office-based surgery practice.

OPCHSM Recommendation

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

Need Summary

The center will provide oral and maxillofacial surgery services in three procedure rooms. The number of projected procedures is 1,100 in Year One and 1.553 in Year Three with Medicaid at 5.00% and Charity Care at 2.00%.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3)(b).

Financial Summary

The total project costs of \$3,719,676 will be funded via members' equity.

| Budget | <u>Year One</u> (2024) | Year Three (2026) |
|----------|---------------------------|----------------------|
| Revenues | \$2,199,235 | \$3,494,455 |
| Expenses | 1,836,972 | 2,561,297 |
| Gain | \$362,263 | \$933,158 |

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

<u>Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:</u>

- 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. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 4. Submission of an executed lease agreement, acceptable to the Department of Health. [BFA]
- 5. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. [CSL]
- 6. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
- 8. Submission of an executed transfer and affiliation agreement, acceptable to the Department. [HSP]
- 9. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
- 10. 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; and h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]

Approval conditional upon:

- 1. This project must be completed by **April 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **July 1**, **2023**, and construction must be completed by **January 1**, **2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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/facilites/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 [HSP]

Council Action Date December 8, 2022

Need Analysis

The service area consists of Suffolk County. The population of Suffolk County in 2020 was 1,525,920 and is projected to decline slightly to 1,494,816 by 2025.

The table below shows the number of patient visits for relevant ambulatory surgery centers in Suffolk County for 2019 through 2021. 2020 visits were significantly impacted by COVID-19.

Patient Visits

| Chas Time | Facility Name | | i dilont violo | | |
|--------------|---|--------|----------------|--------|--|
| Spec Type | Facility Name | 2019 | 2020 | 2021 | |
| Multi | Long Island Ambulatory Surgery Center | 14,642 | 9,270 | 12,053 | |
| Multi | Melville Surgery Center | 5,917 | 4,611 | 4,273 | |
| Multi | North Shore Surgi-Center | 7,226 | 6,364 | 6,215 | |
| Multi | Port Jefferson ASC ² | 2,570 | 3,037 | 0 | |
| Multi | Progressive Surgery Center, LLC 1 | 2,886 | 1,510 | 2,092 | |
| Multi | South Shore Surgery Center | 4,828 | 3,389 | 3,856 | |
| Multi | Suffolk Surgery Center | 5,724 | 3,655 | 3,953 | |
| Multi | The Center for Advanced Spine & Joint Surgery | N/A | N/A | 0 | |
| Tatal Minite | (opened 8/30/21) ² | 40.700 | 04.000 | 00.440 | |
| Total Visits | | 43,793 | 31,836 | 32,442 | |

¹ SPARCS 2020 & 2021 data is for a partial year.

According to Data USA, in 2019, 95.7% of the population of Suffolk County has health coverage as follows:

| Employer Plans | 58.7% |
|-----------------|--------|
| Medicaid | 10.8% |
| Medicare | 13.6% |
| Non-Group Plans | 12.1% |
| Military or VA | 0.542% |

The applicant projects 1,100 procedures in the first year and 1,553 by the third. These projections are based on the current practices of participating surgeons. The applicant states that all of the procedures moving to this center are currently being performed in an office-based setting. The table below shows the projected payor source utilization for Years One and Three.

| | Year One | | Year T | hree |
|--------------|------------|---------|------------|---------|
| Payor | Procedures | % | Procedures | % |
| Medicaid FFS | 5 | 0.45% | 7 | 0.45% |
| Medicaid MC | 50 | 4.55% | 71 | 4.57% |
| Medicare FFS | 165 | 15.00% | 233 | 15.00% |
| Medicare MC | 110 | 10.00% | 156 | 10.05% |
| Comm FFS | 246 | 22.36% | 347 | 22.34% |
| Comm MC | 193 | 17.55% | 273 | 17.58% |
| Private Pay | 309 | 28.09% | 434 | 27.95% |
| Charity Care | 22 | 2.00% | 32 | 2.06% |
| Total | 1,100 | 100.00% | 1,553 | 100.00% |

The Center plans to obtain contracts with the following Medicaid Managed care plans: Affinity, Healthfirst, and United Healthcare. The Center will work collaboratively with local Federally Qualified Health Centers (FQHC) and others to provide service to the under-insured in their service area. The Center has developed a financial assistance policy with a sliding fee scale to be utilized when the Center is operational.

² No SPARCS data located for 2021.

Conclusion

Approval of this project will allow for continued access to oral and maxillofacial surgery services in an outpatient setting for the residents of Suffolk County.

Program Analysis

Program Description

| Proposed Operator | Oral Maxillofacial S.C, LLC |
|--------------------------------|--|
| Doing Business As | Maxillofacial Ambulatory Surgery Center, LLC |
| Site Address | 400 Townline Road |
| | Hauppauge, New York 11788 (Suffolk County) |
| Surgical Specialties | Single-Specialty-Oral and Maxillofacial Surgery |
| Operating Rooms | 0 |
| Procedure Rooms | 3 |
| Hours of Operation | Thursday and Friday 7:00 am to 3 pm |
| Staffing (1st Year / 3rd Year) | 7.20 FTEs / 12.35 FTEs |
| Medical Director(s) | Lynn Pierri, DDS, MDS |
| Emergency, In-Patient, and | Is expected to be provided by: |
| Backup Support Services | St. Catherine of Siena Hospital |
| Agreement and Distance | 4.4 Miles / 11 minutes |
| On-call service | Patients who require assistance during off-hours will engage the |
| | 24-hour answering service to reach the on-call surgeon during hours when the facility is closed. |

Character and Competence

The ownership of Maxillofacial Ambulatory Surgery Center, LLC is:

| Member Name | Interest |
|------------------|----------|
| Lynn Pierri, DDS | 95.00% |
| Thomas DiNapoli | 5.00% |
| Total | 100% |

Lynn Pierri is the proposed Medical Director and member. She is the CEO, President, and Owner of Lynn Pierri DDS, MS, P.L.L.C, the CEO and President of Suffolk Oral & Maxillofacial Ambulatory Surgery Facility, P.C., an office-based surgical practice, and the CEO and President at Dental Implants of Long Island, P.C. She was the CEO and President at Voxel Imaging USA, LLC and the CEO and President of Living Well Essentials, LLC d/b/a American Hair Solutions. She is an Attending Surgeon at Long Island Community Hospital and was previously a Clinical Assistant Professor at SUNY Stony Brook and an Attending Surgeon at North Shore Surgical Center. She received her dental degree at SUNY Stony Brook. She received her medical degree at the University Health Sciences of Antigua School of Medicine in the West Indies. She received her New York teaching certificate at C.W. Post University. She completed her residency in Oral and Maxillofacial Surgery at Bellevue Hospital Center. She completed her fellowship in Oral and Maxillofacial Surgery at the Royal Infirmary of Edinburgh in Scotland.

Thomas DeNapoli is the CFO of Suffolk and Oral Maxillofacial Center. He assists Dr. Pierri with the day-to-day facility and property operations management. He has created a portfolio of strategic investments in both short and long-term residential rental properties. He was previously the President and Co-founder of Jet Drive General Marine Contracting Co. Inc. which was a company specializing in residential and small municipal projects that became a subcontracting company responsible for major infrastructure, residential development, and commercial projects with an annual gross revenue of \$20M.

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. Pierri disclosed two malpractice suits.

- A malpractice suit was filed on February 16, 2021, by a patient against Dr. Pierri and the
 prosthodontist. The patient underwent extractions, bone graft, and implants by Dr. Pierri
 uneventfully but claimed the prosthodontist took an excessive amount of time to create the
 prosthesis. The case is pending.
- A malpractice suit was filed on October 31, 2019, by the patient and alleged pain and suffering. The patient received a partial odontectomy (extraction of an impacted tooth) where the root tip that was on the nerve was intentionally left behind on the molar to prevent paresthesia (numbness) at the patient's advanced age. Years after the procedure, the patient had an infection in the back of her mouth and alleged that it was the root tip. The patient was seen over two years after the procedure by Dr. Pierri and the healing was within normal limits. The case is still 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 will work with the patient to educate them on the availability of primary care services offered by local providers, including the services offered by the Center's backup hospital, St. Catherine of Siena. Prior to leaving the Center, each patient will be provided information concerning the local availability of primary care services. This can be done by any of the clinic's providers, staff, clinicians, or other persons.

The Applicant is committed to serving all persons in need without regard to race, sex, age, religion, creed, sexual orientation, source of payment, ability to pay, or other personal characteristics. The Applicant is committed to the development of a formal outreach program directed to the members of the local community. The purpose of the program will be to inform the community of the benefits derived from, and the latest advances made in pain management, orthopedic surgery, and podiatry. The Applicant plans to contact FQHCs within the proposed catchment area. The Applicant will also develop customized outreach materials and resources to connect with targeted populations. As part of the Center's commitment to enhance access for underserved populations, the Center will contract with two or more Medicaid managed care plans and will see to work collaboratively with other Article 28 providers to develop referral and other collaborative arrangements to enhance access to ASC services to Medicaid and charity care patients.

The Center also plans to coordinate its services with inpatient and or specialty ambulatory facilities to which a patient is referred. The Applicant will also develop a Quality Assurance Program that will include an analysis of the effectiveness of the coordination efforts. The Applicant also commits to providing charity care for persons without the ability to pay and to utilize a discounted fee scale for persons unable to pay the full amount or are uninsured. The proposed budget includes a projected charity care allowance of 2% and projects Medicaid patients at 5%. Self-pay patients projected as 28% of the budget will be offered the discounted rates depending on their ability to pay. However, admission for surgery will be based solely on medical need and ability to pay will not be a factor.

The Center intends to use an Electronic Medical Record (EMR) program that is compatible with New York's RHIO and/or Health Information Exchange. The Applicant commits to becoming a network provider in the provider-led health homes designated by the Department for Suffolk County. The Applicant will consider joining any Accountable Care Organization (ACO) that includes dental care as part of its ACO

contract. The Applicant will make a decision regarding joining ACOs in keeping with its operating agreement.

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

Total Project Cost and Financing

The total project cost for renovations and movable equipment is estimated at \$3,719,676 and will be financed with equity.

| Renovation & Demolition | \$2,223,000 |
|----------------------------|-------------|
| Design Contingency | 222,300 |
| Construction Contingency | 222,300 |
| Architect/Engineering Fees | 220,087 |
| Construction Manager Fees | 174,958 |
| Other Fees | 390,000 |
| Movable Equipment | 244,696 |
| Application Fees | 2,000 |
| Additional Processing Fees | 20,335 |
| Total Project Cost | \$3,719,676 |

BFA Attachment A is the net worth summary for the members of Maxillofacial Ambulatory Surgery Center, LLC, which shows sufficient resources to meet the construction equity requirement.

Operating Budget

The applicant has submitted the first and third year projected operating budgets, as summarized below:

| | Year One | | Year Three | |
|--------------------|-----------------|----------------|-------------------|------------------|
| | <u>2024</u> | | <u>2026</u> | |
| <u>Revenues</u> | Per Visit. | <u>Total</u> | <u>Per Visit.</u> | <u>Total</u> |
| Medicaid FFS | \$1,334.20 | \$6,671 | \$1,335.14 | \$9,346 |
| Medicaid MC | \$1,200.66 | 60,033 | \$1,191.32 | 84,584 |
| Medicare FFS | \$2,187.04 | 360,862 | \$2,466.87 | 574,780 |
| Medicare MC | \$1,964.97 | 216,147 | \$2,216.04 | 345,703 |
| Commercial FFS | \$2,731.20 | 671,874 | \$3,018.61 | 1,047,459 |
| Commercial MC | \$2,484.11 | 479,434 | \$2,892.34 | 789,609 |
| Private Pay | \$1,308.14 | <u>404,214</u> | \$1,481.51 | <u>642,974</u> |
| Total Revenues | | \$2,199,235 | | \$3,494,455 |
| | | | | |
| <u>Expenses</u> | | | | |
| Operating | \$1,320.04 | \$1,452,048 | \$1,393.59 | \$2,164,248 |
| Capital | <u>\$349.93</u> | <u>384,924</u> | <u>\$255.67</u> | <u>397,049</u> |
| Total Expenses | \$1,669.97 | \$1,836,972 | \$1,649.26 | \$2,561,297 |
| | | | | |
| Net Income (Loss) | | \$362,263 | | <u>\$933,158</u> |
| | | | | |
| Procedures | | 1,100 | | 1,553 |
| Cost Per Procedure | | \$1,669.97 | | \$1,649.26 |

The following is noted with respect to the submitted ASC budget.

- The Medicaid Fee-for-Service (FFS) rate is based on the ambulatory patient group (APG) for the downstate region multiplied by APG weight. Medicaid Managed Care (MC) rate is estimated at approximately 90% of the Medicaid FFS rate.
- Medicare FFS rate is projected at the Federal government rate for FASC with the Medicare MC rate estimated at approximately 90% of the Medicare FFS rate.
- The Commercial FFS and MC rates are based on approximately 125% and 114% of the Medicare FFS rate with private payers reflecting a 60% adjustment to the Medicare FFS rate.
- Utilization by payor is based on the member physician's existing office-based surgical practice payer mix and adjustments for community outreach.
- The number and mix of staff were determined by the experience of Lynn Pierri, DDS, MS in providing outpatient oral and maxillofacial surgery services.
- Expenses are based upon the experience of Lynn Pierri, DDS, MS in providing outpatient oral and maxillofacial surgical services in an office-based surgical practice.
- Utilization by payor source for Years One and Three are summarized below:

| | V | | | |
|----------------|-------------------|--------------|-------------------|--------------|
| | <u>Year One</u> | | Year Ti | <u>nree</u> |
| <u>Payor</u> | <u>Procedures</u> | <u>%</u> | <u>Procedures</u> | <u>%</u> |
| Medicaid FFS | 5 | 0.45% | 7 | 0.45% |
| Medicaid MC | 50 | 4.55% | 71 | 4.57% |
| Medicare FFS | 165 | 15.00% | 233 | 15.00% |
| Medicare MC | 110 | 10.00% | 156 | 10.05% |
| Commercial FFS | 246 | 22.36% | 347 | 22.34% |
| Commercial MC | 193 | 17.55% | 273 | 17.58% |
| Private Pay | 309 | 28.09% | 434 | 27.95% |
| Charity Care | <u>22</u> | <u>2.00%</u> | <u>32</u> | <u>2.06%</u> |
| Total | 1100 | 100% | 1553 | 100% |

Lease Rental Agreement

The applicant has submitted a draft Lease Agreement, the terms are summarized below:

| Premises: | 4,732 rentable square feet at 400 Townline Road, Hauppauge, NY 11788 |
|-------------|--|
| Landlord: | 400 Townline LLC and Townline 400 LLC |
| Lessee: | Maxillofacial Ambulatory Surgery Center, LLC |
| Term: | 5 Years with a renewal of one (1) 5-year term |
| Rental: | \$118,302 1st year (\$25 per sq. ft.); 5% annual increase; renewal 3.5% annual |
| | rent increase |
| Provisions: | Maintenance and increases in taxes, insurance, and utilities. |

The lease arrangement is a non-arms-length agreement. The applicant has submitted an affidavit attesting to the common members between the landlord and the operator. Letters from two NYS licensed realtors have been provided attesting to the rental rate being of fair market value.

Capability and Feasibility

Total project costs of \$3,719,676 will be funded via members' equity. The working capital requirement is estimated at \$426,883 based on two months of third-year expenses and will be financed via members' equity. BFA Attachment A is the members' net worth, which shows sufficient resources to meet the project and working capital equity requirements. BFA Attachment B is Maxillofacial Ambulatory Surgery Center, LLC's pro forma balance sheet, which shows operations will start with \$4,146,559 in equity. Maxillofacial Ambulatory Surgery Center estimates a first and third-year operating surplus of \$362,263 and \$933,158, respectively. The budget appears reasonable.

Conclusion

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

| Attachments |
|-------------|
| Attachinens |

| BHFP Attachment | Мар |
|------------------|--|
| BFA Attachment A | Members' Net Worth Summary |
| BFA Attachment B | Maxillofacial Ambulatory Surgery Center, LLC., Pro Forma Balance Sheet |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 8th day of December 2022, 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 single-specialty freestanding ambulatory surgery center (FASC) at 400 Townline Road, Hauppauge, specializing in oral and maxillofacial surgical procedures, 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:

221191 B Maxillofacial Ambulatory Surgery Center, LLC

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

- 1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
- 2. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 4. Submission of an executed lease agreement, acceptable to the Department of Health. [BFA]
- 5. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. [CSL]
- 6. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
- 8. Submission of an executed transfer and affiliation agreement, acceptable to the Department. [HSP]
- 9. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
- 10. 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; and h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **April 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **July 1, 2023,** and construction must be completed by **January 1, 2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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/facilites/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 [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*.



of Health

Department Public Health and Health Planning Council

Project # 221206-E Northern Westchester Facility Project LLC d/b/a Yorktown Center for Specialty Surgery

Program: **Diagnostic and Treatment Center** County:

Establishment Purpose:

Westchester Acknowledged: July 8, 2022

Executive Summary

Description

Northern Westchester Facility Project LLC d/b/a Yorktown Center for Specialty Surgery (Yorktown or the Center), a Delaware Limited Liability Company Article 28 multi-specialty ambulatory surgery center (ASC) at 2651 Strang Boulevard Suite 100 in Yorktown Heights (Westchester County) is requesting to transfer ownership interest to eleven new members and seeking approval for eight members previously admitted under Transfer Notice 191079. Yorktown's current ownership consists of 15 Class A member physicians that own 91.0% of membership units and one Class B member, Merritt Healthcare Holdings Westchester, LLC that owns 9.0% of membership units.

There will be no change in services as a result of this application. George Pazos, MD, who is Board-certified in Otolaryngology, will serve as the Medical Director. The Center maintains a Transfer Agreement for emergency and backup services with Westchester Medical Center, 16.2 miles (19 minutes travel time) from The Center.

OPCHSM Recommendation Contingent Approval is recommended.

Need Summary

There will be no need review per Public Health Law §2801-a (4)

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801a(3).

Financial Summary

There are no project costs for this application. The total purchase price for the 20.044% ownership interest is \$627,622.07 and will be funded with proposed new member equity. The submitted budget for Yorktown indicates an excess of revenues over expenses of \$1.061.585 and \$1.537.479 during the first and third years of operations, respectively.

| Budget | Current | | |
|----------|--------------------|--------------------|-------------------|
| | <u>Year</u> | Year One | <u>Year Three</u> |
| | (2020) | <u>(2023)</u> | <u>(2025)</u> |
| Revenues | \$7,922,257 | \$9,513,335 | \$10,940,336 |
| Expenses | <u>\$7,918,770</u> | <u>\$8,451,750</u> | \$9,402,857 |
| Net | \$3,487 | \$1,061,585 | \$1,537,479 |
| Income | | | |

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 the Operator's Operating Agreement that is acceptable to the Department. [CSL]

- <u>Approval conditional upon</u>:

 1. This project must be completed by **June 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. The continued submission of annual reports to the Department as prescribed in the approval of CON 151277 for the duration of the limited life approval of the facility. [RNR]

Council Action Date December 8, 2022

Program Analysis

Background

Northern Westchester Facility Project, LLC d/b/a Yorktown Center for Special Surgery, an existing freestanding multi-specialty Ambulatory Surgery Center (FASC) seeks approval to transfer 20.044% ownership interest from 16 existing members to 11 new members and seeks approval for eight current members who were previously admitted as a result of a Transfer Notice 191079. The existing FASC is located at 2651 Strang Boulevard in Yorktown Heights (Westchester County). There will be no change in services or Medical Director as a result of this application. Staffing will increase by 1.77 FTEs in Year One and 1.00 FTEs in Year Three.

Character and Competence

The proposed membership Northern Westchester Facility Project, LLC is provided in the chart below.

| Member Name/Title | Current | Proposed |
|--|---------|----------|
| CLASS A MEMBERS | | |
| Arthur Pidoriano, M.D. | 7.3428% | 5.7652% |
| George Pazos, M.D. | 7.0298% | 5.5195% |
| Gabriel Brown, M.D. | 6.7619% | 5.2738% |
| Gregg Cavaliere, M.D. | 6.7619% | 5.2738% |
| George Pianka, M.D. | 6.7619% | 5.2738% |
| Michael Bergstein, M.D. | 6.1411% | 4.8217% |
| Yanir Rubinstein, M.D. | 6.7179% | 5.2738% |
| Donato Perretta, M.D. | 6.7179% | 5.2738% |
| Barry Krosser, M.D. | 5.4040% | 4.2430% |
| John Angelino, M.D. | 5.4040% | 4.2430% |
| Scott Russinoff, M.D. | 5.4040% | 4.2430% |
| Robert Parks, M.D. | 4.9408% | 3.8793% |
| William Losquadro, M.D. | 5.4040% | 4.2430% |
| Kathy Ma, M.D. | 5.4040% | 4.2430% |
| Deborah Reich, M.D. | 4.9408% | 3.8793% |
| ***Neil Dunleavy, M.D. | 0.0000% | 3.1857% |
| ***Jason Hochfield, M.D. | 0.0000% | 3.1857% |
| ***Erich Braun, M.D. | 0.0000% | 3.1857% |
| ***Paul Mignone, M.D. | 0.0000% | 1.3361% |
| ***Opeyemi Daramola, M.D. | 0.0000% | 1.3361% |
| ***Deya Jourdy, M.D. | 0.0000% | 1.3361% |
| ***Rafael Axen, M.D. | 0.0000% | 3.0567% |
| ***Steven Cataldo, M.D. | 0.0000% | 2.1917% |
| ***Gabriel Pitta, M.D. | 0.0000% | 0.8767% |
| ***Kevin Lee, M.D. | 0.0000% | 0.8767% |
| ***Jay Bhangoo, M.D. | 0.0000% | 0.8767% |
| | | |
| CLASS B MEMBER | | |
| Merritt Healthcare Holdings Westchester, LLC | 9.0000% | 8.5067% |
| Matthew Searles (45%) | | |
| Richard Searles (20%) | | |
| William Mulhall (35%) | | |
| Total | 100% | 100% |

^{***}Members Subject to Character and Competence

- **Dr. Giovanni "John" Angelino** is an Interventional Pain Management Physician at Northern Westchester Hospital, an Attending Anesthesiologist at Hudson Valley Hospital, a Partner, Attending Anesthesiologist, and Pain Management Physician at Mount Kisco, and the President of Giovanni Angelino, M.D., P.C. He received his medical degree from Universidad Del Noreste. He completed his residency in Anesthesiology at SUNY Downstate. He completed his fellowship in Pain Management at Emory University. He is board certified in Pain Management.
- **Dr. Rafael Axen** is the Chair of the Department of Anesthesiology and the Site Medical Director of Caremount. He was previously the Chief of Anesthesiology at Bedford Anesthesia, the Medical Director and President of the Medical Staff of the Ambulatory Surgery Center of Westchester, and an Anesthesiologist at Kaiser Permanente. He received his medical degree from Rutgers Medical School. He completed his residency in Anesthesiology at New York Presbyterian Weill Cornell Medical Center. He is board certified in Anesthesiology.
- **Dr. Jatinder Bhangoo** is a Medical Director of Dutchess Ambulatory Surgery Center and the Chairman of Anesthesia of the Northern Division of Caremount. He was previously the Director of Anesthesia at Mid-Hudson Regional Hospital, an Anesthesiologist at Anesthesia Associates of St. Francis, a member of the St. Francis Hospital Performance Improvement Committee, and an Assistant Professor at Stony Brook University Hospital. He received his medical degree from the Ross University School of Medicine in the West Indies. He completed his residency in Anesthesia at Stony Brook University Hospital.
- **Dr. Erich Braun** is a Surgeon and Senior Partner at Caremount Medical Group. He is a Volunteer Firefighter in the Town of Katonah. He received his medical degree from the University of Pennsylvania Medical School. He completed his residency in Ophthalmology at NYU. He completed his Cornea fellowship at UC Irvine.
- **Dr. Steven Cataldo** is an Anesthesiologist at Caremount Medical P.C.. He was an Anesthesiologist at Vyaire Medical Inc. and an Anesthesiologist at Revolutionary Medical Devices, Inc. He received his medical degree from SUNY Downstate Medical Center. He completed his Anesthesia residency at SUNY Downstate Medical Center. He is board eligible.
- **Dr. Opeyemi Daramola** is a Surgeon in Otolaryngology at Caremount, an Attending Physician at Northern Westchester Hospital, and an Adjunct Instructor at Northwestern University. He was a Surgeon at Crystal Run Healthcare, a Surgeon at Penn Medicine Becker ENT & Allergy, an Attending Physician at Nyack Montefiore Hospital, an Attending Physician at the University Medical Center of Princeton, and a Clinical Instructor at Northwestern University. He received his medical degree from the University of Minnesota Medical School. He completed his residency in Otolaryngology at the Medical College of Wisconsin Affiliated Schools. He completed his fellowship in Rhinology at Northwestern University. He is board certified in Otolaryngology.
- **Dr. Neil Dunleavy** is an Orthopedist at Caremount Medical, PC. He was an Orthopedist at Orthopaedic Specialty Group, PC and a Partner at KSF Orthopaedic Center. He received his medical degree from Georgetown University School of Medicine. He completed his residency in Orthopedic Surgery at St. Luke's Roosevelt Hospital Center, Columbia University. He completed his fellowship in Sports Medicine at the University of Chicago Medical Center. He is board certified in Orthopedic Surgery. Dr. Dunleavy discloses ownership interest in the following healthcare facilities:

Tops Surgical Specialty Hospital 2005-2018

- **Dr. Jason Hochfelder** is a Partner at Hudson Valley Bone and Joint and an Independent Medical Examiner at First Choice Evaluations. He received his medical degree from New York University School Of Medicine. He completed his residency in Orthopedics at NYU Hospital for Joint Diseases. He completed his fellowship in hip and knee surgery at Insall Scott Kelly Institute. He is board certified in Orthopedic Surgery.
- **Dr. Deya Jourdy** is an Attending Surgeon and Director of Rhinology at Phelps Memorial Hospital and a Business Partner and Attending Surgeon at ENT and Allergy Associates, LLC. He was a Business Partner, Associate Faculty, an Attending Surgeon at ENT Faculty Practice, LLP, a Clinical Faculty and Attending Surgeon at the University of Miami Hospital, and a Clinical Instructor at the Department of

Otolaryngology. He received his medical degree from Weill Medical College at Cornell University. He was the Research Coordinator at Weill Cornell School of Medicine. He completed his residency in Otolaryngology-Head and Neck Surgery at New York Presbyterian Hospital-Columbia and Cornell and Memorial Sloan Kettering Cancer Center. He completed his fellowship in Rhinology-Endoscopic Sinus and Skull Base Surgery at University of Miami Miller School of Medicine. He is board certified in Otolaryngology.

Dr. Kevin Lee is a Cardiac Anesthesiologist at North American Partners in Anesthesia. He was the Chief of Cardiac Anesthesia and Ambulatory Vascular Surgery at North American Partners in Anesthesia, a Clinical Coordinator and Research Assistant in the Department of Anesthesia at New York Presbyterian Hospital, a Teaching Assistant at Columbia University in the Department of Biology, and a Metallurgical Process Engineer. He received his medical degree from Pennsylvania State University College of Medicine. He completed his residency and fellowship in Anesthesia at New York Presbyterian Hospital-Cornell. He is board certified in Anesthesia.

Dr. William Losquadro is a Plastic Surgeon at Caremount Medical P.C. and the owner of William D. Losquadro, MD Facial Plastic, and Reconstructive Surgery. He is affiliated with the Institute of Aesthetic Surgery and Medicine at Northern Westchester Hospital. He received his medical degree from SUNY Upstate. He completed his residency in Otolaryngology-Head and Neck Surgery at SUNY Upstate Medical University. He completed his fellowship in Facial Plastic and Reconstructive Surgery at University of Illinois at Chicago. He is board certified in Facial Plastic Surgery and Reconstructive Surgery as well as Otolaryngology-Head and Neck Surgery.

Dr. Katherine Ma is an Attending Orthopedic Surgeon at Caremount Medical Group. She was previously a Physical Therapist at Oxford Health Plans, Mount Sinai Sports Therapy Center, the Department of Veteran Affairs, and a private medical practice. She was an Adjunct Faculty Member at the Division of Physical Therapy and a Research Assistant at the New York Medical College Lyme Disease Clinic. She received her medical degree from New York Medical College. She completed her fellowship in Orthopedic Surgery-Foot and Ankle at University of Rochester Medical Center. She is board certified in Orthopedic Surgery.

Dr. Paul Mignone is an Associate and Ophthalmologist at Caremount Medical and Optum Health. He is an Owner and Partner at Mignone Medical Eye Care. He received his medical degree from New York Medical College. He completed his residency in Ophthalmology and his fellowship in Medical Retina at St. Luke's Roosevelt Hospital Center. He is board certified in Ophthalmology.

Dr. Robert Parks is an ENT/Otolaryngologist at Caremount Medical PC, an affiliated ENT with the Ambulatory Surgery Center of Westchester, and an affiliated ENT at New York Presbyterian/Hudson Valley Hospital. He was previously an ENT at Valley ENT. He received his medical degree from Columbia University. He completed his residency in ENT and Otolaryngology at Mount Sinai School of Medicine and Columbia University College of Physicians and Surgeons. He completed his fellowship as a Research Fellow at New York Presbyterian-Columbia University Medical Center. He is board certified in Otolaryngology.

Dr. Donato Perretta is an Orthopedic and Hand Surgeon at Caremount Medical, an Attending Surgeon at the Ambulatory Surgery Center of Westchester, an Attending Surgeon at Northern Westchester Hospital, an Attending Surgeon at Yorktown Center for Special Surgery. He received his medical degree from the New York University School of Medicine. He completed his residency in Orthopedics at NYU Hospital for Joint Diseases. He completed his fellowship in Hand and Upper Extremity Surgery at Massachusetts General Hospital. He is board certified in Orthopedics with a sub-certification in Hand Surgery.

Dr. Arthur Pidoriano is an Orthopedic Surgeon at Caremount Medical PC. He was President of the Medical Staff of NYY Hudson Valley and also served on the Board of Hudson Valley Hospital.

Dr. Gabriel Pitta is an Adult and Pediatric Anesthesiologist at East Manhattan Anesthesia Partners. He was a Staff Anesthesiologist at Northwest Anesthesia Partners. He received his medical degree from Weill Cornell Medical College. He completed his residency in Anesthesia at Yale New Haven Hospital. He

completed his fellowship in Pediatric Anesthesia at Columbia Presbyterian Hospital. He is board certified in Anesthesia.

Dr. Yair Rubinstein is an Orthopedic Surgeon at Caremount Medical, PC. He received his medical degree from the Albert Einstein College of Medicine. He completed his residency in Orthopedics at Montefiore Medical Center. He completed his fellowship in Sports Medicine at Long Beach Memorial Hospital.

Dr. Scott Rusinoff is an Orthopedic Surgeon at Caremount Medical, P.C. and an affiliated Surgeon with New York Presbyterian/Hudson Valley Hospital. He was an Orthopedic Surgeon at Community Orthopedic Associates, an Orthopedic Surgeon at University Orthopedics, and was previously affiliated with Westchester County Medical Center. He received his medical degree from SUNY Downstate Medical Center. He completed his residency in Orthopedics at New York Medical College. He completed his fellowship in Orthopedic Surgery at the Florida Orthopedic Institute. He is board certified in Orthopedic Surgery.

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 disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

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

Financial Analysis

Operating Budget

| - p = : a : g = a a g | sperating badget | | | | | |
|---------------------------|---------------------|------------------|----------------|--------------------|--------------------------|--------------------|
| | Current Year (2020) | | <u>Year Or</u> | <u>ne (2023)</u> | <u>Year Three (2025)</u> | |
| | Per Proc. | Total | Per Proc. | Total | Per Proc. | Total |
| <u>Revenues</u> | | | | | | |
| Commercial MC | \$5,442.34 | \$5,736,222 | \$5,988.64 | \$6,940,829 | \$633.99 | \$7,981,953 |
| Medicare FFS | \$1,508.44 | 988,025 | \$1,658.13 | 1,195,510 | \$504.13 | 1,374,837 |
| Medicare MC | \$1,729.50 | 242,130 | \$1,902.45 | 292,977 | \$834.00 | 336,924 |
| Medicaid MC | \$1,492.15 | 140,262 | \$1,647.74 | 169,717 | \$524.70 | 195,175 |
| Private Pay | \$2,546.65 | 50,933 | \$2,801.32 | 61,629 | \$632.88 | 70,873 |
| All Other ¹ | \$2,782.89 | <u>701,289</u> | \$3,063.39 | <u>848,560</u> | \$1,322.34 | <u>975,844</u> |
| Total Patient Rev. | | \$7,858,860 | | \$9,509,221 | | \$10,935,605 |
| Other Income ² | | <u>63,397</u> | | <u>4,114</u> | | <u>4,731</u> |
| Total Revenue | | \$7,922,257 | | \$9,513,335 | | \$10,940,336 |
| <u>Expenses</u> | | | | | | |
| Operating | \$2,700.61 | \$6,073,672 | \$2,671.69 | \$6,607,101 | \$2,657.16 | \$7,559,623 |
| Capital | <u>820.41</u> | <u>1,845,098</u> | <u>745.92</u> | <u>1,844,649</u> | <u>647.89</u> | <u>1,843,234</u> |
| Total Expenses | \$3,521.02 | \$7,918,770 | \$3,417.61 | \$8,451,750 | \$3,305.05 | \$9,402,857 |
| Net Income | | <u>\$3,487</u> | | <u>\$1,061,586</u> | | <u>\$1,537,479</u> |
| Visits | | 2,249 | | 2,473 | | 2,845 |
| Cost/Visit | | \$3,521.02 | | \$3,417.61 | | \$3,305.05 |

¹ All Other includes Workers' Compensation and No-Fault.

Utilization by payor source during the first and third years is broken down as follows:

| | Current Year | Year One | Year Three |
|---------------|--------------|----------|------------|
| Commercial MC | 46.87% | 46.87% | 46.85% |
| Medicare FFS | 29.12% | 29.15% | 29.14% |
| Medicare MC | 6.22% | 6.23% | 6.22% |
| Medicaid MC | 4.18% | 4.16% | 4.18% |
| Private Pay | 0.89% | 0.89% | 0.88% |
| Charity Care | 1.51% | 1.50% | 1.51% |
| All Other | 11.20% | 11.20% | 11.21% |
| Total | 100.00% | 100.00% | 100.00% |

The following is noted with respect to the submitted budget:

- The current year reflects the facility's 2020 revenues and expenses.
- Staffing mix is based on the operations of the existing Article 28 ambulatory surgery center and the experience of the operator.
- Utilization in Year One and Three is based on an increase in the number of participating surgeons at the center.
- Expenses are based on the historical experience of the current operations.
- As of October 12, 2022, the facility had no outstanding Medicaid overpayment liabilities.

² Other Income includes interest income of \$3,740 and \$59,657 in Provider Relief Funds distributions YCSS received from the U.S. Department of Health Human Services under the CARES Act.

Executed Lease Agreement

The applicant has submitted an executed lease agreement for the existing site, the terms of which are summarized below:

| Date: | January 15, 2016 |
|-------------|---|
| Premises: | 2651 Strang Boulevard, Suite 100, Yorktown Heights, New York, 10598 |
| Landlord: | GHP Strang, LLC |
| Tenant: | Northern Westchester Facility Project, LLC |
| Term: | 15 Years, with an option to renew for one 10-year term. |
| Rent: | Base rent is \$365,400 (\$30,450.00 per month) for the first three years, with 3% increase of base rent thereafter. Additional rent includes an estimated monthly electric payment of \$4,567.50. Security deposit of \$375,840 is due upon execution of the lease. |
| Provisions: | Tenant is responsible for insurance, utilities, and property taxes. |

The applicant submitted an affidavit stating the lease agreement is an arm's length arrangement.

Executed First Amendment to Lease Agreement

The applicant has submitted an executed first amendment to the lease agreement for the existing site between GHP Strang, LLC and Northern Westchester Facility Project, LLC, the terms of which are summarized below:

| Date: | January 18, 2017 |
|-------------|---|
| Premises: | 2651 Strang Boulevard, Suite 100, Yorktown Heights, New York, 10598 |
| Landlord: | GHP Strang, LLC |
| Tenant: | Northern Westchester Facility Project, LLC |
| Term: | 15 Years, with an option to renew for one 10-year term |
| Rent: | Base rent is \$365,400 (\$30,450.00 per month) for the first three years, with 3% increase of base rent thereafter. Additional rent includes an estimated monthly electric payment of \$4,567.50 Security deposit of \$375,840 due upon execution of the lease. |
| Provisions: | Tenant is responsible for insurance, utilities, and property taxes. |

The applicant submitted an affidavit stating the lease agreement is an arm's length arrangement.

Second Amendment to the Administrative Services Agreement The applicant has submitted a Second Amendment to the Administrative Services Agreement (ASA), summarized as follows:

| Date: | August 7, 2021 |
|---|--|
| Company: | Northern Westchester Facility Project, LLC |
| Consulting Company: | Merritt Healthcare Holdings Westchester LLC |
| Term: | 7 years with 1 additional 2-year term. |
| Consulting Services Provided: Organizing, coordinating, and monitoring the construction of additional procedure and operating rooms, organizing and overseeing the procedure and operating rooms, organizing and overseeing the procedure and operating procedures, overseeing accreditation and I process, assisting with financial management including preparation financial statements and provision of data required for tax and governous fillings, coordinating and managing bookkeeping, accounting and administering benefit or insurance plans, human resource managed billing and collections, assisting with administration of utilization, or quality management systems, maintain agreed upon insurance continuations. | |
| | legal services and credentialing support services. |
| Developmental | Prepare pro formas, ROI, and financial projections, assist in obtaining |
| Services: | financing for the project, recommend a site, an architect and builder, and |

| | manage the design and construction process, attend construction meetings and oversee construction, other tasks as mutually agreed upon by the parties. |
|------------------|--|
| Development Fee: | \$200,000 paid in two installments of \$50,000 and \$150,000. |
| Consulting Fee: | \$325,000 (\$27,083.33/month) |

Capability and Feasibility

There are no project costs associated with this application. The submitted budget indicates an excess of revenues over expenses of \$1,061,586 and \$1,537,479 during the first and third years of operations, respectively. Utilization in Year One and Three is based on an increase in the number of participating surgeons at the center. The total purchase price for the 20.044% membership units is \$627,622.07 and will be funded with proposed member equity. BFA Attachment A presents the physician members' personal net worth statements, which indicate sufficient resources overall to fund the equity requirements.

A summary of the 2020 Certified Financial Statements for Yorktown Center for Specialty Surgery is included in BFA Attachment C. For the year ending December 31, 2020, Yorktown reported negative working capital and member's deficit of \$584,614 and \$2,048,186, respectively. The reported negative working capital was driven by post-COVID-19 ramp-up of operations and higher operational costs, negative members' deficit was impacted by accelerated depreciation and first-year losses. During 2020, Yorktown reported income from operations of \$311,776, which was offset by \$371,686 in interest expense, interest income of \$3,740, and grant income of \$59,657, resulting in a net income of \$3,487.

A summary of the Internal Financial Statements for Yorktown Center for Specialty Surgery for the year ended December 31, 2021, is included in BFA Attachment D. These statements show a positive working capital position, a positive net asset position, and a positive operating income of \$1,695,463, which was offset by \$300,731 in other income, and \$787,087 in other expenses resulting in net income of \$1,209.107.

BFA Attachments E is a summary of internal Financial Statements for Yorktown Center for Specialty Surgery for period-ended June 30, 2022, which shows a negative working capital and negative net asset positions, and a positive operating income of \$1,082,609 which was offset by \$457,157 in other expenses, resulting in net income of \$625,452 for the period. Negative working capital and net asset position is due to financial statements being presented on a cash basis and excluding approximately \$1.5M in accounts receivable.

Conclusion

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

Attachments

| BFA Attachment A | Proposed Members' Net Worth Statements |
|------------------|---|
| BFA Attachment B | 2020 Certified Financial Statements |
| BFA Attachment C | December 2021 Internal Financial Statements |
| BFA Attachment D | 2022 Internal Financial Statements |

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 8th day of December 2022, 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 20.044% from sixteen existing members to eleven new members and seek PHHPC approval of eight existing members, 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:

221206 E Northern Westchester Facility Project LLC

d/b/a Yorktown Center for Specialty Surgery

APPROVAL CONTINGENT UPON:

1. Submission of the Operator's Operating Agreement that is acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **June 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. The continued submission of annual reports to the Department as prescribed in the approval of CON 151277 for the duration of the limited life approval of the facility. [RNR]

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*.



of Health

Department Public Health and Health Planning Council

Project # 221213-E

Performance Surgical Center, LLC d/b/a Performance Surgical Center

Program: **Diagnostic and Treatment Center** County: Kings

Establishment July 11, 2022 Purpose: Acknowledged:

Executive Summary

Description

Performance Surgical Center, LLC (PSC), an existing New York limited liability company, requests approval to be established as the new operator of Millennium Ambulatory Surgery Center (Center), an Article 28, multi-specialty freestanding ambulatory surgery center (FASC). The Center is in leased space at 1408 Ocean Avenue, Brooklyn, Kings County. The center provides orthopedic, vascular, podiatric, plastic/hand, spine, gynecologic, and pain management surgery services

On September 21, 2020, Millennium Ambulatory Surgery Center, LLC entered into a purchase agreement (PA) with Performance Surgical Center, LLC., for the sale and acquisition of certain assets for \$2,500,000. The transaction will be finalized upon Public Health and Health Planning Council (PHHPC) approval. Concurrently, 1408 Ocean Avenue, LLC entered into a purchase and sale agreement (PSA) with 1408 Partners LLC. for the sale and acquisition of the real property for \$10,000,000. According to the real property deed, the transaction closed on December 28, 2020.

There is an existing Consulting Services Agreement between Performance Surgical Center, LLC, and Millennium Ambulatory Surgery Center, LLC, that has been in place since September 21, 2020. The Consulting Services Agreement will terminate upon the Department's approval of this application.

| Proposed Operato | <u>or</u> |
|--------------------------|-----------|
| Performance Surgical Cer | nter, LLC |
| <u>Members</u> | <u>%</u> |
| Sandro Starna | 95% |
| Jonathan Phillips, M.D. | 5% |

Jonathan Phillips, M.D., is board certified in Family and Sports Medicine and will be the Center's Medical Director. The Center has an existing Transfer and Affiliation Agreement for backup and emergency services with New York Community Hospital, which is located 1.5 miles (7 minutes travel time) from the Center. The Center also has a Transfer and Affiliation Agreement with Maimonides Medical Center, which is 4.0 miles (15 minutes travel time) from the Center. These Transfer and Affiliation Agreements will be assigned to the new operator of the Center.

OPCHSM Recommendation

Contingent approval with an expiration of the operating certificate five years from the completion of the application.

Need Summary

Anticipating new physicians joining the center, the projected number of procedures is 3,750 in Years One and Three with 25.33% Medicaid and 10.00% Charity Care. The center is current with their SPARCS reporting.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801a(3).

Financial Summary

The \$2,500,000 purchase price for the FASC operations has been funded via a loan from 1408 Partners LLC (the landlord), with no interest and no repayment terms. The FASC's real property was

acquired by 1408 Partners LLC. for \$10,000,000 and closed on December 28, 2020. The real property transaction was funded via \$3,000,000 in members' equity and a \$7,000,000 bank loan with a 10-year term and 30-year amortization at 3.875% interest from Connection bank. There are no project costs associated with this transaction.

| Budget | <u>Year One</u> <u>2023</u> | Year Three 2025 |
|------------|--------------------------------|--------------------|
| Revenues | \$8,511,765 | \$8,551765 |
| Expenses | \$6,202,89 <u>5</u> | \$6,202,895 |
| Net Income | \$2,308,870 | \$2,305,219 |

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

- 1. Submission of an executed lease agreement acceptable to the Department of Health. [BFA]
- 2. 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 on the calendar year. 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
 - d. seven days after ambulatory surgery;
 - e. Data displaying the number of emergency transfers to a hospital;
 - f. Data displaying the percentage of charity care provided;
 - g. The number of no socomial infections recorded during the year reported;
 - h. A list of all efforts made to secure charity cases; and
 - i. A description of the progress of contract negotiations with Medicaid Managed Care plans. [RNR]

Approval conditional upon:

- 1. This project must be completed by **one year from the date of this letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. 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/facilites/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 [HSP].
- 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]

Council Action Date December 8, 2022

Need and Program Analysis

Project Proposal

| Proposed Operator | Performance Surgical Center, LLC |
|--|--|
| Doing Business As | Performance Surgical Center |
| Site Address | 1408 Ocean Avenue |
| | Brooklyn, NY 11230 (Kings County) |
| Shift/Hours/Schedule | Monday through Friday 7:15 am to 5:00 pm |
| Services | Ambulatory Surgery-Multi Specialty |
| | Including, but not limited to: |
| | Orthopedic |
| | Vascular |
| | Podiatry |
| | Plastic/Hand |
| | Spine |
| | Gynecology |
| | Pain Management |
| Staffing (1 st Year/3 rd Year) | 35.3 FTEs/35.3 FTEs |
| Medical Director | Jonathan Phillips, MD |
| Emergency, In-Patient, and Backup | New York Community Hospital |
| Support Services Agreement and | 1.5 miles/7 minutes |
| Distance and Time | |
| | Maimonides Medical Center |
| | 4.0 miles/15 minutes |

Background and Analysis

The service area of Kings County had a population of 2,736,074 in 2020 which is projected to grow to 2,810,876 by 2025. According to Data USA, in 2019, 93.3% of the population of Kings County has health coverage as follows:

| Employer Plans | 41.1% |
|-----------------|--------|
| Medicaid | 32.2% |
| Medicare | 8.01% |
| Non-Group Plans | 11.8% |
| Military or VA | 0.327% |

This facility is located within a Health Professional Shortage Area for primary care and is also designated within a Medically Underserved Area.

The following table shows the Center's Medicaid and charity care utilization for the past two years and projections going forward:

| | 2020 | 2021 | Years One & Three |
|--------------|------|-------|----------------------|
| Procedures | 531 | 436 | 3,750 |
| Medicaid | 0.0% | 32.4% | 25.33% |
| Charity Care | 0.0% | 0.0% | 10.00% |

The increase in the center's Medicaid utilization in 2021 was due to three new physicians performing procedures at the center. The center is projecting 3,750 procedures in Years One and Three with Medicaid utilization being 25.33% and Charity Care being 10.00%. This is based upon the expectation that ten new physicians will be performing surgeries at the center after approval of this project. The center has four operating rooms.

The center currently has contracts with the following Medicaid Managed Care plans Fidelis, HealthFirst, and HIP. The center has a referral agreement with The Family Centers at NYU Langone to provide service to the under-insured in their service area. The center participates in a "Second Chance" program whereby the center reaches out to convicted felons who have no insurance and require surgical services. Staff members also attend Alcoholics Anonymous and drug rehabilitation meetings to reach out to this vulnerable population. The center has a Financial Assistance policy with a sliding fee scale for those patients who need assistance. The center is current with their SPARCS reporting.

Character and Competence

The proposed membership of Performance Surgical Center, LLC are:

| <u>Name</u> | <u>Interest</u> |
|-------------------|-----------------|
| Sandro Starna | 95.0% |
| Jonathan Phillips | <u>5.00%</u> |
| Total | 100.0% |

Sandro Starna is the President of The Starna Group where he is responsible for managing financial and accounting aspects with a specialty in medical practices and ambulatory surgery centers. He communicates with all staff to ensure relevant information and significant changes in data are issued, and manages credit lines and loans, reviews monthly credit activity, monitors for fraud. He was the previous Vice President of Finance at Dream Wate where he was responsible for the preparation of the quarterly consolidated financial statements, reconciliation of all accounts, monthly accrual entries, commission reports, cash management reports based on accounts receivable collections, overhead cost analysis, meeting with executive staff and other teams to review metrics, meeting with shareholders to explain the quarterly results and providing daily cash reports and weekly reports. He was a Tax Senior Associate at J. Gittleson & Associates

Jonathan Phillips is a proposed member and the proposed Medical Director. He is an Owner of JWP, LLC, and is a Sports and Regenerative Medicine Physician at Performance Health. He is the Chairman of the Physician Operations Council which manages operations of the physician group throughout five Florida hospital locations in the Tampa area. He is a Member of the Physicians Group Board of Directors, and he updates board members on the operations and processes of the group and manages physician concerns. He was the Medical Director of S.O.A.R Medicine, a Sports and Family Medicine Physician at a Florida Hospital, a Founder of the Concussion Center at Florida's Wesley Hospital, the Medical Director of the Tampa Bay Storm Football Team, a Consultant Physician for the Tampa Bay Lightning hockey team, the Medical Director of an amateur boxing and MMA league, a Sports Medicine and Family Physician at Suncoast Medical Clinic, a Physician at New Tampa Urgent Care. He received his medical degree from the Medical University of the Americas. He completed his residency in Family Medicine at Latrobe Area Hospital in Pennsylvania. He completed his fellowship in Sports Medicine at the University of South Florida. He is board certified in family medicine with a sub-certification in sports medicine.

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 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

Approval of this project will provide for enhanced access to orthopedic, vascular, podiatry, plastic/hand, spine, gynecology (not abortions), and pain management surgery services in a community-based setting for the residents of Kings County. Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Analysis

Operating Budget

The applicant has submitted the current year (2020) and the first and third year projected operating budgets in 2022 dollars, as summarized below:

| | Current 2020 | | | <u>Year One</u> 2023 | | <u>Year Three</u> 2025 | |
|--------------------|-----------------|-------------------|-----------------|-------------------------|-----------------|---------------------------|--|
| | Per Proc. | <u>Total</u> | Per Proc. | Total | Per Proc. | Total | |
| Revenues | | <u></u> | | <u></u> | <u> </u> | <u></u> | |
| Medicaid – MC | | \$0 | \$361.98 | \$343,884 | \$361.98 | \$343,884 | |
| Medicare - FFS | \$974.83 | 214,463 | \$973.53 | 979,375 | \$973.53 | 979,375 | |
| Medicare – MC | \$969.74 | 83,402 | \$974.08 | 380,866 | \$974.08 | 380,866 | |
| Commercial - FFS | \$6,792.59 | 1,426,443 | \$6,792.55 | 6,514,059 | \$6,792.55 | 6,514,059 | |
| Commercial – MC | \$7,200.00 | 14,400 | \$6,576.00 | 65,760 | ,\$6,576.00 | 65,760 | |
| Other | \$3,837.54 | <u>49,888</u> | \$3,861.37 | <u>227,821</u> | \$3,861.37 | <u>227,821</u> | |
| Total Revenues | | \$1,788,596 | | \$8,511,765 | | \$8,511,765 | |
| | | | | | | | |
| <u>Expenses</u> | | | | | | | |
| Operating | \$2,773.07 | \$1,472,501 | \$1,549.37 | \$5,810,131 | \$1,550.34 | \$5,813,782 | |
| Capital | <u>\$739.67</u> | <u>\$392,764</u> | <u>\$104.74</u> | <u>\$392,764</u> | <u>\$104.74</u> | <u>392,764</u> | |
| Total Expenses | \$3,512.74 | \$1,865,265 | \$1,654.11 | \$6,202,895 | \$1,655.08 | \$6,206,546 | |
| | | | | | | | |
| Net Income (Loss) | | <u>(\$76,669)</u> | | \$2,308,870 | | <u>\$2,305,219</u> | |
| | | | | | | | |
| Utilization | | 531 | | 3,750 | | 3,750 | |
| Cost Per Procedure | | 3,512.74 | | \$1,654.11 | | \$1,655.08 | |

Utilization by the payor for the current, first, and third years is summarized below:

| | Current Year | | Year One | | Year Three | | |
|------------------|-------------------|----------|-------------------|---------------|-------------------|---------------|--|
| | <u>202</u> | | <u>202</u> | <u>2023</u> | | <u>2025</u> | |
| <u>Payor</u> | <u>Procedures</u> | <u>%</u> | <u>Procedures</u> | <u>%</u> | <u>Procedures</u> | <u>%</u> | |
| Medicaid – MC | 0 | 0% | 950 | 25.33% | 950 | 25.33% | |
| Medicare - FFS | 220 | 41.42% | 1,006 | 26.83% | 1006 | 26.83% | |
| Medicare – MC | 86 | 16.20% | 391 | 10.43% | 391 | 10.43% | |
| Commercial - FFS | 210 | 39.55% | 959 | 25.57% | 959 | 25.57% | |
| Commercial - MC | 2 | 0.38% | 10 | 0.27% | 10 | 0.27% | |
| Other | 13 | 2.45% | 59 | 1.57% | 59 | 1.57% | |
| Charity | <u>0</u> | <u>0</u> | <u>375</u> | <u>10.00%</u> | <u>375</u> | <u>10.00%</u> | |
| Total | 531 | 100% | 3,750 | 100% | 3,750 | 100% | |

The following is noted concerning the submitted operating budget:

- Breakeven utilization is 2,733 procedures in the first and third years or approximately 73% of the expected volume.
- Medicare Fee for Service rates reflect the current 2020 rates, while Commercial and Private Pay rates have been adjusted based on experience at the Center.
- Medicare Managed Care rates are based on the facility's current year, 2020, while Medicaid Managed Care rates are based on the Center's average Medicaid Managed Care rate during 2021.
- Utilization and revenue projections are based on the Center's additional capacity of 4 operating rooms as of March 25, 2021. Only 2 operating rooms were available prior to the expansion.
- Projections are supported by letters from ten physicians.
- The projected increase in Medicaid Managed Care is due to three new physicians that will perform procedures covered by Medicaid.

Purchase Agreement (PA)

The applicant submitted an executed PA to acquire certain assets associated with the FASC, which will become effective upon PHHPC approval. The terms are summarized below:

| Date: | September 21, 2020 |
|----------------------------------|---|
| Seller: | Millennium Ambulatory Surgery Center, LLC |
| Buyer: | Performance Surgical Center, LLC previously known as Performance Practice, LLC |
| Asset Acquired: | Rights, title, and interest in the sellers' assets free of liens used in the FASC. Includes tangible personal property, inventory, real property lease, intellectual property, legally transferrable records, phone numbers, email addresses, and goodwill. |
| Excluded Assets | Cash and equivalents, account receivables (before the effective date for the Consulting Agreement), contracts (including provider agreements and provider numbers), and organization documents. |
| Assumption of | Surgery Center lease between the applicant and the 1408 Ocean Avenue, LLC, as |
| Liabilities: | of September 21, 2020, |
| Purchase Price | \$2,500,000 |
| Payment of the Purchase Price | \$1,500,000 paid into escrow on September 14, 2020 500,000 paid into escrow on September 22, 2020 500,000 paid into escrow on February 1, 2022 |

The \$2,500,000 purchase price for the FASC operations has been funded through a loan from 1408 Partners LLC (the landlord), with no interest and no repayment terms.

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 surcharges, assessments or fees due from the transferor under Article 28 of the Public Health Law concerning the period before the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of October 22, 2022, the facility had no outstanding Medicaid liabilities.

Purchase And Sale Agreement

As summarized below, the applicant has submitted an executed PSA to acquire the FASCs real property.

| Date: | September 21, 2020 |
|----------------|---|
| Realty Owners: | 1408 Ocean Avenue, LLC |
| Buyer: | 1408 Partners, LLC |
| Premises Real | Land, buildings, and improvements located at 1408 Ocean Avenue, New York, |
| Property: | New York – Block 6712, lot 62 |
| Payments by | \$10,000,000 |
| Buyer: | \$3,000,000 down payment |
| | \$7,000,000 loan |

The real property purchase closed on December 28, 2020, and was paid as follows:

| Members Equity | \$3,000,000 |
|--|-------------|
| A loan from Connection Bank (10-year term, interest at | \$7,000,000 |
| 3.875%, 30-year amortization) | |

Lease Agreement

The applicant has submitted a draft Lease Agreement; terms are summarized below:

| Premises: | 10,000 sq. ft. on the first floor and cellar level at 1408 Ocean Avenue, Brooklyn, NY 11361 |
|-------------|---|
| Landlord: | 1408 Partners, LLC |
| Tenant: | Performance Surgical Center, LLC |
| Term: | Ending September 30, 2032. Plus (1) 5-year renewal with a 3% yearly increase |
| Payment: | \$360,000 (\$36 per sq. ft.) with a 3% yearly increase |
| Provisions: | Taxes, insurance utilities, and maintenance |

The applicant has provided an affidavit stating the lease is a non-arm length agreement. There is common ownership between the landlord and the applicant. Letters from two NYS licensed realtors have been provided attesting to the rental rate being fair market value.

Capability and Feasibility

The \$2,500,000 purchase price for the FASC operations will be funded via a loan from 1408 Partners LLC (the landlord) with no interest or repayment terms. The FASC's real property was acquired by 1408 Partners LLC. for \$10,000,000 and funded through \$3,000,000 in members' equity and a \$7,000,000 bank loan at stated terms from Connection bank. There are no project costs associated with this transaction.

The working capital requirement is estimated at \$1,033,816 based on two months of first-year expenses and will be funded with members' equity. BFA Attachments A shows sufficient resources to meet the working capital equity requirement. Additionally, Jonathan Phillips, M.D. has provided an affidavit stating his willingness to contribute resources disproportionate to his ownership interest for working capital, if necessary. BFA Attachment B is Performance Surgical Center, LLC. pro forma balance sheet that shows operations will start with \$1,033,816 in equity. Equity includes \$2,200,000 in goodwill, which is not a liquid resource nor recognized for Medicaid reimbursement. Performance Surgical Center, LLC projects an operating surplus of \$2,308,870 and \$2,305,219 in the first and third years. The budget appears reasonable.

Conclusion

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

| | ļ. |
|--------------|----|
| Attachments | ! |
| Attacriments | ļ. |

| BFA Attachment A | Performance Surgical Center, LLC. Members' net worth summary |
|------------------|--|
| BFA Attachment B | Pro Forma Balance Sheet of Performance Surgical Center, LLC |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 8th day of December 2022, 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 Performance Surgical Center, LLC as the new operator of Millenium Ambulatory Surgery Center, a multi-specialty freestanding ambulatory surgical center at 1408 Ocean Avenue, Brooklyn, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER: FACILITY/APPLICANT:

221213 E Performance Surgical Center, LLC d/b/a

Performance Surgical Center

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

- 1. Submission of an executed lease agreement acceptable to the Department of Health. [BFA]
- 2. 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 on the calendar year. 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
 - d. seven days after ambulatory surgery;
 - e. Data displaying the number of emergency transfers to a hospital;
 - f. Data displaying the percentage of charity care provided;
 - g. The number of nosocomial infections recorded during the year reported;
 - h. A list of all efforts made to secure charity cases; and
 - i. A description of the progress of contract negotiations with Medicaid Managed Care plans. [RNR]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **one year from the date of this letter**, including all preopening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. 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/facilites/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 [HSP].
- 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]

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*.



of Health

Department Public Health and Health Planning Council

Project # 221145-B Apple Care Health

Program: **Diagnostic and Treatment Center** County: Kings

Establishment and Construction Acknowledged: Purpose: May 18, 2022

Executive Summary

Description

Apple Care Health, LLC, a New York limited liability company, requests approval to establish and construct an Article 28 Diagnostic and Treatment Center (D&TC) to provide Primary Medical Care, Other Medical Specialties, and Podiatry services.

The applicant plans to provide comprehensive care to individuals living in Brooklyn, with specific emphasis on residents in Crown Heights/ Prospect Heights, with a goal to reduce preventable admissions for patients with medical conditions.

The D&TC will be in leased space on the first floor and basement level of an existing four-story mixed-use building located at 1587 Fulton Street, Brooklyn (Kings County).

The proposed ownership is as follows:

| p p | | | | |
|----------------------------|----------|--|--|--|
| Apple Care Health, LLC | | | | |
| <u>Members</u> | <u>%</u> | | | |
| All Care Tele Health Corp. | 90% | | | |
| Joel Kaufman (100%) | | | | |
| Jeffrey Berman, M.D. | 10% | | | |

Jeffrey Berman, M.D., is board certified in Psychiatry, Addiction Medicine, and Anesthesiology, and will serve as the Center's Medical Director. The applicant expects to enter into a Transfer and Affiliation Agreement for backup and emergency services with Interfaith Medical Center, located 0.3 miles (2 minutes travel time) from the Center.

OPCHSM Recommendation Contingent Approval

Need Summary

The center will be located in an area designated as a Health Professional Shortage Area for Primary Care. The number of projected visits is 6.528 in Year One and 12.920 in Year Three. Medicaid utilization is projected at 65% and Charity Care at 2%.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

Total project costs of \$1,202,557 will be met through member equity of \$120,256, with the remaining \$1,082,301 balance being financed over ten years through Hudsonshine Capital at the firm's five-year cost of funds with an indicative rate of 5%. The projected budget is as follows:

| Budget | Year One | Year Three |
|-------------|-------------|--------------------|
| | <u>2024</u> | <u>2026</u> |
| Revenues | \$910,753 | \$1,802,722 |
| Expenses | 898,942 | \$1,416,534 |
| Gain/(Loss) | \$11,811 | \$386,188 |

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 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. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]
- 4. Submission of an executed loan commitment, acceptable to the Department of Health. [BFA]
- 5. Submission of an executed working capital loan commitment, acceptable to the Department of Health. [BFA]
- 6. Submission of an executed copy of the Articles of Organization of Apple Care Health, LLC that are acceptable to the Department. [CSL]
- 7. Submission of an executed copy of Operating Agreement of Apple Care Health, LLC that is acceptable to the Department. [CSL]
- 8. Submission of a copy of Bylaws of All Care Tele Health Corp that are acceptable to the Department. [CSL]
- 9. Submission of an executed Certificate of Incorporation of All Care Tele Health Corp that is acceptable to the Department. [CSL]
- 10. Submission of a list of board members and directors of All Care Tele Health Corp that is acceptable to the Department. [CSL]
- 11. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

Approval conditional upon:

- 1. This project must be completed by **September 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- Construction must start on or before June 1, 2023, and construction must be completed by June 1, 2024, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]
- 4. 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]

5. 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/hospital/docs/hcs access form 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 [HSP]

Council Action Date December 8, 2022

Need and Program Analysis

Background

| Proposed Operator | Apple Care Health, LLC | |
|--------------------------------|--|--|
| To Be Known As | Apple Care Health | |
| Site Address | 1578 Fulton Street | |
| | Brooklyn, New York 11213 (Kings County) | |
| Specialties | Medical Services-Primary Care | |
| - | Medical Services-Other Medical Specialties | |
| | Cardiology | |
| | Endocrinology | |
| | Gastroenterology | |
| | Oncology | |
| | Orthopedics | |
| | Urology | |
| | Podiatry O/P | |
| Hours of Operation | Sunday through Thursday 9 am to 8 pm | |
| - | Fridays 9 am to 2 pm | |
| Staffing (1st Year / 3rd Year) | 8.60 FTEs / 14.07 FTEs | |
| Medical Director(s) | Dr. Jeffrey Berman, M.D. | |
| Emergency, In-Patient, and | Expected to be provided by | |
| Backup Support Services | Interfaith Medical Center | |
| Agreement and Distance | 0.3 miles / 2 minutes away | |

The primary service area is the neighborhood of Crown Heights in Kings County. The center will be located in a HRSA-designated Primary Care Health Profession Shortage Area as well as a Medically Underserved Area. The population of Kings County was 2,736,074 in 2020 and is expected to grow to 2,810,876 by 2025. According to Data USA, in 2019 93.7% of the population in Kings County has health coverage as follows:

| Employer Plans | 41.7% |
|-----------------|--------|
| Medicaid | 33.2% |
| Medicare | 8.05% |
| Non-Group Plans | 10.5% |
| Military or VA | 0.222% |

The applicant projects 6,528 visits in the first year and 12,920 by the third with 65% Medicaid utilization and 2% Charity Care. The applicant states a commitment to serving all persons in need without regard to ability to pay or source of payment.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease. The table below provides information on the PQI rates for the overall PQI condition. It shows that the PQI rate for the primary service area (zip code 11213) is significantly higher than the New York State rate.

| Hospital Admissions per 100,000 Adults for Overall PQIs | | | |
|---|----------------|----------------|--|
| PQI Rates: 2017 | Zip Code-11213 | New York State | |
| All PQI's | 1,889 | 1,431 | |

Conclusion

The new diagnostic and treatment center will provide additional services to a federally recognized underserved area.

Character and Competence

The members of Apple Health Care, LLC are:

| <u>Name</u> | <u>Interest</u> |
|---------------------------|-----------------|
| All Care Tele Health Corp | 90.00 % |
| Joel Kaufman (100%) | |
| Jeffrey Berman, MD | 10.00% |
| Total | 100.00% |

Jeffrey Berman, MD is a Member and the proposed Medical Director. He is the Director of Behavioral Medicine at the Discovery Institute in New Jersey, an addiction and behavioral health treatment center, the Director of Psychiatry at SOBA College Recovery in New Jersey, an in- and outpatient mental health and addiction treatment center, an Addiction Psychiatry Consultant at North Jersey Recovery Center, and a Clinical Assistant Professor of Psychiatry. He was the Associate Medical Director of Behavioral Health for Bergen Regional Medical Center and the Medical Director of Summit Oaks Hospital in New Jersey. He completed his medical degree at SUNY Upstate Medical Center. He completed his residency in Psychiatry at New Jersey Medical School. He completed his fellowship in Psychiatry at Robert Wood Johnson Medical School in New Jersey. He also completed a residency in Anesthesiology at Maimonides Medical Center and Massachusetts General Hospital. He completed his fellowship in Anesthesiology at Montefiore Medical Center. He is board certified in Psychiatry, Addiction Medicine, and Anesthesiology.

Joel Kaufman is a Licensed General Contractor for Unique Developers Corp. He has successfully completed numerous ground up and gut renovation projects and is a Corporate Real Estate Broker for Realty Guardian Inc. He was previously a Real Estate Agent for Microsoft Realty, King County Realty, and Exit Reality. He was a Volunteer Community Organizer at Cong Shaar Hatfilah where he arranged community affairs and coordinated daily member services.

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. Berman pled no contest that he voluntarily surrendered his license in New Jersey in 1999 for being a habitual user of drugs and practicing medicine while impaired by drugs. In New York State, Dr. Berman had his license suspension lifted with probation for five years with the condition that he is permanently prohibited from practicing clinical anesthesia except for pain management and cannot prescribe medication for himself or his family members.

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.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

Total project costs for renovations and the acquisition of moveable equipment are estimated at \$1,202,557, broken down as follows:

| Renovation & Demolition | \$822,380 |
|----------------------------|--------------|
| Design Contingency | 82,238 |
| Construction Contingency | 82,238 |
| Architect/Engineering Fees | 15,000 |
| Other Fees | 75,000 |
| Movable Equipment | 57,907 |
| Financing Costs | 21,537 |
| Interim Interest Expense | 37,690 |
| CON Application Fee | 2,000 |
| CON Processing Fee | <u>6,567</u> |
| Total Project Cost | \$1,202,557 |

The applicant's financing plan appears as follows:

| Cash Equity (Applicant) | \$120,256 |
|---------------------------------------|-------------|
| Bank Loan (5% interest, 10-year term) | 1,082,301 |
| Total | \$1,202,557 |

BFA Attachment A is the members' net worth which shows sufficient resources to meet the equity requirement. Hudsonshine Capital has provided a letter of interest.

Operating Budget

The applicant has submitted first and third-year operating budgets, in 2022 dollars, as summarized below.

| | <u>Year One</u> | | Year Three | |
|---|--|---|--|--|
| | <u>2024</u> | | <u>20</u> | <u>)26</u> |
| | <u>Per Visit</u> | <u>Total</u> | Per Visit | <u>Total</u> |
| Revenues Medicaid-FFS Medicaid-MC Medicare-FFS Medicare-MC Commercial-FFS Commercial-MC Private Pay Total | \$171.56 \$137.24 \$150.00 \$120.00 \$150.00 \$130.00 \$190.00 | \$55,927 537,586 146,850 39,120 68,550 25,480 37,240 \$910,753 | \$171.56 \$137.24 \$150.00 \$120.00 \$150.00 \$130.00 \$190.00 | \$110,825 1,063,917 290,700 77,520 135,600 50,440 <u>73,720</u> \$1,802,722 |
| Expenses Operating Capital Total | \$99.45 <u>\$38.26</u> \$137.71 | \$649,196 <u>249,746</u> \$898,942 | \$91.33 <u>\$18.31</u> \$109.64 | \$1,179,995 <u>236,539</u> \$1,416,534 |
| Net Income | | \$11,811 | | \$386,188 |
| Total Visits Cost per Visits | | 6,528 \$137.71 | | 12,920 \$109.64 |

Utilization broken down by payor source during Year One and Year Three is as follows:

| | Year One | | Year Th | <u>rree</u> |
|----------------|---------------|--------------|---------------|-------------|
| | <u>202</u> | 2024 | | <u>3</u> |
| <u>Payor</u> | <u>Visits</u> | <u>%</u> | <u>Visits</u> | <u>%</u> |
| Medicaid-FFS | 326 | 4.99% | 646 | 5.00% |
| Medicaid-MC | 3,917 | 60.01% | 7,752 | 60.00% |
| Medicare-FFS | 979 | 15.00% | 1,938 | 15.00% |
| Medicare-MC | 326 | 4.99% | 646 | 5.00% |
| Commercial-FFS | 457 | 7.00% | 904 | 7.00% |
| Commercial-MC | 196 | 3.00% | 388 | 3.00% |
| Private Pay | 196 | 3.00% | 388 | 3.00% |
| Charity | <u>131</u> | <u>2.01%</u> | <u>258</u> | 2.00% |
| Total | 6,528 | 100% | 12,920 | 100% |

The following is noted with respect to the submitted budget:

- Medicaid Fee for Service (FFS) rate is based upon the basic per-visit rate plus cost of capital obtained from the Bureau of D&TC Reimbursement. Medicaid Managed Care is assumed to be 80% of the Medicaid FFS's basic rate.
- Medicare FFS rate is based on the Medicare Part B fee schedule with the Medicare Managed
 Care assumed to be at 80% of the Medicare FFS rate. The rate for Commercial Fee for Service
 is based on the Medicare Part B fee schedule while the Commercial managed care rate is
 approximately 86% of the Medicare Part B fee schedule.
- Staffing and expenses were based on the specific staff requirements to properly and efficiently operate the D&TC along with a review of similar type and size diagnostic and treatment center cost reports.
- Utilization by payor source is based on the demographic of the service area which includes Crown Heights, Prospect Heights, and Weeksville located in Brooklyn Community District 8.
 Which is a medically underserved area, mental health professional shortage area (MHPSA), and health professional shortage area (HPSA).
- Utilization is expected to grow from an increase in demand, community network relationships,
 hospital affiliations, and marketing. Discussions have already taken place with a representative
 of Interfaith Medical Center/One Brooklyn Health system, the proposed hospital for backup and
 emergency services, to receive patients at the center who are in need of outpatient services and
 help to minimize the readmission of patients to the hospital by providing an available source of
 primary and other outpatient care.
- Breakeven utilization for the first year is 6,444 visits.

Lease Rental Agreement

The applicant has submitted an executed lease for the proposed site, the terms of which are summarized below:

| Date: | April 1, 2022 |
|-------------|---|
| Premises: | 3,400 square feet located at 1587 Fulton Street, Brooklyn, NY 11213 |
| Landlord: | Fulton Unique Residence, LLC |
| Lessee: | Apple Care Health, LLC. |
| Term: | 11 years, base rent at \$108,000 in year one (\$31.77 per sq. ft.) |
| Provisions: | Utilities, Maintenance, Insurance and Taxes |

The applicant has provided an affidavit attesting that the lease is a non-arms-length agreement because Joel Kaufman is the sole member of the landlord and a member of the operator. Letters from two NYS licensed realtors have been provided attesting to the rental rate being of fair market value.

Capability and Feasibility

Total project costs of \$1,202,557 will be met through member equity of \$120,256, with the remaining \$1,082,301 balance being financed over ten years through Hudsonshine Capital at the above-stated terms.

Working capital requirements are estimated at \$236,088, based on two months of third-year expenses. Funding will be as follows: \$118,044 from member equity with the remaining \$118,044 satisfied through a three-year loan from Hudsonshine Capital at the firm's five-year cost of funds with an indicative interest rate of 5%. Hudsonshine Capital has provided a letter of interest. Review of BFA Attachments A reveals Joel Kaufman has sufficient resources to meet all the equity requirements. BFA Attachment B is Apple Care Health LLC's pro forma balance sheet that shows operations will start with \$238,300 equity. The Center projects an operating surplus of \$11,811 and \$386,188 in the first and third years. The applicant's budgets appear to be reasonable.

Conclusion

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

| Attachments |
|--------------|
| Attachinents |

| BHFP Attachment | Мар |
|------------------|--|
| BFA Attachment A | Net Worth Statements of Proposed Members of Apple Care Health, LLC |
| BFA Attachment B | Pro Forma Balance Sheet of Apple Care Health, LLC |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 8th day of December 2022, 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 new diagnostic and treatment center at 1578 Fulton Street, Brooklyn, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER: FACILITY/APPLICANT:

221145 B Apple Care Health

APPROVAL CONTINGENT UPON:

- 1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
- 2. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]
- 4. Submission of an executed loan commitment, acceptable to the Department of Health. [BFA]
- 5. Submission of an executed working capital loan commitment, acceptable to the Department of Health. [BFA]
- 6. Submission of an executed copy of the Articles of Organization of Apple Care Health, LLC that are acceptable to the Department. [CSL]
- 7. Submission of an executed copy of Operating Agreement of Apple Care Health, LLC that is acceptable to the Department. [CSL]
- 8. Submission of a copy of Bylaws of All Care Tele Health Corp that are acceptable to the Department. [CSL]
- 9. Submission of an executed Certificate of Incorporation of All Care Tele Health Corp that is acceptable to the Department. [CSL]
- 10. Submission of a list of board members and directors of All Care Tele Health Corp that is acceptable to the Department. [CSL]
- 11. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **September 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **June 1, 2023**, and construction must be completed by **June 1, 2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]

- 4. 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]
- 5. 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/hospital/docs/hcs_access_form_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 [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*.



of Health

Department Public Health and Health Planning Council

Project # 221227-B Parkchester DTC LLC d/b/a Parkchester Diagnostic and Treatment Center

Program: **Diagnostic and Treatment Center** County:

Establishment and Construction Acknowledged: August 11, 2022 Purpose:

Executive Summary

Description

Parkchester DTC LLC is requesting approval to establish and construct a new Article 28 Diagnostic and Treatment Center (D&TC) through the conversion of a private practice. The D&TC will be located in two adjoining leased spaces at 1879 Gleason Avenue and 1211 White Plains Road, Bronx, with the entrance on Gleason Avenue. The applicant proposes to provide primary care, physical therapy, podiatry, and other medical specialties.

| Proposed Operator | | |
|---------------------|--|--|
| Parkchester DTC LLC | | |
| Members Interest | | |
| Neal Polan 95.00% | | |
| Amy Polan 5.00% | | |

The private practice, 1211 WPR Medical Services, PC, is owned by David Weiss, MD and managed by Neal and Amy Polan. Dr. Weiss is the proposed medical director. Of the D&TC.

St. Barnabas Hospital will serve as the backup hospital for the Center. Upon approval of this application, the site will be known as Parkchester Diagnostic and Treatment Center.

OPCHSM Recommendation Contingent Approval

Need Summary The applicant projected 53,375 visits in Year One and 72,790 in Year Three. Medicaid

utilization is projected at 55% and Charity Care at 2% in both Year One and Year Three. The converted DTC will increase services in a Medically Underserved Area where Prevention Quality Indicators evidence a possible lack of preventative care services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3)(b).

Financial Summary

Total project costs of \$4,648,617 will be met through members' equity of \$1,649,817 and grant awards of \$2,988,800 (Statewide Transformation Grant Award (SW) of \$2,700,000 and Capital Restructuring Financing Program (CRFP) of \$288,000) awarded to 1211 WPR Medical Services PC, a private medical practice. Upon approval of this CON, 1211 WPR Medical Service PC will cease operations but exist as a business, and maintain the grant awards received.

| <u>Budget</u> | Year One | Year Three |
|---------------|-------------|------------------|
| Revenues | \$6,604,238 | \$9,006,541 |
| Expenses | 6,445,977 | 8,642,377 |
| Net Income | \$158,261 | <u>\$364,164</u> |

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 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. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 4. Submission of documentation confirming final approval of the Capital Restructuring Financing Program executed grant contract, acceptable to Department of Health. [BFA]
- 5. Submission of documentation confirming final approval of the Statewide Health Care Transformation Program executed grant contract, acceptable to Department of Health. [BFA]
- 6. Submission of an executed lease rental agreement that is acceptable to the Department of Health. [BFA]
- 7. Submission of an executed sublease agreement that is acceptable to the Department of Health. [BFA]
- 8. Submission of a working capital loan that is acceptable to the Department of Health. [BFA]
- 9. Submission of an Operating Agreement that is acceptable to the Department. [CSL]
- 10. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

Approval conditional upon:

- 1. This project must be completed by **September 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- Construction must start on or before June 1, 2023, and construction must be completed by June 1, 2024, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]
- 4. 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]
- 5. 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/hospital/docs/hcs_access_form_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. [HSP]

Council Action Date December 8, 2022

Need and Program Analysis

Program Description

| Proposed Operator | Parkchester DTC | |
|--------------------------------|---|--|
| To Be Known As | Parkchester Diagnostic and Treatment Center | |
| Site Address | 1879 Gleason Avenue | |
| | Bronx, New York 10472 (Bronx County) | |
| Specialties | Medical Services-Primary Care | |
| | Medical Services-Other Medical Specialties | |
| | Cardiology | |
| | Dermatology | |
| | Gastroenterology | |
| | Op hthalmology | |
| | Orthopedic | |
| | Psychiatry | |
| | Urology | |
| | Physical Therapy O/P | |
| | Podiatry O/P | |
| Hours of Operation | Monday through Friday 8 am to 7 pm | |
| | Saturday 8 am 2 pm | |
| Staffing (1st Year / 3rd Year) | 55.58 FTEs / 81.79 FTEs | |
| Medical Director(s) | David Weiss, M.D. | |
| Emergency, In-Patient, and | Expected to be provided by | |
| Backup Support Services | St. Barnabas Hospital | |
| Agreement and Distance | 5.8 miles / 16 minutes away | |

Background

The primary service area encompasses the Parkchester and Soundview neighborhoods in Bronx County. The proposed site is in an HRSA-designated Medically Underserved Area for primary care.

According to Data USA, in 2019 92% of the population in Bronx County has health coverage as follows.

| Employer Plans | 30.8% |
|-----------------|--------|
| Medicaid | 41.8% |
| Medicare | 6.79% |
| Non-Group Plans | 12.1% |
| Military or VA | 0.417% |

The applicant projected 53,375 visits in Year One and 72,790 in Year Three.

| Projected Payor Source | | | | |
|------------------------------------|--------|--------|--|--|
| Insurance Type Year One Year Three | | | | |
| Commercial | 20.00% | 20.00% | | |
| Medicare | 20.00% | 20.00% | | |
| Medicaid | 55.00% | 55.00% | | |
| Private Pay/Other | 3.00% | 2.00% | | |
| Charity Care | 2.00% | 2.00% | | |

Converting the primary care practice to a D&TC will allow for greater access to medical personnel, including increased staffing, without the need for prior appointments. The applicant anticipates this will reduce patient wait times, provide more immediate access to care, and have fewer emergency room visits.

A significant percentage of the area's residents were born outside of the United States and have limited

English proficiency. Parkchester will ensure staff are fluent in the language of the community, and materials will be available in English and Spanish, with accommodations for other dominant languages as needed. The applicant plans to provide services in a culturally sensitive manner. Examples provided include focusing on the availability of same-sex providers and extended hours on holy days.

The goal of this project is to reduce avoidable emergency room visits and increase the overall health of the service area by increasing access to health care. According to the applicant, the proposed service area is comprised of low-income families who often lack knowledge about health options and prevention with limited or no access to care.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease. The table below provides information on the PQI rates for the overall PQI condition.

| Hospital Admissions per 100,000 Adults for Overall PQIs | | |
|---|--------------|----------------|
| PQI Rates: 2017 | Bronx County | New York State |
| All PQI's | 2,196 | 1,431 |

Character and Competence

The members of Parkchester DTC LLC. are:

| <u>Name</u> | <u>Interest</u> | |
|-------------|-----------------|--|
| Neal Polan | 95.00% | |
| Amy Polan | 5.00% | |
| Total | 100.00% | |

Neal Polan is the President and Principal Shareholder of Insight Management Corp. where he provides services in strategic acquisition, reorganizations, and operating solutions for small to middle-market companies in healthcare. He is a Partner and Principal Owner of PMC Medical Management, LLC, and KABAET 4, LLC where he is responsible for the day-to-day operating healthcare and ancillary healthcare services for five multi-specialty healthcare facilities. Mr. Polan serves on the Board of Directors of the Dr. Ramon Tallaj Foundation which offers grants, scholarships, and awards for students committed to the study of medicine and healthcare-related fields. He led the successful acquisition and management reorganization of Sterling Optical, which was in bankruptcy at the time of acquisition. He became a Joint Venture Partner/Operating Partner in Bronxdocs, a system of multi-specialty medical facilities in the Bronx. He was a Strategic Advisor to Corinthian Medical IPA for over five years.

Amy Polan is the Administrative Manager for PMC Medical Management PC where she is responsible for the involvement, implementation, supervision, and review of all facets and decisions made that impact daily operations. She is accountable for decisions that directly affect patient care, the medical office environment, compliance, and staffing. She interacts with the Office Manager, Human Resources, the Director of Operations, and the protocol advisor.

David Weiss, MD is the proposed Medical Director. He is the Owner of 1211 WPR Medical Services PC. He received his medical degree from New York Medical College. He completed his residency in Internal Medicine at Lenox Hill Hospital. He completed his fellowship in Pulmonary Disease at Norwalk Hospital. He is board certified in Internal Medicine and Pulmonology.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

The new DTC will increase access to services in a medically underserved area, where high PQI rates evidence a possible lack of preventive care services. The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3)(b).

Financial Analysis

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, during the first and third years of operation, summarized below:

| | <u>Year One</u> | | Year Three | |
|----------------------|-----------------|--------------------|----------------|------------------|
| | Per Visit | <u>Total</u> | Per Visit | <u>Total</u> |
| <u>Revenues</u> | | | | |
| Commercial FFS | \$125.00 | \$800,625 | \$125.00 | \$1,091,875 |
| Commercial MC | \$105.00 | 448,245 | \$105.00 | \$611,415 |
| Medicare FFS | \$125.00 | 867,375 | \$125.00 | \$1,182,875 |
| Medicare MC | \$100.00 | 373,600 | \$100.00 | \$509,500 |
| Medicaid FFS | \$167.76 | 451,114 | \$169.02 | \$615,064 |
| Medicaid MC | \$126.76 | 3,383,104 | \$126.76 | \$4,613,612 |
| Private Pay | \$175.00 | <u>280,175</u> | \$175.00 | <u>\$382,200</u> |
| Total Revenues | | \$6,604,238 | | \$9,006,541 |
| | | | | |
| Expenses | | | | |
| Operating | \$95.66 | \$5,106,056 | \$100.89 | \$7,343,857 |
| Capital | <u>\$25.10</u> | \$1,339,921 | <u>\$17.84</u> | \$1,298,520 |
| Total Expenses | \$120.77 | \$6,445,977 | \$118.73 | \$8,642,377 |
| | | | | |
| Net Income | | <u>\$158,261</u> | | <u>\$364,164</u> |
| Utilization (Visits) | | 53,375 | | 72,790 |

Expense and utilization assumptions are based on the actual experience of the existing multispecialty medical practice.

Utilization broken down by payor source for the first and third years are as follows:

| | - 7 - 7 | |
|----------------|--------------|--------------|
| <u>Payor</u> | Year One | Year Three |
| Commercial FFS | 12.00% | 12.00% |
| Commercial MC | 8.00% | 8.00% |
| Medicare FFS | 13.00% | 13.00% |
| Medicare MC | 7.00% | 7.00% |
| Medicaid FFS | 5.00% | 5.00% |
| Medicaid MC | 50.00% | 50.00% |
| Private Pay | 3.00% | 3.00% |
| Charity Care | <u>2.00%</u> | <u>2.00%</u> |
| Total | 100.00% | 100.00% |

Total Project Cost and Financing

The total project cost, which is for new construction and the acquisition of moveable equipment, is estimated at \$4,648,617, further broken down as follows:

| New Construction | \$2,800,000 |
|----------------------------|---------------|
| Design Contingency | 50,000 |
| Construction Contingency | 420,000 |
| Planning Consultant Fees | 216,200 |
| Architect/Engineering Fees | 505,000 |
| Other Fees (Consultant) | 150,000 |
| Moveable Equipment | 480,000 |
| CON Fee | 2,000 |
| Additional Processing Fee | <u>25,417</u> |
| Total Project Cost | \$4,648,617 |

The applicant's financing plan appears as follows:

| Equity (Members) | \$1,649,817 |
|------------------------|-------------|
| Transformation Grants: | |
| Statewide | \$2,700,000 |
| CRFP | \$288,800 |

Lease Rental Agreements

The applicant has submitted a signed proposed sublease rental agreement for the space at 1211 White Plains Road that they will occupy:

| Proposed Date: | May 1, 2023 |
|----------------|---|
| Premises | 4,184 square feet located at 1211 White Plains Road, Bronx, New York. |
| Sublessor | PMC Medical Management, LLC |
| Sublessee | Parkchester DTC, LLC |
| Term | The sublessee shall commence on May 1, 2023 and expire on December 31, 2026. |
| Rental | From May 1, 2023 and ending on December 31, 2023, the rent shall be \$146,400 (\$34.99 per sq. ft.) |
| | Commencing on January 1, 2024, Base Rent shall be increased by 2.5%. |
| Provisions | The fixed rent shall include all water charges, utility, and real estate taxes. |

The applicant has submitted an affidavit stating that this lease will be a non-arm's length lease arrangement in that there is a relationship. Also, the applicant submitted two real estate letters attesting to the reasonableness of the per-square-foot rental.

The applicant has submitted a draft lease agreement for the space at 1897 Gleason Avenue that they will occupy:

| Premises | 9,060 square feet located at 1897 Gleason Avenue, Bronx, New York. |
|------------|--|
| Lessor | Kabaet 3RE, LLC |
| Lessee | Parkchester DTC, LLC |
| Term | 15 years |
| Rental | Year 1-5: \$320,000 annually (\$35.32 per sq.ft.). Every five-year anniversary the annual rent shall be increased by Consumer Price Index for Wage Earners and Clerical Workers. |
| Provisions | The lessee shall be responsible for real estate taxes, maintenance, and utilities. |

The applicant has submitted an affidavit indicating that the lease agreement will be a non-arm's length lease arrangement in that there is a relationship between the lessor and the lessee. Furthermore, the

applicant has submitted two real estate letters attesting to the reasonableness of the per-square-foot rental.

Capability and Feasibility

Total project costs of \$4,648,617 will be met through members' equity of \$1,649,817 and grant awards of \$2,988,800 (Statewide Transformation Grant Award (SW) of \$2,700,000 and Capital Restructuring Financing Program (CRFP) of \$288,000) awarded to 1211 WPR Medical Services PC. The private practice, 1211 WPR Medical Services PC, is the awardee of the SW and CRFP grant awards. Upon approval of this CON, 1211 WPR Medical Service PC will cease operations.

Working capital requirements are estimated at \$1,440,396, equivalent to two months of third-year expenses. The applicant will finance \$720,198 at an interest rate of 6% for a three-year term. The remainder, \$720,198, will be provided as equity via the proposed members' resources. BFA Attachment A, the personal net worth statements of the proposed members of Parkchester DTC LLC, indicates the availability of sufficient funds for the equity contribution. BFA Attachment B is the pro forma balance sheet of Parkchester DTC, LLC, indicating a positive net asset position of \$5,368,815 as of the first day of operation.

The submitted budget indicates a net income of \$158,261 and \$364,164 during the first and third years, respectively. Revenues are based on current reimbursement methodologies for diagnostic and treatment center services. The submitted budget appears reasonable.

Conclusion

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

|--|

| BHFP Attachment | Мар |
|------------------|--|
| BFA Attachment A | Personal Net Worth Statement of Proposed Members |
| BFA Attachment B | Pro Forma Balance Sheet |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 8th day of December 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a diagnostic and treatment center at 1879 Gleason Avenue, Bronx, perform renovations and construct new space adjoining the existing building – CRFP, 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:

221227 B Parkchester DTC LLC d/b/a Parkchester

Diagnostic and Treatment Center

APPROVAL CONTINGENT UPON:

- 1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
- 2. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
- 4. Submission of documentation confirming final approval of the Capital Restructuring Financing Program executed grant contract, acceptable to Department of Health. [BFA]
- 5. Submission of documentation confirming final approval of the Statewide Health Care Transformation Program executed grant contract, acceptable to Department of Health. [BFA]
- 6. Submission of an executed lease rental agreement that is acceptable to the Department of Health. [BFA]
- 7. Submission of an executed sublease agreement that is acceptable to the Department of Health. [BFA]
- 8. Submission of a working capital loan that is acceptable to the Department of Health. [BFA]
- 9. Submission of an Operating Agreement that is acceptable to the Department. [CSL]
- 10. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **September 1, 2024**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **June 1, 2023,** and construction must be completed by **June 1, 2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]
- 4. 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]

5. 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/hospital/docs/hcs_access_form_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. [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*.



of Health

Department Public Health and Health Planning Council

Project # 221231-B A Friendly Face Akademy, Corp.

Program: **Diagnostic and Treatment Center** County: Richmond **Establishment and Construction** Acknowledged: July 22, 2022 Purpose:

Executive Summary

Description

A Friendly Face Akademy, Corp., an existing New York domestic business corporation. requests approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) in renovated space at 1887 Richmond Avenue, Staten Island (Richmond County). The proposed center requests certification for primary care, other medical specialties, and physical therapy, serving both the pediatric and adult populations.

| Proposed Operator | | |
|--------------------------------|-----|--|
| A Friendly Face Akademy, Corp. | | |
| Shareholders % | | |
| Ella Goldin | 50% | |
| Anna Marie Dorelien | 50% | |

Leonid Goldin, M.D., who is board certified in Internal Medicine will serve as Medical Director. The Center is negotiating a Transfer and Affiliation Agreement for emergency and backup services with Richmond University Medical Center 2.4 miles and 6 minutes travel time from the proposed Center.

OPCHSM Recommendation Contingent Approval

Need Summary

The applicant projects 8,837 visits in Year One and 17,480 in Year Three. Medicaid utilization is projected at 60% and Charity Care at 2% in both years.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

Total project costs of \$466,082 are proposed to be met with \$46,608 members' equity and a \$419,474 bank loan for a five-year term with a 6% interest rate. Hudson Shine Capital has provided a letter of interest for the loan at the stated terms.

| Budget | Year One | Year Three | |
|------------|---------------|------------------|--|
| | <u>(2023)</u> | <u>(2025)</u> | |
| Revenues | \$1,232,927 | \$2,438,730 | |
| Expenses | 1.069,482 | <u>1,692,541</u> | |
| Net Income | \$163,445 | \$746,189 | |

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 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
- 2. Submission of an executed loan commitment for total project costs, acceptable to the Department of Health. [BFA]
- 3. Submission of an executed loan commitment for working capital, acceptable to the Department of Health. [BFA]
- 4. Submission of copies of stock certificates that are acceptable to the Department. [CSL]
- 5. Submission of a copy of Bylaws that are acceptable to the Department. [CSL]
- 6. Submission of a copy of a Certificate of Incorporation that is acceptable to the Department. [CSL]
- 7. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

Approval conditional upon:

- 1. This project must be completed by **December 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- Construction must start on or before July 1, 2023, and construction must be completed by September 1, 2023, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]
- 4. 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]
- 5. 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/hospital/docs/hcs_access_form_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. [HSP]

Council Action Date December 8, 2022

Need Analysis

Background and Analysis

The primary service area encompasses the South Beach and Willowbrook communities in Staten Island. The following services will be provided: primary care, physical therapy, and other medical specialties. The number of projected visits for the facility is 8,837 in Year One and 17,480 in Year Three.

According to Data USA, in 2019 95.9% of the population in Richmond County had health coverage as follows:

| Employer Plans | 56.6% |
|-----------------|--------|
| Medicaid | 16.7% |
| Medicare | 12.7% |
| Non-Group Plans | 9.53% |
| Military or VA | 0.336% |

The applicant projects the following payor mix:

| Payor | Year One | Year Three |
|-------------------|----------|------------|
| Commercial | 14.99% | 15.00% |
| Medicare | 20.00% | 20.00% |
| Medicaid | 60.00% | 60.00% |
| Private Pay/Other | 3.00% | 3.00% |
| Charity Care | 2.00% | 2.00% |
| Total Visits | 8,837 | 17,480 |

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease. The table below provides information on the PQI rates for the overall PQI condition. It shows that the PQI rate for Richmond County is higher than the New York State rate.

| Hospital Admissions per 100,000 Adults for Overall PQIs | | | |
|---|----------------|-------|--|
| PQI Rates: 2017 | New York State | | |
| All PQI's | 1.525 | 1.431 | |

With the establishment of A Friendly Face Academy, Corp. the applicant proposes to address preventable admissions through treatment and education. The applicant cited a 2019 Richmond University Medical Center Needs Assessment for Richmond County finding that county residents had a slightly higher premature death rate. Contributing factors included relatively higher rates of smoking and death due to drug overdose. Staten Island represents a large smoking population (24%), while the Take Care New York Goal 2020 is 12% or fewer smokers. The applicant plans to provide outreach programs with community leaders, church groups, and schools to help educate members of the community on the causes of diseases and identify symptoms to help them receive earlier treatment.

Conclusion

The new center will increase access to services where elevated PQI rates indicate a possible lack of preventive care services.

Program Analysis

Program Description

| Proposed Operator | A Friendly Face Akademy, Corp | |
|--|---|--|
| To Be Known As | A Friendly Face Akademy | |
| Site Address | 1887 Richmond Avenue | |
| | Staten Island, New York 10314 (Richmond County) | |
| Services | Medical Services-Primary Care | |
| | Medical Services-Other Medical Specialties | |
| | Neurology | |
| | Orthopedics | |
| | Cardiology | |
| | Pulmonology | |
| | Physical Therapy O/P | |
| Hours of Operation | Sunday through Thursday 9 am to 8 pm | |
| | Fridays 9 am to 2 pm | |
| Staffing (1 st Year / 3 rd Year) | 11.60 FTEs / 18.49 FTEs | |
| Medical Director(s) | Leonid Goldin, M.D. | |
| Emergency, In-Patient, and Backup | Expected to be provided by | |
| Support Services Agreement | Richmond University Medical Center | |
| Distance and Time | 2.4 miles / 6 minutes away | |

Character and Competence

The members of A Friendly face Akademy, Corp. are:

| <u>Name</u> | <u>Interest</u> |
|---------------------|-----------------|
| Ella Goldin | 50% |
| Anna Marie Dorelein | 50% |
| Total | 100% |

Anna Marie Dorelein is the CEO, Clinical Director, and Founder of A Friendly Face (AFF), a treatment center for pediatric patients with autism, where she is responsible for training staff to assess the clients and build treatment plans and work with providers on carrying out treatment plans, conducting workshops and continuous trainings on various topics related to autism, conduct assessments, and generate related behavior plans to ensure effective implementation of all treatment and programs for all staff. She also facilitates meetings with administrators to ensure appropriate support and services are rendered to each client, she supervises and trains interventionists to ensure effective implementation of treatment plans and adherence to professional and legal requirements are demonstrated. She directly provides instruction, training, and support to students, interventionists, and family members during home and community visits.

Ella Goldin is the CFO and Founder of A Friendly Face (AFF). She established and operated four AFF treatment centers in New York City and New Jersey. She established partnerships with hospitals and providers who treat patients with autism and provide specialized training to ER doctors and medical professionals who serve special needs children. She advocates for the special needs population with a strong tie to the local community, providing pro bono trainings to the families affected and to professionals who provide educational services. She contracts and credentials all AFF board-certified providers and facilities into the 13 largest medical insurance carriers in New York City and New Jersey. She oversees Patient Management, Payroll, Billing, Human Resources, Quality Assurance, and Training Departments. She is an Independent P&C Insurance Broker at Capital Insuring Group. She was a Founder and Independent Broker Owner at EG Realty, an Analyst in the Asset Backed Securities Department at Morgan Stanley, and a Junior Analyst in the Equities Management Department.

Leonid Goldin is the proposed Medical Director. He is a Family Practice Physician at 21st Century Medical PC. He was previously an Attending Physician and Emergency Room Physician at Kingsbrook Jewish Medical Center, an Attending Physician at Park Nursing Home, and an Attending Physician at Resort Nursing Home. He was the Founder and Independent P&C Insurance Broker of Capital Insuring Group, the Founder and Independent Broker Owner of EG Realty, an Analyst of the Asset Backed Securities Department, and a Junior Analyst at Goldman Sachs. He received his medical degree from Pavlov First State Medical University and Kursk State Medical University. He completed his residency in Internal Medicine at Kingsbrook Jewish Medical Center and Woodhull Medical and Mental Health Center.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

The total project cost for leasehold improvements, renovations, and moveable equipment is \$466,082:

| Renovation & Demolition | \$206,000 |
|-----------------------------|--------------|
| Design Contingency | 20,600 |
| Construction Contingency | 20,600 |
| Architect /Engineering Fees | 31,000 |
| Other Fees | 55,000 |
| Moveable Equipment | 115,849 |
| Financing Costs | 9,996 |
| Interim Interest Expense | 2,499 |
| CON Fee | 2,000 |
| Additional Processing Fee | <u>2,538</u> |
| Total Project Cost | \$466,082 |

The applicant's financing plan is as follows:

| Member's Equity | \$46,608 |
|-------------------------------------|-----------|
| Bank loan (6% interest, 5-year term | \$419,474 |
| Total Financing | \$466.082 |

Joseph Fuchs, a loan originator, has provided a letter of interest for the loan at the stated terms. BFA attachment A is the net worth statement of the members of A Friendly Face Akademy, Corp. which indicates sufficient resources to meet the equity requirements of this application.

Operating Budget

The applicant has submitted their first-and third-year operating budget, in 2021 dollars, as shown below:

| | Year One (2023) | | Year Three (2025) | |
|-----------------|-----------------|------------------|-------------------|------------------|
| | Per Visit | <u>Total</u> | Per Visit | <u>Total</u> |
| Revenues | | | | |
| Commercial FFS | \$165 | \$145,860 | \$165 | \$288,420 |
| Commercial MC | \$120 | 52,920 | \$120 | 104,880 |
| Medicare FFS | \$150 | 198,900 | \$150 | 393,300 |
| Medicare MC | \$120 | 53,040 | \$120 | 104,880 |
| Medicaid FFS | \$169 | 74,707 | \$169 | 147,723 |
| Medicaid MC | \$135 | 657,150 | \$135 | 1,299,967 |
| Private Pay | \$190 | <u>50,350</u> | \$190 | <u>99,560</u> |
| Total Revenues | | 1,232,927 | | \$2,438,730 |
| | | | | |
| <u>Expenses</u> | | | | |
| Operating | \$103 | \$909,986 | \$88 | \$1,540,298 |
| Capital | <u>\$21</u> | <u>159,496</u> | <u>\$9</u> | <u>152,243</u> |
| Total Expenses | \$124 | \$1,069,482 | \$97 | \$1,692,541 |
| | | | | |
| Net Income | | <u>\$163,445</u> | | <u>\$746,189</u> |
| | | | | |
| Visits | | 8,837 | | 17,480 |

Utilization by payor source during the first and third years is broken down as follows:

| | Year One (2023) | | Year Three (2025) | |
|----------------|-----------------|--------------|-------------------|--------------|
| | <u>Visits</u> | <u>%</u> | <u>Visits</u> | <u>%</u> |
| Commercial FFS | 884 | 10.00% | 1,748 | 10.00% |
| Commercial MC | 441 | 4.99% | 874 | 5.00% |
| Medicare FFS | 1,326 | 15.01% | 2,622 | 15.00% |
| Medicaid MC | 442 | 5.00% | 874 | 5.00% |
| Medicaid FFS | 442 | 5.00% | 874 | 5.00% |
| Medicaid MC | 4,860 | 55.00 | 9,614 | 55.00% |
| Private Pay | 265 | 3.00% | 524 | 3.00% |
| Charity Care | <u>177</u> | <u>2.00%</u> | <u>350</u> | <u>2.00%</u> |
| Total | 29,545 | 100.0% | 44,956 | 100.0% |

The following is noted with respect to the submitted budget:

- The Medicaid Fee for Service reimbursement rate is based on the base rate plus the cost of capital as obtained from the NYSDOH, Bureau of D&TC Reimbursement.
- Medicaid Managed Care is assumed to be 80% of the Medicaid APG Fee for service rate.
- Commercial Insurance and Medicare Fee for Service rates are based on the Medicare part B fee schedule.
- Medicare Managed Care and Commercial Managed Care are based on 80% of the Medicare Part B Fee schedule.

Lease Agreement

The applicant has submitted an executed lease agreement for site control of the facility, the terms of which are summarized below:

| Date: | May 1, 2022 |
|-----------|--|
| Premises: | 1887 Richmond Avenue, Lower Level & Suite I on the first floor, Staten Island NY |
| Landlord: | AFF Holding LLC |
| Tenant: | A Friendly Face Akademy, Corp. |

| Rental: | Base rent \$84,000 annually (\$7,000 per month) for year one, 4.8% increase thereafter. |
|-------------|---|
| Term: | 10 years |
| Provisions: | Real estate taxes, maintenance, personal property insurance, and pro rata share of electricity, water, and gas. |

The applicant submitted an affidavit that the lease is a non-arm's length agreement as the landlord and tenant have parties in common. Letters from two New York real estate brokers were submitted attesting to the reasonableness of the rent.

Capability and Feasibility

The total project cost is \$466,082 and will be met with \$46,608 proposed members' equity and a \$419,474 bank loan for a five-year term with a 6% interest rate. Working capital requirements are estimated at \$282,090 based on two months of third-year expenses and will be met with \$141,045 proposed member's equity, and a \$141,045 bank loan for a three-year term with a 6% interest rate. BFA Attachment A is the net worth of the proposed members which indicates the availability of sufficient funds for stated levels of equity. Joseph Fuchs, a loan originator from Hudson Shine Capital, has provided a letter of interest for both the project cost and working capital loans at the stated terms. BFA Attachment C, the pro forma balance sheet for the applicant, indicates that the facility will initiate operations with members' equity of \$748,172.

The submitted budget indicates the facility will generate net income of \$163,445 and \$746,189 in the first and third years, respectively. Revenues are based on prevailing reimbursement methodologies for D&TCs. The budget appears reasonable.

Conclusion

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

| Attachmer | nts |
|-----------|-----|

| BHFP Attachment | Мар |
|------------------|--|
| BFA Attachment A | Net Worth Statement of A Friendly Face Akademy, Corp |
| BFA Attachment B | Pro Forma Balance Sheet, A Friendly Face Akademy, Inc. |

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 8th day of December 2022, 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 new diagnostic and treatment center for primary care and other medical specialties at 1887 Richmond Avenue, Staten Island, 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:

221231 B A Friendly Face Akademy, Corp.

APPROVAL CONTINGENT UPON:

- 1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
- 2. Submission of an executed loan commitment for total project costs, acceptable to the Department of Health. [BFA]
- 3. Submission of an executed loan commitment for working capital, acceptable to the Department of Health. [BFA]
- 4. Submission of copies of stock certificates that are acceptable to the Department. [CSL]
- 5. Submission of a copy of Bylaws that are acceptable to the Department. [CSL]
- 6. Submission of a copy of a Certificate of Incorporation that is acceptable to the Department. [CSL]
- 7. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **December 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. Construction must start on or before **July 1, 2023**, and construction must be completed by **September 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [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]
- 4. 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]

5. 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/hospital/docs/hcs_access_form_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. [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*.



of Health

Department Public Health and Health Planning Council

Project # 221265-B JAL 28 LLC d/b/a A Merryland Health Center

Program: **Diagnostic and Treatment Center** County: Kings

Purpose: **Establishment** Acknowledged: July 15, 2022

Executive Summary

Description

JAL 28 LLC d/b/a A Merryland Health Center (Center), an Article 28 licensed Diagnostic & Treatment Center (D&TC), requests approval to be established as the operator of A Merryland Health Center, currently operated by A Merryland Operating LLC. A Merryland Health Center is located at 2873 West 17th Street, Brooklyn, New York, and is certified to provide primary care, optometry, podiatry, and therapy physical O/P. As part of this application, the applicant is seeking to add other medical specialties to the Center's operating certificate.

On October 28, 2019, A Merryland Operating LLC filed a petition for reorganization under Chapter 11 of the Bankruptcy Code. As a result, BNBN Management, LLC entered into an Asset Purchase Agreement (APA), dated July 30, 2021, for the sale of assets of A Merryland Operating LLC. The parties subsequently entered into an Amended and Restated APA dated November 1, 2021., The Amended APA has been assigned to JAL 28, LLC, the applicant, through an assignment agreement.

The sole member of JAL 28, LLC is Jonathan Liebermann. The applicant will have a transfer and affiliation agreement with Conev Island Hospital. The medical director will be Leonid Ischov, MD.

OPCHSM Recommendation Contingent Approval is recommended

Need Summary

The Center is located in a HRSA designated Medically Underserved Area and a Health Professional Shortage Area for Primary Care. The applicant projects 20,354 visits in the first year and 33,300 in the third with Medicaid utilization at 45% and Charity Care at 2%.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

The purchase price for the facility is \$1.600.000 and will be paid with equity by the proposed member.

| Budget | <u>Year One</u> <u>2023</u> | Year Three 2025 |
|------------|--------------------------------|--------------------|
| Revenues | \$2,664,282 | \$4,427,522 |
| Expenses | 1,990,163 | <u>2,884,622</u> |
| Net Income | \$674,119 | \$1,542,900 |

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 lease assignment that is acceptable to the Department of Health. [BFA]
- 2. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]

Approval conditional upon:

- This project must be completed by one year from the date of the recommendation letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. 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]
- 3. 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/facilites/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 [HSP]

Council Action Date December 8, 2022

Need and Program Analysis

Program Description

| Proposed Operator | JAL 28 LLC |
|--|---|
| Doing Business As | A Merryland Health Center |
| Site Address | 2873 West 17 th Street |
| | Brooklyn, NY 11224 (Kings County) |
| Shift/Hours/Schedule | Monday through Friday 8:30 am to 5:00 pm |
| | Saturday 10:00 am to 4:00 pm |
| Services | Medical Services-Primary Care |
| | Medical Service-Other Medical Specialties |
| | Optometry O/P |
| | Podiatry O/P |
| | Physical Therapy O/P |
| Staffing (1 st Year/3 rd Year) | 10.85 FTEs/18.95 FTEs |
| Medical Director | Leonid Isakov, MD |
| Emergency, In-Patient, and Backup | Coney Island Hospital |
| Support Services Agreement and | 2.0 miles/7 minutes |
| Distance and Time | |

The primary service area is the neighborhood of Coney Island in Kings County. The Center is located in a HRSA designated Medically Underserved Area and a Health Professional Shortage Area for Primary Care.

The population of Kings County was 2,736,074 in 2020 and is expected to grow to 2,810,876 by 2025. According to Data USA, in 2019, 93.7% of the population in Kings County had health coverage as follows:

| Employer Plans | 41.7% |
|-----------------|--------|
| Medicaid | 33.2% |
| Medicare | 8.05% |
| Non-Group Plans | 10.5% |
| Military or VA | 0.222% |

The applicant projects 20,354 visits in the first year and 33,300 in the third with Medicaid utilization at 45% and Charity Care at 2%. The applicant is committed to serving all persons in need without regard to the ability to pay or source of payment.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease. The table below provides information on the PQI rates for the overall PQI condition. It shows that the PQI rate for the primary service area (zip codes 11214, 11223, and 11224) is significantly higher than the New York State rate.

| Hospital Admissions per 100,000 Adults for Overall PQIs | | |
|--|-------|-------|
| PQI Rates: 2017 Zip Codes-11214, 11223, 11224 New York State | | |
| All PQI's | 1,533 | 1,431 |

Character and Competence

The proposed sole member of JAL 28, LLC is **John Liebermann**. John Liebermann is the Operations Manager of Omega Health Inc. where he plans, organizes, and manages activities for physicians, clinics, and other health programs, liaises with staff and board members to ensure consistent delivery of care, and stays abreast of changing laws and regulations and notifies staff. He also oversees areas of financial

planning including accounting budgets, reporting, and expenditures, and maintains operational records for internal and external audiences. He oversees the recruitment, hiring, scheduling, and training of staff. He develops and implements strategies for quality assessment of treatment services and general operations. Previously, he was the CEO of SafeGuard Staffing and the Operations Manager of Williamsburg Pediatrics

Leonid Isakov, MD is the proposed Medical Director. He is an owner of Ocean Medical PC. Previously, he was a part-time Staff Physician at Staten Island University Hospital, a part-time Physician at Pediatric Private Offices in different locations in Brooklyn and Queens, and a Pediatric Hospitalist at St. Luke's Roosevelt. He received his medical degree from Central Asia Medical Pediatric Institute in Russia. He completed his residency in Pediatrics at Maimonides Medical Center. He is board certified in Pediatrics.

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

Approval of this project will allow for continued access to a variety of medical services for the residents of Coney Island and the surrounding communities in Kings County. Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Analysis

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for the first and third years as follows:

| | <u>Year One</u> | | <u>Year Three</u> | |
|-----------------|-----------------|------------------|-------------------|----------------|
| | Per Visit | <u>Total</u> | Per Visit | <u>Total</u> |
| <u>Revenues</u> | | | | |
| Commercial FFS | \$140.00 | \$712,320 | \$142.80 | \$1,188,810 |
| Medicare FFS | \$175.00 | \$106,925 | \$178.50 | \$178,322 |
| Medicare MC | \$140.00 | \$569,800 | \$142.80 | \$951,048 |
| Medicaid FFS | \$149.83 | \$609,808 | \$149.93 | \$997,868 |
| Medicaid MC | \$117.86 | \$599,672 | \$120.22 | \$1,000,808 |
| Private Pay | \$200.00 | \$203,600 | \$204.00 | \$339,660 |
| Less Bad Debt | | (\$137,843) | | (\$228,994) |
| Total Revenues | | \$2,664,282 | | \$4,427,522 |
| | | | | |
| <u>Expenses</u> | _ | _ | _ | _ |
| Operating | \$78.64 | \$1,600,569 | \$74.75 | \$2,489,249 |
| Capital | <u>\$19.14</u> | <u>389,594</u> | <u>\$11.87</u> | <u>395,373</u> |
| Total Expenses | \$97.78 | 1,990,163 | \$86.63 | \$2,884,622 |
| | | | | |
| Net Income | | <u>\$674,119</u> | | \$1,542,900 |
| | | | | |
| Utilization: | | 20,354 | | 33,300 |

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

- This entity is currently in bankruptcy and revenue and expense assumptions are based on the historical experience of the current operator.
- Their current Medicare and Medicaid Managed Care contracts are providing reimbursement at a level below their actual costs. They are in the process of renegotiating these rates to provide for higher reimbursement. Due to ongoing bankruptcy proceedings, they have incurred additional expenses not typically associated with daily operations.
- The Center relocated operations at the end of 2021, and as a result, they incurred significant onetime costs related to the move.

Utilization broken down by payor source for the first and third year are as follows:

| <u>Payor</u> | Year One | Year Three |
|----------------|--------------|--------------|
| Commercial FFS | 25.00% | 25.00% |
| Medicare FFS | 3.00% | 3.00% |
| Medicare MC | 20.00% | 20.00% |
| Medicaid FFS | 20.00% | 20.00% |
| Medicaid MC | 25.00% | 25.00% |
| Private Pay | 5.00% | 5.00% |
| Charity Care | <u>2.00%</u> | <u>2.00%</u> |
| Total | 100.00% | 100.00% |

Amended and Restated Asset Purchase Agreement (APA)

The applicant has submitted an executed Amended and Restated Asset Purchase Agreement. The Amended APA has been assigned to JAL 28, LLC, the applicant, through an assignment agreement.

| Date | November 1, 2021 |
|------------------------------|--|
| Purpose | The sale of the D&TC licensed under Article 28 of the New York State Public Health |
| | Law located at 1704-06 Mermaid Avenue, Brooklyn, New York. |
| Seller | A Merryland Operating LLC |
| Purchaser | BNBN Management, LLC, or its designee, with an address at 4403 15 th Avenue Brooklyn, New York 11224. |
| Purchase Price | \$1,600,000 |
| Payment of Purchase Price | \$50,000 of the purchase price was previously paid by the Purchaser of the Seller upon the execution of a letter of intent for this transaction, \$110,000 shall be placed in escrow and \$1,440,000 will be paid at closing. |
| Assets Acquired | Furniture and equipment, supplies, goodwill the debtor's domain name, together with all other domain names owned by Debtor, telephone numbers and fax numbers of the Seller, custody of the patient records of the Seller for those patients treated by the Seller, all books and records relating to the operation of the business prior to the Closing, all of debtor's cash and accounts receivable due to Debtor resulting from the conduct of the Business prior to the Closing Date and security deposits pertaining to any assigned leases. |
| Excluded Assets | Employee Benefit Plans and all causes of action, including, bankruptcy avoidance claims, together with insurance refunds and tax refunds. |
| Assumed Liabilities | None |

The applicant has submitted an affidavit, acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement, or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor, of its liability and responsibility.

Lease Rental Agreement

The applicant has provided an executed lease assignment for the site they will occupy.

| Date | October 1, 2020 |
|------------|---|
| Premises | The premises located at 2873 West 17th Street, |
| | Brooklyn, New York. |
| Lessor | 1256 Ocean Avenue, LLC |
| Lessee | A Merryland Operating LLC |
| Term | 10 years |
| Rental | Year One through Year Two: \$126,000 annually |
| | Year Three: \$131,040 annually |
| | Year Four: \$136,281 annually |
| | Year Five: \$147,402 annually |
| | Year Six: \$153,298 annually |
| | Year Seven: \$159,470 annually |
| | Year Eight: \$153,807 annually |
| | Year Nine: \$172,439 annually |
| | Year Ten: \$179,337 annually |
| Provisions | The tenant shall be responsible for real estate |
| | taxes, utilities, and maintenance. |

Sub-Lease Assignment and Assumption

The applicant has submitted a draft Assignment and Assumption of the standing lease agreement, as detailed below:

| Date | Effective November 18, 2022 |
|------------|--|
| Premises | The premises located at 2873 West 17th Street, |
| | Brooklyn, New York. |
| Assignor | BNBN Management, LLC |
| Assignee | JAL 28, LLC |
| Term | 10 years |
| Rental | Year One through Year Two: \$126,000 annually Year Three: \$131,040 annually Year Four: \$136,281 annually Year Five: \$147,402 annually Year Six: \$153,298 annually Year Seven: \$159,470 annually Year Eight: \$153,807 annually Year Nine: \$172,439 annually Year Ten: \$179,337 annually |
| Provisions | The tenant shall be responsible for real estate taxes, utilities, and maintenance. |

Capability and Feasibility

There are no project costs associated with this application. The purchase price for the facility is \$1,600,000 to be met with equity by the proposed member. Working capital requirements are estimated at \$480,770, which is equivalent to two months of third-year expenses. The proposed member will provide equity to meet the working capital requirement. BFA Attachment A indicates that the proposed member has sufficient funds to meet the purchase price and the working capital requirement. BFA Attachment C, the pro forma balance sheet of the applicant, indicates a positive net asset position of \$3,175,347 on the first day of operations.

The submitted budget indicates a net income of \$674,119 and \$1,542,900 during the first and third years, respectively. Revenues are based on current reimbursement methodologies for primary care services. The submitted budget appears reasonable.

BFA Attachment B is the 2021 certified financial statements of A Merryland Operating, LLC. As shown, the entity had a negative working capital position, net asset position, and incurred a loss of (\$31,481) in 2021. The applicant has indicated the reason for losses stems from the current Medicare and Medicaid managed care contracts, which are currently at a reimbursement rate below actual costs. The current operator has been unable to attract a sufficient number of patients, and due to minimal marketing efforts, the operations relocated at the end of 2021. As a result, there were high one-time costs that the center incurred as a result.

Conclusion

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

Attachments

| BFA Attachment A | Net Worth Statement of proposed member |
|------------------|---|
| BFA Attachment B | 2021 certified financial statement of A Merryland Operating |
| BFA Attachment C | Pro Forma Balance Sheet |

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 8th day of December 2022, 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 JAL 28 LLC as the new operator of A Merryland Health Center, a diagnostic and treatment center at 2873 West 17th Street, Brooklyn, currently operated by A Merryland Operating LLC, and certify Medical Services - Other Medical Specialties, 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.

<u>NUMBER</u>: <u>FACILITY/APPLICANT</u>:

221265 B JAL 28 LLC d/b/a A Merryland Health Center

APPROVAL CONTINGENT UPON:

- 1. Submission of an executed lease assignment that is acceptable to the Department of Health. [BFA]
- 2. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

- 1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
- 2. 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]
- 3. 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/facilites/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 [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*.



of Health

Department Public Health and Health Planning Council

Project # 192204-E Highland Nursing Home, Inc. d/b/a North Country Nursing & Rehabilitation Center

Program: **Residential Health Care Facility**

Establishment Purpose:

St. Lawrence County: Acknowledged: October 24, 2019

Executive Summary

Description

Highland Nursing Home, Inc., the current operator of a 140-bed, proprietary, Article 28 residential health care facility (RHCF) located at 182 Highland Road, Massena (Saint Lawrence County), requests approval to transfer 100% ownership of its capital stock (200 shares) to ten new shareholders (collectively the "Buyers"). Lea Sherman, Jeffrey Goldstein, and Alexander Sherman are the current shareholders of the RHCF (collectively the "Sellers"). 182 Highland Road, LLC, a separate entity, owns the facility's real property.

On November 30, 2018, Lea Sherman, Jeffrey Goldstein, and Alexander Sherman entered into a Stock Purchase Agreement (SPA) (the Agreement) to sell all issued and outstanding capital stock in the Corporation to David Landa and Menajem (Mark) Salamon or their designees. There were two subsequent amendments to the SPA resulting in the following proposed ownership:

| Proposed Operator | | | |
|-------------------|---------------|----------|--|
| Highland Nurs | ing Home, | Inc. | |
| Shareholders: | Shares | <u>%</u> | |
| Menajem Salamon | 60 | 30.0% | |
| Mordejai Salamon | 34 | 17.0% | |
| Joshua Landa | 22 | 11.0% | |
| Joseph Landa | 22 | 11.0% | |
| David Landa | 21 | 10.5% | |
| Suri Reich | 10 | 5.0% | |
| Yossi Mayer | 10 | 5.0% | |
| Blimie Perlstein | 10 | 5.0% | |
| Hellen Majerovic | 9 | 4.5% | |
| Tirtza Salamon | 2 | 1.0% | |

The purchase price for the shares is \$1,863,461, which represents the balance due on a \$2,050,000 Promissory Note (10-year term at 3% interest) made between 182 Highland Road, LLC (as Lender) to the current shareholders (Lea Sherman, Jeffrey Goldstein, and Alexander Sherman as Borrowers) to enable their purchase of the shares in Highland Nursing Home, Inc. in 2016. The proposed new shareholders will assume repayment of the Promissory Note to 182 Highland Road, LLC.

Highland Nursing Home, Inc. leases the premises from 182 Highland Road, LLC for 30 years. There is a relationship between the proposed new shareholders of Highland Nursing Home, Inc. and the members of 182 Highland Road, LLC in that ownership is overlapping but not identical.

OPCHSM/OALTC Recommendation Contingent Approval is recommended.

Need Summary

There will be no need review per Public Health Law §2801-a (4).

Program Summary

There will be no change in beds or services provided. The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

The purchase price of the stock is \$1,863,461 funded through the assumption of a 10-year Promissory Note at 3% interest. The \$1,863,461 Promissory note balance will be canceled upon the closing of the stock purchase agreement, per note seven in the 2021 certified financial statement of Highland Nursing Home, Inc. There are no project costs associated with this application.

| Budget | <u>Year One</u> 2023 | Year Three 2025 |
|------------|-------------------------|--------------------|
| Revenues | \$15,057,577 | \$15,432,907 |
| Expenses | 14,905,708 | <u>15,074,618</u> |
| Net Income | \$151,869 | \$358,289 |

Recommendations

Long Term Care Ombudsman Program
The LTCOP recommends Approval. (See LTCOP Attachment A)

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 photocopy of the Certificate of Assumed Name, acceptable to the Department. [CSL]
- 2. Submission of a photocopy of a list of the Board of Directors, acceptable to the Department. [CSL]
- 3. Submission of a photocopy of an executed Resolution of the Board of Directors, acceptable to the Department. [CSL]
- 4. Submission of a photocopy of executed Shareholder Stock Certificates, acceptable to the Department. [CSL]
- 5. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]

Approval conditional upon:

1. This project must be completed by **June 1**, **2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date December 8, 2022

Program Analysis

Facility Information

| | Existing | Proposed | |
|-------------------|----------------------------|-----------------------------------|--------|
| Facility Name | North Country Nursing and | North Country Nursing and | |
| | Rehabilitation Center | Rehabilitation Center | |
| Address | 182 Highland Road | Same | |
| | Massena, NY 13662 | | |
| RHCF Capacity | 140 | Same | |
| ADHCP Capacity | N/A | N/A | |
| Type of Operator | Business Corporation | Business Corporation | |
| Class of Operator | Proprietary | Proprietary | |
| Operator | Highland Nursing Home Inc. | Highland Nursing Home Inc. | |
| | | | |
| | | | 30.0% |
| | | , | 17.0% |
| | | Joshua Landa | 11.0% |
| | | Joseph Landa | 11.0% |
| | | David Landa | 10.5% |
| | | Suri Reich | 5.0% |
| | | Yossi Mayer | 5.0% |
| | | Blimie Perlstein | 5.0% |
| | | Helen Majerovic | 4.5% |
| | | Tirtza Salamon | 1.0% |
| | | | |
| | | *President and Chief Executive Of | fficer |
| | | ** Vice President | |

Character and Competence

Experience

Menajem (Mark) Salamon is a Licensed New York State, and New Jersey nursing home administrator. He lists concurrent employment at Gold Crest Care Center located in Bronx, NY as a Licensed Nursing Home Administrator since 2011, and the Chief Executive Officer of Highland Nursing Home Inc. (the subject facility) since May 2019. He holds a bachelor's degree with additional coursework. He discloses the following healthcare facility ownership interest:

| Advanced Center for Nursing and Rehabilitation (CT) | (2.5%) | 10/16 – present |
|---|---------|-----------------|
| West Haven Center for Nursing and Rehab (CT) | (41.5%) | 11/21—present |
| Southport Center for Nursing and Rehab (CT) | (41.5%) | 11/21—present |
| New Haven Center for Nursing and Rehab (CT) | (41.5%) | 11/21—present |
| Waterbury Center for Nursing and Rehab (CT) | (41.5%) | 11/21—present |
| Torrington Center for Nursing and Rehab (CT) | (41.5%) | 11/21—present |

Mordejai Salamon lists employment as Director of Business Development at Gold Crest Care Center since 2014. His responsibilities include marketing, implementation of new strategic initiatives, and optimizing occupancy. He indicates no previous employment. He holds a bachelor's degree. He discloses the following healthcare facility ownership interest:

| Advanced Center for Nursing and Rehabilitation (CT) | (10%) | 10/16 - present |
|---|-------|-----------------|
| West Haven Center for Nursing and Rehab (CT) | (7%) | 11/21—present |
| Southport Center for Nursing and Rehab (CT) | (7%) | 11/21—present |
| New Haven Center for Nursing and Rehab (CT) | (7%) | 11/21—present |
| Waterbury Center for Nursing and Rehab (CT) | (7%) | 11/21—present |
| Torrington Center for Nursing and Rehab (CT) | (7%) | 11/21—present |

Joshua Landa is currently a student at Yeshiva Tiferes Yisrael in Brooklyn, NY. He discloses the following healthcare facility interest:

| Advanced Center for Nursing and Rehabilitation (C | CT) (15%) | 10/16 – present |
|--|------------|--------------------|
| Torrington Center For Nursing and Rehabilitation (| CT) (36.5° | %) 11/21 – present |

Joseph Landa is currently a financial supervisor at Hollis Park Nursing Home. He has held this position since February 2021, prior to this he was a student. He holds a bachelor's degree/. He discloses the following healthcare facility interests:

| Advanced Center for Nursing and Rehabilitation (CT) | (15%) | 10/16 – present |
|--|---------|-----------------|
| Waterbury Center For Nursing And Rehabilitation (CT) | (36.5%) | 11/21 – present |

David Landa lists employment as an owner of = Dividends and Nursing Homes. He holds a high school diploma. He discloses the following health care facility ownership interests:

| Windsor Park Nursing Home | (22.5%) | 6/86 - present |
|---|----------|-----------------|
| Sunrise Manor | (28.5%) | 2/93 – present |
| Gold Crest Care Center | (40%) | 2/96 – present |
| Fieldston Lodge Care Center | (26%) | 9/03 – present |
| Affinity Skilled Living & Rehabilitation Center | (15.66%) | 12/05 – present |

Suri Reich discloses employment at Wellsville Manor Care Center Social Services Department remotely since 2016 from her home in Brooklyn, NY. Previously her employment was Beth Jacob of Boro Park as a teacher between 2007 and 2016. Ms. Reich has a high school diploma and discloses the following ownership interests:

| Oak Hill Rehab and Nursing | (10%) | 2/19 – present |
|------------------------------|-------|----------------|
| River View Rehab and Nursing | (10%) | 2/19 – present |

Yossi Mayer discloses employment at Fieldstone Lodge Skilled Nursing Facility located in Bronx, NY in the Maintenance Department since 2017. He has a bachelor's degree. Mr. Mayer discloses the following ownership interests:

| Oak Hill Rehab and Nursing | (10%) | 2/19 - present |
|--|---------|-----------------|
| River View Rehab and Nursing | (10%) | 2/19 – present |
| West Haven Center for Nursing and Rehab (CT) | (1.25%) | 11/21 – present |
| Southport Center for Nursing and Rehab (CT) | (1.25%) | 11/21 – present |
| Waterbury Center for Nursing and Rehab (CT) | (1.25%) | 11/21 – present |
| Torrington Center for Nursing and Rehab (CT) | (1.25%) | 11/21 – present |

Blimie Perlstein discloses that she is the owner of P&G brokerage, Inc. since 1994. P&G is an insurance brokerage located in Brooklyn, NY. Ms. Perlstein has a high school diploma and discloses no ownership interest in any healthcare facilities.

Helen Majerovic discloses employment at Flawless Dental as a receptionist. She has a high school diploma. Ms. Majerovic discloses the following ownership interests:

| Oak Hill Rehab and Nursing | (5%) | 2/19 – present |
|------------------------------|------|----------------|
| River View Rehab and Nursing | (10% | 2/19 – present |

Tirtza Salamon discloses no employment history for the past ten years. Ms. Salamon discloses no ownership interest in any healthcare facilities.

Quality Review

| | | CMS Star Rating Criteria - 10 NYRRC 600.2(b)(5)(iv) | | | | | |
|------------------|----------------|---|----------------|----------------|-------------------|--|--|
| | | Duration of Ownership | | | | | |
| | | < 48 | 8 Months | 48 mor | 48 months or more | | |
| | | | Percent of | | Percent of | | |
| | <u>Total</u> | Number of | Nursing Homes | Number of | Nursing Homes | | |
| | <u>Nursing</u> | <u>Nursing</u> | With a Below | <u>Nursing</u> | With a Below | | |
| Proposed Owner | <u>Homes</u> | <u>Homes</u> | Average Rating | <u>Homes</u> | Average Rating | | |
| Joseph Landa | 2 | 1 | 100% | 1 | 100% | | |
| Joshua Landa | 1 | 0 | n/a | 1 | 100% | | |
| David Landa | 5 | 0 | n/a | 5 | 40% | | |
| Suri Reich | 1 | 1 | 100% | 0 | n/a | | |
| Yossi Mayer | 6 | 6 | 83.33% | 0 | n/a | | |
| Helen Majerovic | 2 | 2 | 50% | 0 | n/a | | |
| Blimie Perlstein | 0 | n/a | n/a | n/a | n/a | | |
| Mordejai Salamon | 5 | 4 | 100% | 1 | 100% | | |
| Menajem Salamon | 6 | 5 | 100% | 1 | 100% | | |
| Tirtza Salamon | 0 | n/a | n/a | n/a | n/a | | |

Duration of Ownership as of 12/08/2022

Data Date: 09/2022

New York: Four of the applicants own seven New York facilities. Oak Hill Rehab and Nursing and Fieldston Lodge Care Center are 1-star overall rated facilities. Affinity Skilled Living is a 2-star overall rated facility. Regarding Oak Hill Rehab and Nursing, one of the three health inspection surveys which were used to calculate the health inspection rating occurred while the proposed owners had operational control. The 1-star staffing rating is wholly attributable to the proposed owners. Regarding Fieldston Lodge Care Center and Affinity Skilled Living and Rehabilitation Center, the applicant states:

This facility's Overall rating was impacted by the staffing rating, which decreased from two (2) stars to one (1) star as a result of a change in the CMS staffing calculation, which provides for a higher value being attributed to Registered Nurses versus Licensed Practical Nurses. Since the COVID-19 pandemic began, the facility has had difficulties with hiring and retaining qualified Registered Nurses and has instead hired multiple Licensed Practical Nurses in order to provide the best-possible nursing coverage in a difficult labor market...

As for the subject facility, Menajem (Mark) Salamon, a member of the proposed ownership group, entered into an employment agreement on May 31, 2019, with Highland Nursing Center, Inc. The May 2019 CMS Star Ratings indicate the facility had a 2-star overall, 1-star health inspection, 3-star quality, and 4-star staffing ratings at the time Mr. Salamon initiated his affiliation. The October 2022 Ratings indicate the overall, health inspection, quality measure, and staffing ratings are all now 1 star. Per the applicant:

Mr. Salamon has extensive experience with operating skilled nursing facilities, and it is expected that his experience will result in improved Star Ratings at the facility going forward.

Connecticut: Four of the applicants own six Connecticut facilities, all of which are rated below average. Advanced Center for Nursing and Rehabilitation is a 2-star overall rated facility. As per the applicant: The operator is working with clinical and operational leaders to achieve higher quality standards, which should improve this facility's Overall Star Rating to three..." The facility also has a below-average, 1-star staffing rating. Regarding the other facilities, the applicants state "The proposed new shareholders became affiliated with this facility in November 2021 and are in the process of making operational improvements...

CMS Star Ratings

| CMS Star Ratings Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|-----------------------------|--------------------|---------|----------------------|--------------------|----------|
| New York | | | | | |
| Highland Nursing Center | Subject Facility | * | * | * | * |
| Gold Crest Care Center | Current | **** | **** | **** | ** |
| Gold Crest Care Center | 02/1996** | * | * | **** | * |
| Windsor Park Nursing | Current | **** | **** | *** | *** |
| Home | 06/1986** | *** | **** | ** | * |
| River View Rehabilitation | Current | *** | *** | **** | * |
| and Nursing Center | 01/2019 | * | * | ** | *** |
| | Current | *** | **** | **** | * |
| Sunrise Manor | 02/1993** | *** | *** | * | **** |
| | Current | ** | ** | **** | * |
| Affinity Skilled Living | 12/2005** | * | * | *** | * |
| | Current | * | ** | ** | * |
| Oak Hill Rehab and Nursing | 01/2019 | * | ** | *** | * |
| | Current | * | * | **** | ** |
| Fieldston Lodge Care Center | 09/2003** | ** | * | *** | **** |
| Connecticut | <u> </u> | | • | | |
| Advanced Center for | Current | ** | *** | **** | * |
| Nursing and Rehabilitation | 10/2016 | * | * | *** | *** |
| West Haven Center For | Current | ** | ** | **** | * |
| Nursing & Rehabilitation | 11/2021 | *** | ** | **** | *** |
| Waterbury Center For | Current | ** | * | **** | * |
| Nursing And Rehab | 11/2021 | ** | * | *** | **** |
| Donologro At Novelleys | Current | * | * | *** | * |
| Regalcare At New Haven † | 11/2021 | * | * | ** | *** |
| Torrington Center for | Current | * | * | *** | * |
| Nursing & Rehabilitation | 11/2021 | * | * | **** | *** |

| Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|--------------------------|--------------------|---------|----------------------|--------------------|----------|
| Southport Center For | Current | * | * | ** | ** |
| Nursing & Rehabilitation | 11/2021 | * | * | ** | ** |

[†] Special Focus Facility Candidate

**Earliest data as of 12/2009

Data date: 09/2022

Enforcement History

River View Rehabilitation and Nursing Care Center:

A federal CMP in the amount of \$3,250 was assessed on 10/23/2020

Oak Hill Rehab and Nursing:

- A federal CMP in the amount of \$655 was assessed on 12/7/2020
- A federal CMP in the amount of \$975 was assessed on 12/14/2020
- A federal CMP in the amount of \$1,310 was assessed on 11/15/2021
- A federal CMP in the amount of \$1,965 was assessed on 11/22/2021

Fieldston Lodge Care Center:

A federal CMP in the amount of \$5,000 was assessed on 3/2/2022

Advanced Center for Nursing and Rehabilitation (CT):

- A federal CMP in the amount of \$9,750 was assessed for 10/31/18 surveillance findings
- A federal CMP in the amount of \$4,274 was assessed for 8/23/17 surveillance findings
- Federal CMPs in the amounts of \$54,645 and \$17,209 were assessed for 1/19/2017 surveillance findings.

Torrington Center for Nursing and Rehabilitation (CT):

A federal CMP in the amount of \$650 was issued on 1/3/2022

Program Review

No changes in the program or physical environment are proposed in this application. The applicant states that it does plan to utilize staffing agencies and may utilize Five Star Staffing Inc. or any other suitable staffing provider for its staffing needs in the future. The applicant indicates that the facility does currently utilize P&G Insurance Brokers and the applicant plans to continue utilizing the services of P&G Insurance brokers in the future.

Conclusion

The individual background review indicates the applicants have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

The applicant has provided the current year (2021) operations and an operating budget, in 2023 dollars, for the first and third years of operations after the change in ownership. The budget is summarized below:

| | Current Year 2021 | | | <u>ir One</u> 023 | <u>Year Three</u> 2025 | |
|-----------------|----------------------|----------------------|----------------|----------------------|---------------------------|------------------|
| | Per Diem | Total | Per Diem | <u>Total</u> | Per Diem | <u>Total</u> |
| Revenues | | | | | | |
| Medicaid-FFS | \$203.33 | \$4,925,361 | \$203.32 | \$5,861,180 | \$203.33 | \$6,007,709 |
| Medicaid-MC | \$177.04 | 343,465 | \$177.04 | 343,465 | \$177.00 | 352,052 |
| Medicare-FFS | \$584.71 | 6,172,741 | \$584.70 | 7,345,561 | \$584.70 | 7,529,200 |
| Medicare-MC | \$584.71 | 349,069 | \$585.06 | 415,393 | \$584.86 | 425,777 |
| Private Pay | \$300.97 | 880,337 | \$300.95 | 1,047,601 | \$300.95 | 1,073,792 |
| All Other* | | <u>44,377</u> | | <u>44,377</u> | | <u>44,377</u> |
| Total Revenue | | \$12,715,350 | | \$15,057,577 | | \$15,432,907 |
| | | | | | | |
| <u>Expenses</u> | | | | | | |
| Operating | \$162.81 | \$6,552,025 | \$224.33 | \$10,660,342 | \$222.33 | \$10,829,252 |
| Capital | <u>\$211.02</u> | <u>8,492,144</u> | <u>\$89.34</u> | <u>4,245,366</u> | <u>\$87.16</u> | <u>4,245,366</u> |
| Total Expense | \$373.83 | \$15,044,169 | \$313.67 | \$14,905,708 | \$309.49 | \$15,074,618 |
| | | | | | | |
| Oper Income | | <u>(\$2,328,819)</u> | | <u>\$151,869</u> | | <u>\$358,289</u> |
| | | | | | | |
| Patient Days | | 40,243 | | 47,521 | | 48,709 |
| Utilization (%) | | 78.75% | | 93.00% | | 95.32% |

^{*} Includes Investment income and vending machine revenues

Notes concerning the submitted RHCF operating budget follow:

- The operating loss of (\$2,328,819) is before considering \$2,518,368 from the Medicare Relief Grant of \$1,180,732 and Employee Retention Credit of \$1,337,636, which brings Net Income to \$189,549.
- The current year reflects the facility's 2021 revenues and expenses.
- Medicaid revenue is based on the facility's current 2021 Medicaid Regional Pricing rate. The per diems for Medicaid Manage Care is the daily rate experienced by the facility during 2021.
- The current year Medicare rate is the actual daily rate experienced by the facility during 2021. The forecasted year one and year three Medicare rate is based on the average daily rate experienced during 2021. The forecasted Private Pay rate is based on the average daily rate experienced during 2021.
- Projected expenses are based on the current operator's 2021 costs, adjusted to include inflation and increased volume. The incremental cost consists primarily of increased labor costs related to hiring additional clinical, aides/orderlies, housekeeping, and food service staff (53.30 FTEs in year one) to accommodate the increased patient volume.
 - The projected percentage of direct care staffing costs to projected facility revenues is 40.39% in year one and year three, exceeding the 40% requirement in Public Health Law 2808.
 - The percentage of direct resident care costs to projected facility revenue is 70.75% in year one and 71.70% in year three, exceeding the 70% requirement in Public Health Law 2808.
 - The facility's projected profit percentage is forecasted to be 1.01% in year one and 2.32% in year three, less than the 5% maximum outlined in Public Health Law 2808.
- The facility's projected utilization is 93% in year one and 95.32% in year three. Occupancy at 97.9% as of August 17, 2022, exceeds these projections and is a significant recovery from the pandemic impact when the utilization in the last three years averaged 63.9% and was 78.75% at year-end 2021. The breakeven utilization is projected at 92.33% for the first year.

- Current year staffing is based on 2021 staffing levels and a 78.75% occupancy rate. Staffing in years
 one and three are based on a planned increase in utilization. The facility currently has 96 FTEs.
 Additional staffing will be sourced from multiple area nursing staffing agencies.
- Projected utilization by payor source for the first and third year after the change in ownership is:

| | Current Year | | Year One | | <u>Year Three</u> | |
|---------------|--------------|--------------|--------------|--------------|-------------------|--------------|
| | <u>20</u> | <u> </u> | <u>2023</u> | | <u>2025</u> | |
| <u>Payor</u> | <u>Days</u> | <u>%</u> | <u>Days</u> | <u>%</u> | <u>Days</u> | <u>%</u> |
| Medicaid -FFS | 24,224 | 60.19% | 28,827 | 60.66% | 29,547 | 60.66% |
| Medicaid-MC | 1,940 | 4.82% | 1,940 | 4.08% | 1,989 | 4.08% |
| Medicare-FFS | 10,557 | 26.23% | 12,563 | 26.44% | 12,877 | 26.44% |
| Medicare-MC | 597 | 1.48% | 710 | 1.49% | 728 | 1.49% |
| Private Pay | <u>2,925</u> | <u>7.27%</u> | <u>3,481</u> | <u>7.33%</u> | <u>3,568</u> | <u>7.33%</u> |
| Total | 40,243 | 100.% | 47,521 | 100.% | 48,709 | 100% |
| | | | | | | |

Stock Purchase Agreement (SPA)

The applicant submitted an executed SPA to acquire the operating entity's corporate stock. The terms are summarized below:

| Date: | November 30, 2018 |
|-----------------|---|
| Operator: | Highland Nursing Home, Inc. |
| Seller: | Lea Sherman, Jeffrey Goldstein, Alexander Sherman |
| Buyers: | David Landa, Menajem (Mark) Salamon, or their designees |
| Asset Acquired: | 100% of the issued and outstanding corporate stock in Highland Nursing Home, Inc. |
| Purchase Price: | \$2,050,000 |
| Payment of | \$300,000 * paid upon execution, held in escrow; |
| Purchase Price: | \$1,750,000 balance due at closing |

^{*}This amount was held in escrow, and all interest accrued thereon was refunded to the Buyers at the Real Estate closing (May 31, 2019).

First Amendment to Stock Purchase Agreement:

The applicant submitted an executed First Amendment to assign David Landa and Menajem Salamon's rights under the original Agreement to ten new shareholders. The terms are summarized below:

| Date: | July 10, 2019 |
|----------------------------|---|
| Sellers: | Lea Sherman, Jeffrey Goldstein, Alexander Sherman |
| Original Buyers: | David Landa and Menajem Salamon and their designees |
| New Buyers: | Joseph Landa, (13.75%, 27.5 shares); Joshua Landa, (13.75%, 27.5 shares); Menashe Eisen, (5%, 10 shares); Suri Reich, (5%, 10 shares); Yossi Mayer, (5%, 10 shares); Hellen Majerovic, (4.50%, 9 shares); Blimie Perlstein, (5%, 10 shares); Mordejai Salamon, (17%, 34 shares); Menajem Salamon, (30%, 60 shares); Tirtza Salamon, (1%, 2 shares). |
| Provision: | Acquisition of stocks in Highland Nursing Home, Inc. The Original Buyers assign, transfer, and release their right, title, and interest as Buyers under the Stock Purchase Agreement dated November 30, 2018, to New Buyers. |
| Price: | \$1,863,461 (balance due on a \$2,050,000 Promissory Note between Lea Sherman, Jeffrey Goldstein, and Alexander Sherman as borrowers and 182 Highland Road, LLC as Lender) |
| Payment of Purchase Price: | \$1,863,461 via assumption of a 10-year Promissory Note at 3% interest between the current shareholders (Sellers, Borrowers) and 182 Highland Road, LLC (Lender) |

Second Amendment to Stock Purchase Agreement:

The applicant submitted an executed Second Amendment whereby Menashe Eisen withdraws as Buyer. David Landa will replace Menashe Eisen as one of the ten proposed shareholders of Highland Nursing Home, Inc. The terms are summarized below:

| Date: | July 1, 2022 |
|------------------|--|
| Sellers: | Lea Sherman, Jeffrey Goldstein, Alexander Sherman |
| Original Buyers: | David Landa and Menajem Salamon and their designees |
| New Buyers: | Joseph Landa, (11%, 22 shares); Joshua Landa, (11%, 22 shares); David Landa, (10.5%, 21 shares); Suri Reich, (5%, 10 shares); Yossi Mayer, (5%, 10 shares); Hellen Majerovic, (4.50%, 9 shares); Blimie Perlstein, (5%, 10 shares); Mordejai Salamon, (17%, 34 shares); Menajem Salamon, (30%, 60 shares); Tirtza Salamon, (1%, 2 shares). |

The \$1,863,461 purchase price for the operations' corporate stock will be satisfied by the assumption of the balance due on a Promissory Note (original principal valued at \$2,050,000) between Lea Sherman, Jeffrey Goldstein, and Alexander Sherman (Borrowers) and 182 Highland Road LLC (Lender). Sellers' expenses of \$416,640 related to the original SPA and Real Estate Contract were refunded at the Real Estate closing. Per note seven in the 2021 certified financial statement, the \$1,863,461 note balance will be canceled upon the closing of the stock purchase agreement.

Original Real Estate Purchase Agreement:

The applicant submitted a copy of the original real property purchase agreement and original lease agreement, the terms of which were summarized below:

| Date: | June 23, 2016 |
|--------------------|---|
| Seller: | Highland Nursing Home, Inc. |
| Buyer: | Highland Realty Co, LLC (proposed initially, rights later assigned) |
| Asset Transferred: | Real property located at 182 Highland Road, Massena, NY 13662 |
| Purchase Price: | \$4,950,000 |
| Payment of | \$4,950,000 cash at closing |
| Purchase Price: | _ |

Original Lease Agreement and First Amendment

The applicant has submitted an executed original lease agreement, and first amendment, the terms of which were summarized below:

| Date: | August 10, 2016, and First Amended on December 4, 2018 |
|-----------------|--|
| Premises: | 140-bed RHCF located at 182 Highland Road, Massena, NY 13662 |
| Owner/Landlord: | Highland Realty Co., LLC (proposed initially, rights later assigned) |
| Lessee: | Highland Nursing Home, Inc. |
| Term: | 30 years (amended to start with the closing of the Real Property Contract and terminate 30 years later) |
| Rent: | \$360,000 plus annual debt repayment (principal + interest estimated at \$501,866 per year), totaling approx. \$861,866 per year (\$71,822 per month). |
| Provisions: | Triple Net |

On November 30, 2018, Highland Realty Co, LLC assigned its rights under the agreement for the sale of real property dated June 23, 2016, and the facility's lease agreement dated August 10, 2016, as amended December 4, 2018, to 182 Highland Road, LLC.

Assignment of Agreement for sale of Real Property and Lease

The applicant has submitted an executed agreement for the assignment of the sale of real property agreement and the facility's lease agreement:

| Date: | November 30, 2018 |
|-------------|---|
| Assignor: | Highland Realty Co, LLC |
| Assignee: | 182 Highland Road, LLC |
| Assignment: | Assignor assigns all its rights, title, and interest to and under the real property |
| | sale agreement and the lease. |

The applicant confirms that the closing for the real property occurred on May 31, 2019. 182 Highland Road LLC leases the facility to Highland Nursing Home, Inc. for a term of 30 years.

The purchase price of the real property was satisfied as follows:

| The parenage price of the real property was calculed as renewe. | |
|---|--------------------|
| Equity – 182 Highland Road LLC Members | \$742,500 |
| Loan (M&T Bank, assumed outstanding realty loan debt, five years at 4% one- | |
| month Libor or 5.74%, (as of December 18, 2019) and one 5-year extension at | |
| 5.50% plus one-month Libor, 25-year amortization) | <u>\$4,207,500</u> |
| Total | \$4,950,000 |

Second Amendment to Lease

The applicant has submitted an executed second amendment to the lease agreement, the terms of which are summarized below:

| Date: | March 26, 2018 |
|-------------|--|
| Lessor | 182 Highland Road, LLC |
| Lessee: | Highland Nursing Home, Inc. |
| Term: | 30 years |
| Rental: | \$360,000 plus annual debt repayment obligations (principal + interest estimated at \$501,866 per year), totaling approx. \$861,866 per year (\$71,822 per month). |
| Provisions: | Triple Net |

The lease arrangement is a non-arm's length agreement. The applicant has submitted an affidavit attesting to the relationship between the landlord and tenant.

Capability and Feasibility

The proposed new shareholders will acquire 100% of Highland Nursing Home, Inc.'s corporate stock for \$1,863,461, to be funded via a 10-year Promissory Note at a 3% interest rate (original principal of \$2,050,000) between the current shareholders (Borrowers) and 182 Highland Road, LLC (Lender). The \$1,863,461 Promissory note balance will be canceled upon the closing of the stock purchase agreement, per note seven in the 2021 certified financial statement of Highland Nursing Home, Inc. 182 Highland Road LLC is the current property owner and has leased the facility to Highland Nursing Home, Inc. for a term of 30 years. There is a relationship between the proposed shareholders of Highland Nursing Home, Inc. and the members of 182 Highland Road, LLC in that ownership is overlapping but not identical. There are no project costs associated with this application.

The working capital requirement is estimated at \$2,484,285, based on two months of Year One expenses. Funding will be provided from the entity's ongoing operations. BFA Attachment A is the net worth summaries for the proposed Buyers of Highland Nursing Home, Inc.'s corporate stock, and indicates they have sufficient resources to meet equity requirements. BFA Attachment C is Highland Nursing Home, Inc.'s pro forma balance sheet, which shows the entity will start with \$3,617,174 in equity. Equity includes \$1,359,817 in goodwill, which is not a liquid resource nor recognized for Medicaid reimbursement. If goodwill were eliminated, the total net assets would become \$2,257,357.

The submitted budget projects a net income of \$151,869 and \$358,289 in the first and third years. Operating revenues are estimated to increase by approximately \$2,342,227 from the Current Year to

Year One. This revenue increase is primarily from growing patient days and utilization to 93% in the first year. Overall expenses are projected to decrease by \$138,461 by the first year following the approval of this project. Reductions in rent of \$4,246,778 drive this decrease in overall expenses. However, decreases in capital expenses are offset by an increase in operating expenses of \$4,108,317. The budget appears reasonable.

BFA Attachment D is a Financial Summary of Highland Nursing Home, Inc. for 2019 through 2021. The RHCF had average positive working capital, average positive net assets, and average positive net income. BFA Attachment E is the Internal Financials as of May 31, 2022, which show positive working capital, net assets, and an operating profit of \$1,702,680.

BFA Attachment F is the proposed members' ownership interest in New York nursing homes. New York State-affiliated nursing homes on a combined basis had average positive working capital, average positive net assets, and average positive net income for the period from 2019 through 2021. In 2021 each affiliated nursing home maintains positive working capital, positive net assets, and positive net income.

Conclusion

Based on the preceding, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

| LTCOP Attachment | Long Term Care Ombudsman Program Recommendation |
|------------------|--|
| BFA Attachment A | Highland Nursing Home, Inc Proposed Stockholders' Net Worth |
| BFA Attachment B | Current Owners of the Real Property |
| BFA Attachment C | Pro Forma Balance Sheet |
| BFA Attachment D | 2019-2021 Financial Summary of Highland Nursing Home, Inc and 2021 |
| | certified financial statement. |
| BFA Attachment E | Internal Financials Highland Nursing Home, Inc. May 31, 2022. |
| BFA Attachment F | Proposed members' ownership interest in Affiliated RHCFs |

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 8th day of December 2022, 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 100 percent shareholder interest to ten new shareholders, 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.

<u>NUMBER</u>: <u>FACILITY/APPLICANT</u>:

192204 E Highland Nursing Home, Inc. d/b/a North

County Nursing & Rehabilitation Center

APPROVAL CONTINGENT UPON:

- 1. Submission of a photocopy of the Certificate of Assumed Name, acceptable to the Department. [CSL]
- 2. Submission of a photocopy of a list of the Board of Directors, acceptable to the Department. [CSL]
- 3. Submission of a photocopy of an executed Resolution of the Board of Directors, acceptable to the Department. [CSL]
- 4. Submission of a photocopy of executed Shareholder Stock Certificates, acceptable to the Department. [CSL]
- 5. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **June 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [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*.



Public Health and Health Planning Council

Project # 202034-E Ulster NH Operations LLC d/b/a Golden Hill Center for Rehabilitating and Nursing

Program: Residential Health Care Facility County: Ulster

Purpose: Establishment Acknowledged: August 18, 2020

Executive Summary

Description

Ulster NH Operation, LLC, an existing limited liability company, requests approval to be established as the new operator of Golden Hill Nursing and Rehabilitation Center, a 280-bed residential health care facility (RHCF) at 99 Golden Hill Drive, Kingston (Ulster County).

Golden Hill Planning Corporation, Inc. is the current operator of the facility. Pursuant to the Asset Purchase Agreement (APA) dated November 22, 2019, Ulster NH Operation, LLC agreed to purchase the RHCF from Golden Hill Planning Corporation, Inc for \$3,000,000 plus assumption of liabilities. Upon approval, the facility will be named Golden Hill Center for Rehabilitation and Nursing.

On November 22, 2019, Ulster NH Realty, LLC and Golden Hill Acquisition, LLC entered into a Contract of Sale for the real estate whereby Ulster NH Realty, LLC agreed to purchase the real estate associated with the facility. Upon approval of this application, Ulster NH Realty, LLC will lease the RHCF to Ulster NH Operation, LLC for a term of 40 years.

Ownership of the RHCF before and after the requested change is as follows:

| Current | | |
|--|--------|--|
| Golden Hill Planning Corporation, Inc. | | |
| Orly Lieberman | 9.54% | |
| Tibor Lebovich | 28.10% | |
| Alex Berger | 8.33% | |
| Edward Farbenblum | 44.13% | |
| Solomon Klein | 9.90% | |

| Proposed | | |
|----------------------------|--------|--|
| Ulster NH Operation, LLC | | |
| CW Kingston Operating, LLC | 48.50% | |
| Chava Wolofsky (100%) | | |
| KF Kingston Operating, LLC | 17.00% | |
| Solomon Klein (100%) | | |
| ES Kingston Operating, LLC | 17.00% | |
| Ernest Schlesinger (100%) | | |
| ED Kingston Operating, LLC | 9.50% | |
| Ezriel Drebin (100%) | | |
| SE Kingston Operating, LLC | 8.00% | |
| Shoshana Markovitz (100%) | | |

OPCHSM/OALTC Recommendation Contingent Approval

Need Summary

There will be no changes to beds or services as a result of this application. Occupancy as of July 27, 2022, was 86.1% for the facility and 82.8% for Ulster County.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

The purchase price for the operation is \$3,000,000 to be met via equity from the proposed members. The purchase price for the real estate is \$37,600,000 to be met via equity of \$3,008,000 from the proposed members of the realty entity and a loan of \$34,592,000 at an interest rate of 6% for a 30-year term.

The submitted budget indicates a projected net income of \$1,555,859 and \$1,683,131 in the first and third years of operations, respectively.

| | Year One | Year Three |
|------------|--------------|--------------|
| Revenues | \$33,759,867 | \$34,502,563 |
| Expenses | 32,204,008 | 32,819,432 |
| Net Income | \$1,555,859 | \$1,683,131 |

Recommendations

Long Term Care Ombudsman Program

The LTCOP recommends Approval. (See LTCOP Attachment A)

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 loan commitment for the real estate, that is acceptable to the Department of Health. [BFA]
- 2. Submission of an executed lease agreement, that is acceptable to the Department of Health. [BFA]
- 3. Submission of an executed asset purchase agreement that is acceptable to the Department of Health. [BFA]
- 4. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
- 5. Submission of a photocopy of the Certificate of Assumed Name, acceptable to the Department. [CSL]
- 6. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. [CSL]
- 8. Submission of a photocopy of the Application for Authority for CW Kingston Operations LLC, acceptable to the Department. [CSL]
- 9. Submission of a photocopy of an amended and executed Operating Agreement for CW Kingston Operations LLC, acceptable to the Department. [(CSL]
- 10. Submission of a photocopy of the Application for Authority for ED Kingston Operations LLC, acceptable to the Department. [CSL]
- 11. Submission of a photocopy of an amended and executed Operating Agreement for ED Kingston Operations LL, acceptable to the Department. [CSL]
- 12. Submission of a photocopy of an amended and executed Articles of Organization for KF Kingston Operations, LLC, acceptable to the Department. [CSL]
- 13. Submission of a photocopy of an amended and executed Operating Agreement for KF Kingston Operations, LLC, acceptable to the Department. [CSL]
- 14. Submission of a photocopy of an amended and executed Articles of Organization for ES Kingston Operations LLC, acceptable to the Department. [CSL]
- 15. Submission of a photocopy of an amended and executed Operating Agreement for ES Kingston Operations LLC, acceptable to the Department. [CSL]
- 16. Submission of a photocopy of an amended and executed Articles of Organization for SE Kingston Operations, LLC, acceptable to the Department. [CSL]
- 17. Submission of a photocopy of an amended and executed Operating Agreement for SE Kingston Operations, LLC, acceptable to the Department. [CSL]
- 18. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
- 19. Submission of a photocopy of an amended and executed Partial Assignment of Membership Interests, acceptable to the Department. [CSL]

<u>Approval conditional upon</u>:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [PMU]

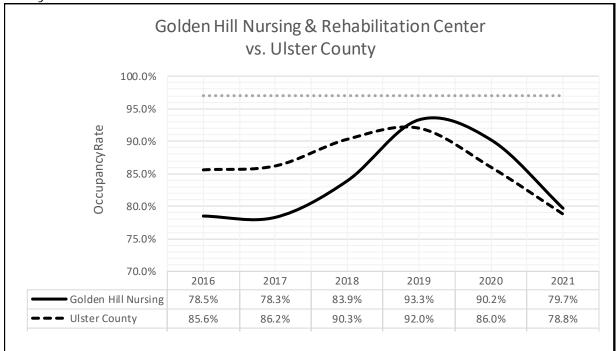
Council Action Date December 8, 2022

Need Analysis

Project Description

Ulster NH Operation LLC is requesting approval to become the established operator of Golden Hill Nursing & Rehabilitation Center, a 280-bed Article 28 residential health care facility (RHCF) located at 99 Golden Hill Drive, Kingston, 12401 in Ulster County.





Occupancy, as of September 21, 2022, was 88.9% for the facility and 85.5% for Ulster County.

Medicaid Access

To ensure that the Residential Health Care Facility needs of the Medicaid population are met, 10 NYCRR §670.3 requires applicants to accept and admit a reasonable percentage of Medicaid residents in their service area. The benchmark is 75% of the annual percentage of residential health care facility admissions that are Medicaid-eligible individuals in their planning area. This benchmark may be increased or decreased based on the following factors:

- the number of individuals within the planning area currently awaiting placement to a residential health care facility and the proportion of total individuals awaiting such placement that are Medicaid patients and/or alternate level of care patients in general hospitals;
- the proportion of the facility's total patient days that are Medicaid patient days and the length of time that the facility's patients who are admitted as private paying patients remain such before becoming Medicaid eligible;
- the proportion of the facility's admissions who are Medicare patients or patients whose services are paid for under provisions of the federal Veterans' Benefit Law;
- the facility's patient case mix based on the intensity of care required by the facility's patients or the extent to which the facility provides services to patients with unique or specialized needs;
- the financial impact on the facility due to an increase in Medicaid patient admissions.

An applicant will be required to make appropriate adjustments in its admission policies and practices to meet the resultant percentage. The facility's Medicaid admissions rate was above the threshold of 75% of the Ulster County rate.

| Medicaid Access | 2019 | 2020 | 2021 |
|------------------------|-------|-------|-------|
| Ulster County Total | 27.1% | 21.6% | 22.7% |
| Ulster Threshold Value | 20.3% | 16.2% | 17.0% |
| Golden Hill Nursing | 34.1% | 27.3% | 26.9% |

Conclusion

There will be no changes to beds or services as a result of this project. Based upon weekly census data, current occupancy, as of July 27, 2022, was 86.1% for the facility and 82.8% for Ulster County.

Program Analysis

Facility Information

| | Existing | Proposed |
|-------------------|--|---|
| Facility Name | Golden Hill Nursing and Rehabilitation | Golden Hill Center for Rehabilitating and |
| | Center | Nursing |
| Address | 99 Golden Hill Drive | Same |
| | Kingston, NY 12401 | |
| RHCF Capacity | 280 | Same |
| ADHCP Capacity | N/A | Same |
| Type of Operator | Business Corporation | Limited Liability Company |
| Class of Operator | Proprietary | Proprietary |
| Operator | Golden Hill Planning Corporation, Inc. | Ulster NH Operation, LLC |
| | Shareholders | <u>Members</u> |
| | Solomon Klein 9.90% | CW Kingston Operating, LLC 48.5% |
| | Orly Lieberman 9.54% | Chava Wolofsky (100%) |
| | Tibor Lebovich 28.10% | KF Kingston Operating, LLC 17.0% |
| | Alex Berger 8.33% | Solomon Klein* (100%) |
| | Edward Farbenblum 44.13% | ES Kingston Operating, LLC 17.0% Ernest Schlesinger (100%) |
| | | ED Kingston Operating, LLC 9.5% Ezriel Drebin (100%) |
| | | SE Kingston Operating, LLC 8.0% |
| | | Shoshana Markovitz (100%) |
| | | *Managing Member |

No changes in the program or physical environment are proposed in this application.

Character and Competence

Experience

Chava Wolofsky indicates no employment history for the last ten years. Chava Wolofsky has a diploma from Bais Yaakov Academy and discloses the following interests in health care facilities.

Out-of-State Nursing Homes

| Alaska Gardens Health and Rehabilitation (19.70%) [WA] | 01/2021 to present |
|--|--------------------|
| Hawthorne Center for Rehabilitation and Healing of Ocala (17.5%) [FL] | 08/2021 to present |
| Hawthorne Center for Rehabilitation and Healing of Brandon (17.5%) [FL] | 08/2021 to present |
| Hawthorne Center for Rehabilitation and Healing of Sarasota (17.5%) [FL] | 08/2021 to present |
| Forest Hill Center Health Care (19%) [NJ] | Pending |
| The Place at Pepper Hill 22.75% [SC] | Pending |
| Solaris Healthcare Lake Bennet (19%) [FL] | Pending |
| Solaris Healthcare Palatka (19%) [FL] | Pending |

| Out-of-State Independent Living Facilities Hawthorne Estates of Ocala (17.50%) [FL] Hawthorne Estates of Brandon (17.5%) [FL] | 04/2021 to present Pending |
|---|-------------------------------|
| Out-of-State Assisted Living Facilities | |
| Hawthorne Inn of Brandon (17.50%) [FL] | 08/2021 to present |
| Hawthorne Inn of Lakeland (17.50%) [FL] | 08/2021 to present |

Solomon Klein indicates current employment at Sightrite an eyecare business since February 2013. Solomon Klein has an associate degree from Touro College and discloses the following interests in health care facilities:

| Nursing Homes Ten Broeck Center for Rehabilitation & Nursing (10%) [NY] Clove Lakes Healthcare and Rehabilitation Center (9.9%) [NY] Golden Hill Nursing and Rehabilitation Center (9.9%) [NY] | 10/2018 to present 02/2020 to present 09/2020 to present |
|--|---|
| Out-of-State Nursing Homes TimberRidge Center for Rehab & Healing (28.5%) [FL] Century Health & Rehabilitation Center (25%) [FL] Northbrook Center for Rehabilitation and Healing (25%) [FL] Santa Rosa Center for Rehabilitation and Healing (25%) [FL] Ybor City Healthcare & Rehabilitation (25%) [FL] Sandy Ridge Health & Rehabilitation (25%) [FL] Hawthorne Center for Rehabilitation and Healing of Ocala (41%) [FL] Hawthorne Center for Rehabilitation and Healing of Brandon (44%) [FL] Hawthorne Center for Rehabilitation and Healing of Sarasota (44%) [FL] The Place at Pepper Hill (45%) [SC] Solaris Healthcare Lake Bennet (57%) [FL] Solaris Healthcare Palatka (57%) [FL] Forest Hill Center Rehabilitation and Healing (43%) [NJ] | 09/2019 to present 03/2020 to present 03/2021 to present 04/2021 to present 08/2021 to present 08/2021 to present Pending Pending Pending Pending Pending |
| End Dated Ownership Abbey Woods Centerfor Rehab & Healing (6%) [MO] | 04/2017 to 6/2019 |
| Out-of-State Independent Living Facilities Hawthorne Estates of Ocala (44%) [FL] Hawthorne Estates of Brandon (44%) [FL] | 07/2021 to present 07/2021 to present |
| Out-of-State Assisted Living Facilities Hawthorne Inn of Ocala (41%) [FL] Hawthorne Inn of Brandon (44%) [FL] Hawthorne Inn of Lakeland (44%) [FL] | 04/2021 to present 08/2021 to present 08/2021 to present |

Ernest Schlesinger discloses employment as the Chief Executive Officer of Sightrite, an eyecare business since January 2013. Ernest Schlesinger has a diploma from Yeshiva Taras Chesed and discloses the following health facility interests:

| Nursing Homes | |
|---|--------------------|
| Dumont Center for Rehabilitation and Nursing Care (2.5%) [NY] | 07/2010 to present |
| St James Rehabilitation & Healthcare Center (10%) [NY] | 08/2012 to present |
| Bellhaven Centerfor Rehabilitation & Nursing Care (5%) [NY] | 03/2010 to present |
| The Grand Pavilion at Rockville Centre (5%) [NY] | 08/2012 to present |
| Westhampton Care Center (17%) [NY] | 02/2018 to present |
| Ten Broeck Center for Rehabilitation & Nursing (13%) [NY] | 10/2018 to present |

Out-of-State Nursing Homes

| Big Bend Woods Healthcare Center (10%) [MO] | 01/2016 to present |
|---|--------------------|
| Washington Square Healthcare Center (6%) [OH] | 01/2014 to present |
| Greenery Centerfor Rehab and Nursing (15%) [PA] | 06/2016 to present |
| TimberRidge Center for Rehab & Healing (13%) [FL] | 09/2019 to present |

End Dated Ownership

Abbey Woods Centerfor Rehabilitation and Healing (50%) [MO] 04/2017 to 06/2019

Ezriel Drebin indicates self-employment in healthcare management and acquisitions. The applicant also indicates the position of Director of Operations at Infinite Care since September 2019. Ezriel Drebin has a diploma from Yeshiva Gedolah Toronto and discloses the following health facility ownership interests:

| Out-of-State Nursing Homes | |
|---|--------------------|
| Century Center Health & Rehabilitation Center (8%) [FL] | 03/2019 to Present |
| Northbrook Health & Rehabilitation (8%) [FL] | 03/2019 to Present |
| Santa Rosa Health & Rehabilitation Center (8%) [FL] | 03/2019 to Present |
| Ybor City Healthcare & Rehabilitation (8%) [FL] | 03/2019 to Present |
| Sandy Ridge Health & Rehabilitation (8%) [FL] | 03/2019 to Present |
| TimberRidge Center for Rehab & Healing (10%) [FL] | 09/2019 to Present |
| Hawthorne Center for Rehabilitation and Healing of Ocala 5% [FL] | 04/2021 to Present |
| Hawthorne Center for Rehabilitation and Healing of Brandon 2% [FL] | 07/2021 to Present |
| Hawthorne Center for Rehabilitation and Healing of Sarasota 2% [FL] | 07/2021 to Present |
| Forest Hill Center for Rehabilitation and Healing (3%) [NJ] | Pending |
| | |
| Out-of-State Independent Living Facilities | |
| Hawthorne Estates of Brandon 2% [FL] | 07/2021 to Present |
| Hawthorne Estates of Ocala 2% [FL] | Pending |
| Out of Otale Assistant Living Facilities | |

Out-of-State Assisted Living FacilitiesHawthorne Inn of Ocala 5% [FL]04/2021 to PresentHawthorne Inn of Brandon 2% [FL]07/2021 to PresentHawthorne Inn of Lakeland 2% [FL]07/2021 to Present

Shoshana Markovitz is licensed as a Registered Nurse License in New Jersey. The applicant discloses employment as Registered Nurse and VFC (Vaccine for Children) Coordinator at Dr. Neil Gittleman located in Lakewood, NJ since 2/2018. Shoshana Markovitz has an M.S.N in Pediatric Primary Care Nurse Practitioner from Seton Hall University School of Nursing and a master's in science and Nursing from John Hopkins University. Shoshana Markovitz discloses no health facility ownership interests.

Quality Review

The proposed owners have been evaluated, in part, on the distribution of CMS Star ratings for their portfolios. For all proposed owners the distribution of CMS star ratings for their facilities meet the standard described in state regulations.

| CMS Star Rating Criteria - 10 NYCRR 600.2(b)(5)(iv) | | | | | | |
|---|---------------------------|------|----------|-------------------------------|---|--|
| Duration of Ownership | | | | | | |
| | | < 48 | 3 Months | 48 mor | nths or more | |
| Proposed Owner | Total Nursing Homes | | | Number of Nursing Homes | Percent of Nursing Homes with a Below Average Rating | |
| Chava Wolofsky | 4 | 4 | 75% | 0 | n/a | |
| Ernest Schlesinger | 10 | 1 | 0 | 9 | 22% | |
| Ezriel Drebin | 9 | 9 | 44.44% | 0 | n/a | |
| Solomon Klein | 12 | 11 | 45.45% | 1 | 0 | |
| Shoshana Markovitz | 0 | n/a | n/a | n/a | n/a | |

Duration of Ownership as of 12/8/2022

The CMS Special Focus Facility (SFF) program includes nursing homes that have a history of serious quality issues or are included in a special program to stimulate improvements in their quality of care.

New York: The proposed owner's portfolio includes ownership in eight New York facilities. Seven of the New York facilities in the ownership portfolio have CMS overall quality ratings of average or higher. The remaining facility, Golden Hill Nursing and Rehabilitation Center, has a CMS overall quality rating of below average or lower. When asked to explain the low overall CMS ratings for Golden Hill Nursing and Rehabilitation Center the applicants indicated the following:

The two-star rating in the Overall category was due primarily to the fact that the facility's staffing rating went from two stars to one star. Since the COVID-19 pandemic began, the facility has experienced difficulties in hiring and retaining qualified Registered Nurses. As a result, the facility has hired Licensed Practical Nurses in order to provide the best possible nursing coverage to its residents despite these difficult circumstances in the labor market.

Florida: The proposed owner's portfolio includes ownership in nine Florida facilities. Five of the Florida facilities have CMS overall quality ratings of average or higher. The remaining four Florida facilities have CMS overall quality ratings of below average or lower. When asked to explain the low overall CMS ratings for the four facilities (Santa Rosa Center for Rehabilitation and Healing, Hawthorne Center for Rehabilitation and Healing of Brandon, Northbrook Center for Rehabilitation & Healing, and Hawthorne Center for Rehabilitation and Healing of Sarasota) the applicants indicated the following:

Prior to Ezriel Drebin and Solomon Klein becoming members of Santa Rosa Center for Rehabilitation and Healing in March of 2020, the facility received an Immediate Jeopardy (IJ) violation. This violation has since been remedied by the facility, but the violation is still impacting the facility's Overall Star Rating. It is expected that the facility's Overall Rating will improve within the near term, as this violation ages and has a lesser impact on scoring.

The low rating at Hawthorne Center for Rehabilitation and Healing of Brandon was a result of a survey conducted on February 17, 2022, the facility received a G-level violation, along with three (3) IJ violations: F600 (Free from Abuse and Neglect); F609 (Reporting of Alleged Violations); and F610 (Investigate / Prevent / Correct Alleged Violation). Although three (3) IJ violations were received, these violations all related to one (1) incident and one (1) resident. All three (3) of these IJ violations have since been removed and the facility's Plan of Correction has been approved. Due to the above citation for resident harm or potential harm for abuse or neglect at Hawthorne Center for Rehabilitation and Healing of Brandon, CMS has indicated on the facility profile an icon of a red circle with a hand in it on the Nursing Home Compare website. Hawthorne Center for Rehabilitation and Healing of Brandon is also designated by CMS as a Special Focus Facility Candidate, which is a program that includes nursing homes that have a history of serious quality issues or are included in a special program to stimulate improvements in their quality of care.

The applicant states that the reason for the low star rating (2 stars in the Overall category) at Northbrook Center for Rehabilitation & Healing was due to two (2) Immediate Jeopardy (IJ) deficiencies that were received by the facility on April 13, 2022. These deficiencies have since been corrected and the fines associated with these deficiencies have also been paid. As such, it is expected that the facility's Overall star rating will increase to three (3) stars within the near term.

The applicant states the reason for the low overall star rating at Hawthorne Center for Rehabilitation and Healing of Ocala is the facility's staffing rating was adjusted from two (2) stars down to one (1) star. This is a result of a recent Payroll Based Journal report submission that contained an error that resulted in CMS reducing the facility's staffing rating to one (1) star for a period of six months. The facility has corrected this error and expects the overall staffing rating to return to three (3) stars in the overall category.

Missouri: The proposed owner's portfolio includes ownership in one Missouri facility. When asked to explain the low overall CMS rating at Big Bend Woods, the applicant indicated:

The rules in Missouri regarding whether a member has control of a facility are different than those in New York State. As such, although Ernest Schlesinger is a 10% member of this facility, he indicates

that he does not exercise control over the day-to-day operations of the facility. This facility is designated by CMA as a Special Focus Facility Candidate, which is a program that includes nursing homes that have a history of serious quality issues or are included in a special program to stimulate improvements in their quality of care.

Ohio: The proposed owner's portfolio includes ownership in one Ohio facility. The Ohio facility currently has a CMS overall quality rating of average or higher.

Pennsylvania: The proposed owner's portfolio includes ownership in one Pennsylvania facility. The Pennsylvania facility currently has a CMS overall quality rating of below average or lower. When asked to explain the low overall CMS rating at The Greenery the applicant indicated:

The rules in Pennsylvania regarding whether a member has control of a facility are different than those in New York State. As such, although Ernest Schlesinger is a 15% member of this facility, he indicates that he does not exercise control over the day-to-day operations of the facility.

Washington: The proposed owner's portfolios include ownership in one Washington facility. The Washington facility currently has a CMS overall quality rating of below average. When asked to explain the low overall CMS rating at Alaska Gardens Health and Rehabilitation, the applicant indicated:

Staffing has been an issue. The facility has hired a recruiter, contracted with several staffing agencies, and increased their presence on internet job boards related to open positions. Regarding the low health inspection rating, the facility attributes this to several deficiencies that were cited during surveys conducted at the facility in prior years. However, recent surveys conducted during 2022 have resulted in fewer deficiencies than in prior years. The applicant states that this reflects the facility's focus on improvement in this area and expects the health inspection rating will increase to three stars in the near term.

CMS Star Ratings

Currently Owned Nursing Homes

| Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|--|----------------------------------|---------|----------------------|--------------------|----------|
| New York | | | | | |
| Golden Hill Nursing and | Subject Facility | ** | *** | **** | * |
| Rehabilitation Center | 09/2020 | **** | **** | **** | ** |
| Dumont Center for | Current | **** | **** | **** | *** |
| Rehabilitation and Nursing Care | 07/2010 Data as of 11/2010 | * | * | *** | *** |
| The Grand Pavilion at Rockville Centre | Current | **** | **** | **** | ** |
| | 08/2012 | ** | ** | *** | ** |
| Weathern ton Care Center | Current | *** | *** | **** | * |
| Westhampton Care Center | 02/2018 | **** | *** | **** | *** |
| St James Rehabilitation & | Current | **** | **** | **** | ** |
| Healthcare Center | 08/2012 | ** | *** | **** | * |
| Bellhaven Center for | Current | *** | *** | **** | ** |
| Rehabilitation & Nursing Care | 03/2010 | * | ** | *** | * |
| Ten Broeck Center for | Current | *** | *** | **** | * |
| Rehabilitation & Nursing | 10/2018 | **** | **** | **** | ** |

| Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|---|--------------------|---------|----------------------|--------------------|----------|
| Clove Lakes Healthcare and | Current | *** | **** | **** | * |
| Rehabilitation Center | 02/2020 | **** | **** | **** | *** |
| Florida | | | | | |
| Hawthorne Center for Rehab & | Current | *** | *** | *** | **** |
| Healing of Sarasota | 08/2021 | *** | ** | ** | **** |
| Hawthorne Center for | Current | * | * | **** | *** |
| Rehabilitation and Healing of Brandon † | 08/2021 | ** | * | **** | **** |
| Hawthorne Center for | Current | ** | *** | **** | * |
| Rehabilitation and Healing of Ocala | 04/2021 | **** | ** | **** | **** |
| Century Center for | Current | **** | **** | *** | **** |
| Rehabilitation and Healing | 03/2020 | **** | *** | ** | **** |
| Northbrook Center for | Current | ** | ** | **** | **** |
| Rehabilitation & Healing | 03/2020 | **** | *** | **** | **** |
| Sandy Ridge Center for | Current | **** | **** | *** | **** |
| Rehabilitation and Healing | 03/2020 | **** | **** | *** | **** |
| TimberRidge Center for Rehab | Current | **** | **** | ** | **** |
| & Healing | 09/2019 | *** | **** | *** | * |
| Santa Rosa Center for | Current | * | * | **** | **** |
| Rehabilitation and Healing | 03/2020 | **** | *** | *** | **** |
| Ybor City Healthcare & | Current | **** | **** | **** | *** |
| Rehabilitation Center | 03/2020 | **** | **** | **** | **** |
| Missouri | | | | • | |
| Big Bend Woods Healthcare | Current | * | * | *** | * |
| Center † | 01/2016 | * | * | **** | *** |
| Ohio | | | | | |
| Washington Square Healthcare | Current | **** | **** | **** | * |
| Center | 01/2014 | ** | ** | **** | *** |

| Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|---------------------------|--------------------|---------|----------------------|--------------------|----------|
| Pennsylvania | | | | | |
| Greenery Center for Rehab | Current | ** | ** | **** | ** |
| and Nursing | 06/2016 | * | * | * | * |
| Washington | | | | | |
| Alaska Gardens Health and | Current | * | ** | *** | * |
| Rehabilitation | 01/2021 | ** | ** | **** | *** |

Data date: 09/2022

† Special Focus Facility Candidate

End-Dated Nursing Homes

| Facility | Ownership Since | Overall | Health Inspection | Quality Measure | Staffing |
|----------------------------|--------------------|---------|----------------------|--------------------|----------|
| Missouri | | | | | |
| Abbey Woods Center for | 06/2019 | * | * | ** | * |
| Rehabilitation and Healing | 04/2017 | *** | ** | ** | **** |

Enforcement History

Clove Lakes Healthcare and Rehabilitation Center, NY:

- The facility was fined \$2,000 pursuant to Stipulation and Order NH-21-104 issued on June 2, 2021, for surveillance findings on February 24, 2021. A federal CMP in the amount of \$5,000 was also assessed on 2/24/2021. The facility failed to establish and maintain an Infection Control Program to ensure the health and safety of residents to help prevent the transmission of COVID.
- The facility was assessed a federal CMP of \$650.00 on 9/11/2021 for failure to report COVID data.

Golden Hill Nursing and Rehabilitation Center, NY:

- The facility was fined \$2,000 pursuant to Stipulation and Order NH-21-234 issued on 12/16/2021, for surveillance findings on August 31, 2021. Deficiencies were found under Quality of Care.
- The facility was assessed a federal CMP of \$655.14 on 1/4/2021 for failure to report COVID data.

Westhampton Care Center, NY:

- The facility was fined \$14,000 pursuant to Stipulation and Order NH-22-116 for surveillance findings on January 18, 2022, under 10 NYCRR 415.19(a)(1)(2) Infection Control and 10 NYCRR 415.12 (H)(2) Quality of Care. A federal CMP in the amount of \$11,435.00 was also assessed on 1/18/2022. The facility failed to establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection. The facility also failed to provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care subject to the resident's right of self-determination.
- The facility was fined \$10,000 pursuant to Stipulation and Order NH-19-003 issued on January 3, 2019, for surveillance findings on September 10, 2018. A federal CMP in the amount of \$7,036 was also assessed on 9/10/2018. The facility failed to develop and implement written policies and procedures that prohibit mistreatment, neglect, or abuse of residents, and misappropriation of resident property.

Sandy Ridge Health & Rehabilitation:

• The facility was assessed federal CMPs of \$650.00 on 8/3/2020, \$975.00 on 10/12/2020, \$1300.00 on 10/19/2020, and \$1625.00 on 10/26/2020 for failure to report COVID data.

Northbrook Center for Rehabilitation and Healing:

- The facility was assessed federal CMPs of \$650.00 on 12/28/2020 and \$975.00 on 01/10/2022 for failure to report COVID data.
- The facility was assessed a federal CMP of \$13,490.00 on 4/13/2022 from two J level deficiencies related to prevention of abuse and neglect (F600) and Cardio-Pulmonary Resuscitation (CPR) (F678).

TimberRidge Center for Rehab & Healing:

- The facility was assessed a federal CMP of \$20,635 on 4/3/2020 for failure to ensure that a
 nursing home area is free from accident hazards and provides adequate supervision to prevent
 accidents.
- The facility was assessed federal CMPs of \$655.00 on 5/10/2021 for failure to report COVID data.

Century Health & Rehabilitation Center:

• The facility was assessed federal CMPs of \$650.00 on 6/21/2021 for failure to report COVID data.

Hawthorne Center for Rehabilitation and Healing of Brandon:

- The facility was assessed a federal CMP of \$359,085.00 on 12/10/2021 from a G level deficiency and three IJ level deficiencies related to prevention of abuse and neglect (F600), reporting of abuse (F609), and investigation of abuse (F610).
- The facility was assessed a federal CMPs of \$650.00 on 1/11/2021, \$983.00 on 1/18/2021, \$1,300.00 on 6/28/2021, \$1,625.00 on 7/5/2021, and \$1,950 on 8/16/2021 for failure to report COVID data.

Big Bend Woods Healthcare Center:

- The facility was assessed a federal CMP of \$84,240 on 5/24/2021 the facility must provide appropriate pressure ulcer care and prevent new ulcers from developing.
- On 5/24/2021 the facility was cited for failure to provide appropriate treatment and care according to orders, resident's preferences, and goals Federal Tag 684 at a G level.
- The facility was assessed a federal CMP of \$44,782 on 1/4/2021 the facility must provide appropriate treatment and care according to orders, resident's preferences, and goals.
- The facility was assessed federal CMPs of \$655.00 on 6/7/2021, \$983.00 on 6/21/2021, \$1300.00 on 6/28/2021, and \$1625.00 on 7/5/2021 for failure to report COVID data.
- On 3/18/2020 Big Bend Woods Healthcare Center was cited for failure to provide basic life support, including CPR, prior to the arrival of emergency medical personnel, subject to physician orders and the resident's advance directives Federal Tag 678 at a J level.
- The facility was assessed a federal CMP of \$19,910 on 1/28/2020 the facility must provide appropriate treatment and care according to orders, resident's preferences, and goals.
- The facility was assessed a federal CMP of \$11,443 on 3/3/2017 the facility must give residents proper treatment to prevent new bed (pressure) sores or heal existing bed sores.

Greenery Center for Rehab and Nursing:

- The facility was assessed a federal CMP of \$27,688.00 on 9/27/2019 the facility must ensure that
 a nursing home area is free from accident hazards and provides adequate supervision to prevent
 accidents.
- On 9/27/2019, the facility was cited for failure to provide appropriate treatment and care according to orders, residents' preferences, and goals. Federal Tag 684 at a G level.

Bellhaven Center for Rehabilitation and Nursing Care:

 The facility was fined \$2,000.00 pursuant to Stipulation and Order NH-22-066 issued for surveillance findings on October 19, 2021, under 10 NYCRR 415.19(a) Infection Control. The facility was also assessed a federal CMP of \$5,000.00 on 10/19/2021 for failure to establish and maintain an infection prevention and control program to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. The facility was assessed federal CMPs of \$650.00 on 3/22/2021, \$975.00 on 6/14/2021, \$1300.00 on 6/28/2021, \$1300.00 on 6/28/2021, \$1625.00 on 8/23/2021, \$1,950.00 on 9/13/2021, \$2,275.00 on 9/20/2021, \$4,000.00 on 11/15/2021, and \$5000.00 on 11/29/2021 for failure to report National Health Safety data.

Conclusion

All health care facilities are in substantial compliance with all rules and regulations. The individual background review indicates the applicants have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, during the first and third year:

| | Current Year 2021 | | <u>Year One</u> <u>2023</u> | | <u>Year Three</u> <u>2025</u> | |
|--------------------|----------------------|------------------|--------------------------------|------------------|----------------------------------|--------------|
| | Per PD | <u>Total</u> | Per PD | <u>Total</u> | Per PD | <u>Total</u> |
| Revenues | | | | | | |
| Medicare FFS | \$562.24 | \$8,000,658 | \$562.22 | \$9,200,756 | \$562.22 | \$9,403,173 |
| Medicare MC | \$562.24 | 1,468,005 | \$562.17 | 1,688,206 | \$562.19 | 1,725,347 |
| Medicaid FFS | \$263.92 | 13,643,397 | \$263.92 | 15,689,906 | \$263.92 | 16,035,084 |
| Medicaid MC | \$263.92 | 1,786,481 | \$263.93 | 2,054,454 | 263.91 | 2,099,652 |
| Private Pay | \$726.96 | 4,456,996 | \$726.92 | 5,125,545 | \$726.94 | 5,238,307 |
| Cares Act Rev | | 1,576,550 | | 0 | | 0 |
| Misc. Rev | | <u>965</u> | | <u>1,000</u> | | 1,000 |
| Total Revenues | | \$30,933,052 | | \$33,759,867 | | \$34,502,563 |
| <u>Expenses</u> | _ | - | _ | | _ | |
| Operating | \$313.25 | \$25,510,075 | \$293.52 | \$27,488,856 | \$293.63 | \$28,104,280 |
| Capital | <u>\$57.90</u> | <u>4,715,152</u> | \$50.3 <u>5</u> | <u>4,715,152</u> | \$49.26 | 4,715,152 |
| Total Expenses | \$371.15 | \$30,225,227 | \$343.87 | 32,204,008 | \$342.90 | \$32,819,432 |
| Net Income | | \$707,825 | | \$1,555,859 | | \$1,683,131 |
| Utilization (Days) | | 81,436 | | 93,651 | | 95,712 |
| Occupancy | | 79.68% | | 91.64% | | 93.65% |

The following is noted with respect to the submitted budget:

- The Medicare and Private Pay rates are projected from the current market rates.
- The current year's Medicaid rate is based on the facility's Medicaid rate per 2019 RHCF-4 cost report information.
- The current occupancy rate of Golden Hill Nursing and Rehabilitation Center was 85.4% as of August 17, 2022, as tracked in the New York State Health Commerce System. The applicant has indicated that the projected increase in patient days and recovery to exceed pre-pandemic utilization will result from the applicant's plan to continue effectively marketing the facility to prospective residents. The facility's marketing campaign will continue to focus on communication and relationship building with the area doctors, hospitals, and resident family members regarding improvements being made at the facility. In addition, the applicant plans to invest further in the facility by upgrading and beautifying resident rooms, as well as the gymnasium and resident dining rooms.

Utilization detailed by payor source for the current year, year one, and year three are as follows:

| _ | Current Year | Year One | Year Three |
|-----------------------|--------------|-------------|--------------|
| <u>Payor</u> | <u>2021</u> | <u>2023</u> | <u> 2025</u> |
| Medicare FFS | 17.47% | 17.47% | 17.47% |
| Medicare Managed Care | 3.21% | 3.21% | 3.21% |
| Medicaid FFS | 63.48% | 63.48% | 63.48% |
| Medicaid Managed Care | 8.31% | 8.31% | 8.31% |
| Private Pay | 7.53% | 7.53% | 7.53% |
| Total | 100.00% | 100.00% | 100.00% |

Asset Purchase Agreement

The applicant has submitted a draft asset purchase agreement for the purchase of the operation:

| Purpose | Seller desires to sell, and Buyer desires to purchase, certain assets of Seller |
|---------------------|--|
| 1 dipose | relating to the Facility. |
| Purchaser | Ulster NH Operation, LLC |
| Seller | Golden Hill Planning Corporation |
| | |
| Assets Acquired | Business and operation of the Facility, all inventory, supplies, and other articles |
| | of personal property, all Facility contracts, agreements, leases, undertakings, |
| | commitments, and other arrangements which Buyer elects to assume, the name "Golden Hill Nursing and Rehabilitation Center" and any other trade |
| | names, logos, trademarks and service marks associated with the Facility, all |
| | security deposits and prepayments, if any, for future services held by the |
| | Seller, all menus, policies and procedures manuals and computer software, all |
| | telephone numbers and telefax numbers used by the Facility, copies of all |
| | books and records in the possession of Seller, all resident/patient records |
| | relating to the Facility, good will in connection to the Facility, all accounts |
| | receivable related to services rendered by the Facility and all cash, marketable |
| | securities, deposits and cash equivalents in the New Operating account and |
| | new payroll account. |
| Excluded Assets | All insurance, policies, and claims relating to events occurring before the |
| | Effective Date, all retroactive rate increases, regulation from rate appeals, audits |
| | or otherwise, concerning third party payments, all amounts due from parties |
| | related to Seller, all financial books and records of Seller, including, but not |
| | limited to organizational and other corporate type records, all accounts |
| | receivable relating to services rendered by the Facility before the Effective Date |
| | and the real property, and improvements thereon, and any rights relating to the |
| | ownership thereof. |
| Assumed Liabilities | Buyer shall assume at the Closing, all liabilities and obligations to the Facility |
| | arising on or after the Effective Date, all of Sellers's Accounts Payable and other |
| | liabilities accruing on or after the Effective Date, and all healthcare, Medicare, |
| <u> </u> | and Medicaid overpayment and assessments liabilities. |
| Purchase Price | \$3,000,000 plus assumption of liabilities. |
| Payment | Cash at Closing |

The applicant has submitted an affidavit, acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement, or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor, of its liability and responsibility. Currently, there are no outstanding overpayment liabilities.

Real Estate Purchase Agreement

The applicant has submitted an executed real estate purchase agreement:

| Date | November 22, 2019 |
|----------------|--|
| Premises | The premises located at 99 Golden Hill Dr, Kingston, New York. |
| Seller | Golden Hill Acquisition, LLC |
| Purchaser | Ulster NH Realty, LLC |
| Purchase Price | \$37,600,000 |
| Payment of | \$400,000 Initial Deposit to Escrowee |
| Purchase | \$400,000 additional deposit upon the expiration of the Due Diligence Period |
| Price | \$36,800,000 at Closing |

The applicant will finance the purchase price as follows:

| Equity | \$3,000,000 |
|----------------------------------|--------------|
| Bank Loan (6% for a30-year term) | \$34,592,000 |

Lease Rental Agreement

The applicant has submitted a draft lease agreement:

| Premises | The site located at 99 Golden Hill Dr, Kingston, New York |
|------------|--|
| Lessor | Ulster NH Realty LLC |
| Lessee | Ulster NH Operation LLC |
| Term | 25 years |
| Rental | Year One: \$3,760,000 with a 2% increase thereafter. |
| Provisions | The lessee shall be responsible for maintenance, real estate taxes, utilities, and |
| | insurance. |

The applicant has indicated that the lease agreement will be a non-arm's length lease arrangement in that there is a relationship between the landlord and the tenant.

Capability and Feasibility

The purchase price for the operation is \$3,000,000 and will be met via equity from the proposed members' personal resources. The purchase for the real estate is \$37,600,000 and will be met via equity of \$3,008,000 from the proposed members of the realty entity and a loan of \$34,592,000 at an interest rate of 6% for a 30-year term. BFA Attachment A shows the members of the realty entity have sufficient funds to meet the equity requirements.

Working capital requirements are estimated at \$5,469,905, which is equivalent to two months of third-year expenses. The proposed members of the operating entity will provide equity from their personal resources to meet the working capital needs. Mr. Solomon Klein has submitted a disproportionate share affidavit attesting that he is willing to contribute personal resources disproportionate to his ownership interest in the entity. BFA Attachment A is the net worth statements of the proposed members of Ulster NH Operation, LLC, which indicates the availability of sufficient funds for the working capital requirement.

The submitted budget indicates a net income of \$1,555,859 and \$1,683,131 during the first and third years, respectively. Revenues are based on current reimbursement methodologies. The submitted budget appears reasonable.

As shown in BFA Attachment C, Golden Hill Nursing and Rehabilitation Center had an average positive working capital position and an average positive net asset position from 2019 through 2021. Also, the entity achieved an average net income of \$1,651,508 from 2019 through 2021.

BFA Attachment D is the financial summaries for the other facilities owned by the proposed members. As shown in BFA Attachment E, all the affiliated nursing homes had an average positive working capital position and an average positive net asset position during the period shown except for Westhampton and

Clove Lakes. Westhampton had a negative working capital position in 2019 and Clove Lakes had a negative working capital position, negative net asset position, and losses in 2019 and 2020. All the other facilities that the proposed members own achieved an average net income for the period shown except for Clove Lake.

Conclusion

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

Attachments

| LTCOP Attachment | Long Term Care Ombudsman Program Recommendation |
|------------------|---|
| BFA Attachment A | Net Worth Statement of Proposed Members of Operating Entity |
| BFA Attachment B | Ownership of the Realty Entity |
| BFA Attachment C | Financial Summary - Golden Hill Nursing |
| BFA Attachment D | Financial Summary - Other Owned Nursing Facilities |

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 8th day of December 2022, 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 Ulster NH Operation LLC as the new operator of the 280-bed residential health care facility located at 99 Golden Hill Drive, Kingston, currently operated as Golden Hill Nursing and Rehabilitation Center, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

<u>NUMBER</u>: <u>FACILITY/APPLICANT</u>:

202034 E Ulster NH Operations LLC d/b/a Golden Hill

Center for Rehabilitating and Nursing

APPROVAL CONTINGENT UPON:

- 1. Submission of a loan commitment for the real estate, that is acceptable to the Department of Health. [BFA]
- 2. Submission of an executed lease agreement, that is acceptable to the Department of Health. [BFA]
- 3. Submission of an executed asset purchase agreement that is acceptable to the Department of Health. [BFA]
- 4. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR]
- 5. Submission of a photocopy of the Certificate of Assumed Name, acceptable to the Department. [CSL]
- 6. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. [CSL]
- 8. Submission of a photocopy of the Application for Authority for CW Kingston Operations LLC, acceptable to the Department. [CSL]
- 9. Submission of a photocopy of an amended and executed Operating Agreement for CW Kingston Operations LLC, acceptable to the Department. [(CSL]
- 10. Submission of a photocopy of the Application for Authority for ED Kingston Operations LLC, acceptable to the Department. [CSL]
- 11. Submission of a photocopy of an amended and executed Operating Agreement for ED Kingston Operations LL, acceptable to the Department. [CSL]
- 12. Submission of a photocopy of an amended and executed Articles of Organization for KF Kingston Operations, LLC, acceptable to the Department. [CSL]
- 13. Submission of a photocopy of an amended and executed Operating Agreement for KF Kingston Operations, LLC, acceptable to the Department. [CSL]
- 14. Submission of a photocopy of an amended and executed Articles of Organization for ES Kingston Operations LLC, acceptable to the Department. [CSL]
- 15. Submission of a photocopy of an amended and executed Operating Agreement for ES Kingston Operations LLC, acceptable to the Department. [CSL]
- 16. Submission of a photocopy of an amended and executed Articles of Organization for SE Kingston Operations, LLC, acceptable to the Department. [CSL]
- 17. Submission of a photocopy of an amended and executed Operating Agreement for SE Kingston Operations, LLC, acceptable to the Department. [CSL]
- 18. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
- 19. Submission of a photocopy of an amended and executed Partial Assignment of Membership Interests, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [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*.



of Health

Department Public Health and Health Planning Council

Project # 211087-E

The Premier Center for Rehabilitation of Westchester, LLC d/b/a Springvale Nursing and Rehabilitation Center

Program: **Residential Health Care Facility**

Establishment Purpose:

County: Westchester Acknowledged: April 6, 2021

Executive Summary

Description

The Premier Center for Rehabilitation of Westchester, LLC, an existing New York limited liability company, requests approval to be established as the new operator of Bethel Nursing and Rehabilitation Center, an existing 200-bed, Article 28 Residential Health Care Facility (RHCF) at 67 Springvale Road, Croton-On-Hudson (Westchester County), currently operated by The Bethel Springvale Hursing Home, Inc. Once approved by PHHPC, the facility will be named Springvale Nursing and Rehabilitation Center.

On October 30, 2020, Bethel Springvale Nursing Home Inc. entered a Purchase and Sale Agreement for the realty whereby 67 Springvale Road, LLC agreed to purchase the realty associated with the facility and lease the space to The Premier Center for Rehabilitation of Westchester, LLC. The Asset Purchase Agreement is for The Premier Center for Rehabilitation of Westchester, LLC (operations). An Adult Day Health Care Program (ADHDP) associated with Bethel Nursing and Rehabilitation Center will close and therefore is not part of this application.

The proposed ownership of the nursing home is as follows:

| The Premier Center for Rehal | |
|------------------------------|-----------------|
| of Westchester, LLC | |
| <u>Members</u> | <u>Interest</u> |
| Bethel Op Holdings, LLC | 42.5% |
| Leah Sod (99%) | |
| Zahava Bobker (1%) | |
| JSB Bethel Holdings, LLC | 42.5% |
| Sorah Bleier (80%) | |
| Aharon Bleier (20%) | |
| Joel Schwartz | 10% |
| Lisa Safia | 5% |
| Total | 100% |

The Proposed realty owner is 67 Springvale Road, LLC whose members are listed below:

| 67 Springvale Road, LLC | |
|-------------------------|-----------------|
| <u>Members</u> | <u>Interest</u> |
| JLS Equities, LLC | 45% |
| Jacob Sod (100%) | |
| JSB Holdco, LLC | 45% |
| Jonathan Bleier (100%) | |
| Joel Schwartz | 10% |
| Total | 100% |

OPCHSM/OALTC Recommendation Contingent Approval

Need Summary

There will be no changes to beds or services as a result of this project. Occupancy, as of May 18, 2022, was 52.0% for the facility and 84.6% for Westchester County.

Program Summary

The individual background review indicates the applicants have met the standard for approval as set forth in Public Health Law §2801-a(3)

Financial Summary

The total purchase price is \$40,000,000, allocated as follows: \$8,000,000 for the

operations and \$32,000,000 for the realty interests. The Premier Center for the Rehabilitation of Westchester, LLC secured a loan with a payout period of 36 months at a rate of 6% amortized over 25 years for the operations. 67 Springfield Road, LLC submitted a letter of interest for \$32,000,000 at a 6% interest rate for term 25-year term for the realty.

| <u>Budget</u> | Year One | Year Three |
|---------------|--------------|--------------|
| Revenues | \$19,965,600 | \$23,010,200 |
| Expenses | \$19,711,929 | \$22,427,429 |
| Net Income | \$253,671 | \$582,771 |

Recommendations

Long Term Care Ombudsman Program

The LTCOP recommends Approval. (See LTCOP Attachment A)

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 commitment for the purchase of the realty, acceptable to the Department of Health. [BFA]
- 2. Submission of an executed commitment for the purchase of the operations, acceptable to the Department of Health. [BFA]
- 3. Submission of an executed lease agreement acceptable to the Department. [BFA]
- 4. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR].
- 5. Submission of a plan to continue to enhance access to Medicaid residents. At a minimum, the plan should include, but not necessarily be limited to, ways in which the facility will: a. Reach out to hospital discharge planners to make them aware of the facility's Medicaid Access Program; b. Communicate with local hospital discharge planners on a regular basis regarding bed availability at the nursing facility; and identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility and inform them about the facility's Medicaid Access policy, and c. Identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility and inform them about the facility's Medicaid Access policy. [RNR]
- 6. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of Bethel Op Holdings LLC, acceptable to the Department. [CSL]
- 8. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of JSB Bethel Holdings LLC, acceptable to the Department. [CSL]
- Submission of photocopy of an amended and executed Second Amendment of the Operating Agreement of The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]
- 10. Submission of an executed Lease Agreement between 67 Springvale Road LLC and The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]

Approval conditional upon:

 This project must be completed by one year from the date of the recommendation letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date December 8, 2022

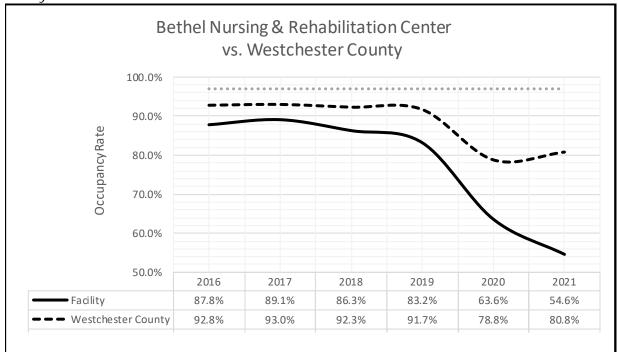
Need and Program Analysis

Program Information

| | Existing | Proposed |
|-------------------|---------------------------------|--|
| Facility Name | Bethel Nursing & Rehabilitation | Springvale Nursing and Rehabilitation |
| | Center | Center |
| Address | 67 Springvale Road | Same |
| | Croton-On-Hudson, NY 10520 | |
| RHCF Capacity | 200 beds | Same |
| ADHCP Capacity | Offsite – 25 | None |
| Type of Operator | Not-for-profit corporation | Limited Liability Company |
| Class of Operator | Voluntary | Proprietary |
| Operator | Bethel Springvale Nursing | The Premier Center for Rehabilitation of |
| | Home, Inc. | Westchester, LLC |
| | | |
| | | <u>Members</u> |
| | | Bethel Op Holdings LLC 42.5% |
| | | Leah Sod* (99%) |
| | | Zahava Bobker (1%) |
| | | JSB Bethel Holdings LLC 42.5% |
| | | Sorah Bleier* (80%) |
| | | Aharon Bleier (20%) |
| | | Joel Schwartz 10.0% |
| | | Lisa Sofia 5.0% |
| | | |
| | | *Managing Member |

The ADHCP is not included in the sale of this facility and is an excluded asset. No administrative services or consulting agreements are proposed in this application. The applicant does not intend to utilize any staffing agencies upon their assumption of ownership.

Analysis



2020 occupancy was impacted by COVID-19. Recently, the current operator has sent most new residents to two related facilities, Bethel Nursing Home Company and the Knolls.

In order to improve occupancy, the new operator intends to implement a new marketing plan to reposition the facility in the community, to promote the skills of the new operator, and to have a dedicated admissions team that will reach out to local hospitals and physicians to coordinate the continuation of patient care. Per the weekly census data, the occupancy, as of September 21, 2022, was 54.5% for the facility and 85.5% for Westchester County

Medicaid Access

To ensure that the Residential Health Care Facility needs of the Medicaid population are met, 10 NYCRR §670.3 requires applicants to accept and admit a reasonable percentage of Medicaid residents in their service area. The benchmark is 75% of the annual percentage of residential health care facility admissions that are Medicaid-eligible individuals in their planning area. An applicant will be required to make appropriate adjustments in its admission policies and practices to meet this benchmark which can be adjusted by the following factors:

- the number of individuals within the planning area currently awaiting placement to a residential health care facility and the proportion of total individuals awaiting such placement that are Medicaid patients and/or alternate level of care patients in general hospitals;
- the proportion of the facility's total patient days that are Medicaid patient days and the length of time that the facility's patients who are admitted as private paying patients remain such before becoming Medicaid eligible;
- the proportion of the facility's admissions who are Medicare patients or patients whose services are paid for under provisions of the federal Veterans' Benefit Law;
- the facility's patient case mix based on the intensity of care required by the facility's patients or the extent to which the facility provides services to patients with unique or specialized needs;
- the financial impact on the facility due to an increase in Medicaid patient admissions.

The facility's Medicaid admissions rate was below the threshold of 75% of the Westchester County rate for 2019 and 2020.

| Medicaid Access | 2019 | 2020 | 2021 |
|-------------------------------|-------|-------|-------|
| Westchester County Total | 28.4% | 31.3% | 27.2% |
| Westchester Threshold Value | 21.3% | 23.5% | 20.4% |
| Bethel Nursing & Rehab Center | 20.6% | 19.6% | 40.3% |

Character and Competence - Assessment

Leah Sod holds a bachelor's degree in psychology from Queens College and reports employment as a real estate consultant. They disclose the following health facility ownership interest:

New York Facilities

Massapequa Center Rehabilitation and Nursing Center (5%)

11/2017 to Present

Zahava Bobker is an Administrative Assistant at Premier Healthcare Management LLC in Great Neck, NY, with previous employment listed as a Customer Service Assistant at Fairmont Insurance Brokers Ltd. in Brooklyn, NY. They do not disclose any licenses or degrees. Zahava Bobker discloses the following health facility interests:

Maryland Facilities

Sterling Care at Frostburg Village (0.12%)

Sterling Care at South Mountain (0.12%)

Sterling Care Harbor Pointe (Asst. Living) (0.12%)

01/2018 to present 01/2018 to present 01/2018 to present

<u>Pending</u>

CON 192237 JAG Operating LLC d/b/a Foltsbrook Center for Nursing and Rehabilitation

Aharon Bleier is the current Director of Operations for Wym Op Holdings, and he indicates previous employment at Highfield Gardens Care Center as Accounts Receivable/ Accounts Payable Manager. Aharon Bleier holds a Rabbinical degree from Tiferes Israel. He discloses the following health facility interests:

New York Facilities

Massapequa Center for Nursing (5%) 11/2017 to present Sunset Nursing & Rehabilitation (9.9%) 02/2019 to present

Pennsylvania Facilities

Wyomissing Health and Rehabilitation Center (80%) 10/2019 to present

Pending

CON 192237 JAG Operating LLC d/b/a Foltsbrook Center for Nursing and Rehabilitation

Sorah Bleier discloses employment at Peer Bais Yaacov of Rockland as a teacher, and previously she was a teacher at Beth Rochelle. She holds a teaching degree from BJJ Seminary. Sorah Bleier discloses the following health facility ownership interest:

New York Facilities

Highfield Gardens Care Center (9%)

09/2010 to present

Lisa Sofia discloses employment as a CEO/Consultant at BHO Services, the Executive Director at Deer Meadows Retirement Community (CCRC), and the CEO at Premier Healthcare Management LLC concurrently. She has a Master's Degree in Public Health Education from Saint Joseph's University. Lisa Sofia discloses the following health facility ownership interest:

Pennsylvania Facilities

Pleasant Acres (3%) 10/2018 to present Willow TerraceWT Operating LLC (5%) 05/2018 to present

Joel Schwartz discloses employment at The Schwartz Group NY, LLC, as a healthcare investor, and previously he was employed as the General Manager for Medfast Billing, Inc., a medical billing company. He has a high school diploma. Joel Schwartz discloses the following health facility ownership interests:

New York Facilities

Leroy Village Green Residential Healthcare Facility (10%)

O2/2019 to present
Sunset Nursing and Rehab Center (9%)

01/2019 to present

Florida Facilities

Manatee Springs Rehab and Nursing Center (7%)

Page Rehabilitation and Healthcare Center (10%)

04/2017 to present
01/2019 to present

Quality Review

| | C | CMS Star Rating Criteria - 10 NYCRR 600.2(b)(5)(iv) | | | | |
|---------------------------------|---------------------------|---|--|----------------------------------|--|--|
| | | | Duration of Ownership | | | |
| | | < 48 | 8 Months | 48 mor | nths or more | |
| <u>Proposed</u> <u>Owner</u> | Total Nursing Homes | Number of Nursing Homes | Percent of Nursing Homes With a Below Average Rating | Number of Nursing Homes | Percent of Nursing Homes With a Below Average Rating | |
| Aharon Bleier | 3 | 2 | 50% | 1 | | |
| Sorah Bleier | 1 | 0 | | 1 | 100% | |
| Zahava Bobker | 2 | 0 | | 2 | 100% | |
| Joel Schwartz | 4 | 3 | 66.66% | 1 | | |
| Leah Sod | 1 | 0 | | 1 | | |
| Lisa Sofia | 2 | 0 | | 2 | 100% | |

Duration of Ownership as of 12/8/2022

Data as of: 09/2022

The proposed owners' portfolio includes ownership in four New York facilities. Two of the New York facilities have a CMS overall quality rating of average or higher.

Sunset Nursing and Rehabilitation Center currently has a one-star overall category. The applicant states: Since Aharon Bleier and Joel Schwartz joined as shareholders of the facility in 2019, several steps have been taken to address quality and improve operations. These steps include implementing a new Electronic Medical Record system (in March 2019), which has improved efficiency and outcomes across all disciplines. Furthermore, the facility retained the services of an on-site consultant (in May 2021) to review quality and overall operations. These shareholders have also aligned the facility's policies and procedures with the shareholders' larger affiliated facilities to take advantage of best practices. This was a key factor in helping the facility maintain quality operations throughout the COVID-19 pandemic. Furthermore, the shareholders have implemented additional recruiter positions at the facility and throughout the organization to focus on interviewing and hiring high-quality staff members. Finally, the shareholders have strengthened the facility's clinical team by supplying regional Quality Assurance Nurses who provide routine audits of regulatory requirements.

Highfield Gardens Care Center has a two-star overall category. The applicant states: The facility has hired a new administration team to achieve and maintain these improvements. Since the change in the senior management team, the facility has maintained five (5) stars in the Quality Measures rating. This rating has been maintained by conducting monthly Quality Measure meetings with the clinical and medical teams to review each resident's goal of care and to ensure that residents' needs are being met. The facility's last two (2) health inspections under the new leadership resulted in only two (2) minor, D-level tags. This facility was the first facility in New York State to have an annual, post-COVID-19 survey. Since that time, the facility improved from four (4) stars to five (5) stars in the Quality Measures rating, from one (1) star to three (3) stars in the Staffing rating and from one (1) star to three (3) stars in the Overall rating. However, the most-recent star rating calculation, which was based on May 2022 information, resulted in a decrease in the Staffing and Quality Measures categories based on an isolated nursing incident, which resulted in a loss of one (1) Health Inspection rating star, which then resulted in the facility receiving two (2) stars in the Overall category.

The proposed owners' portfolio includes ownership in three Pennsylvania facilities, all of which are below average. Pleasant Acres Rehabilitation and Nursing is on the Special Focus Facility Candidate List. According to the applicant, this was the result of poor survey results from 2019. As such, the applicant is expecting that the facility will drop off the list within the next 90 days based on results from the last three annual surveys. Looking ahead, the facility is pleased to report that it had a very positive health inspection survey during the first quarter of 2022, and it is expected that the Health Inspection star rating will improve, as should the facility's overall star rating. In addition, the facility is in the process of hiring additional Registered Nurses and other staff, which should also serve to enhance the facility's staffing rating and the overall rating.

Willow Terrace Rehabilitation and Nursing Center currently shows two stars in the overall category. According to the applicant, the facility graduated from the Special Focus Facility program in 2020. The facility is expecting to receive the results of its most-recent survey any day and it is expected that this survey will result in minimal negative findings. As such, the applicant expects that this facility will have three stars in the near term.

The proposed owner's portfolio includes two Maryland facilities, two of which are below average. Sterling Care at Frostburg Village currently has a two-star rating overall rating. The applicant states: This facility has not had a health inspection survey in more than three (3) years. However, the facility is pleased to report that it has moved from having one (1) star in the Overall category during 2018, 2019, 2020 and 2021 to having two (2) stars in the Overall category as of April 2022, due to its four (4) stars in the Quality Measures rating. The facility also reports that its Quality Measures rating is very close to becoming five (5) stars. As a result, it is expected that this facility's Overall rating will move up to three (3) stars within the near term.

Sterling Care at South Mountain shows two (2) stars in the Overall category with five (5) stars in Quality Measures. The applicant states: This facility was purchased in 2018 and the facility's last full recertification survey was in November of 2019, in which the facility received four (4) D-level (no harm

with the potential for minimal harm) deficiencies. The facility has not had a recertification survey in almost three (3) years. The Overall rating has been negatively impacted by the facility's Staffing rating of one (1) star. Over the past several years, the facility has experienced difficulties in hiring and retaining qualified RNs. As a result, the facility has hired Licensed Practical Nurses (LPNs) to provide the nursing coverage for its residents, despite the difficult circumstances in the labor market. Since the newly updated CMS staffing calculation provides for a higher value to be attributed to RNs versus LPNs, the facility's Staffing rating has decreased during 2022. To mitigate the effects of this situation, the facility utilizes the services of multiple nursing staffing agencies and continuously works to fill any gaps the facility may experience due to the shortage of qualified RNs.

The proposed owner's portfolio includes two Florida facilities, one of which is below average. Page Rehabilitation and Healthcare Center currently has a two-star overall rating. The applicant states: The facility recently had its annual survey and the results were very positive and resulted in minimal deficiencies. As a result, the facility's overall star rating is expected to increase once these survey results are reflected in CMS records.

| Facility | Ownership Since | Overall | Health Inspection | Quality Measures | Staffing |
|---|---------------------|---------|----------------------|---------------------|----------|
| New York | | | | | |
| Bethel Nursing & Rehabilitation Center | Subject Facility | ** | ** | *** | ** |
| Highfield Gardens Care | Current | **** | *** | **** | ** |
| Center Of Great Neck | 09/2010 | **** | *** | **** | **** |
| Leroy Village Green | Current | *** | *** | **** | *** |
| Leloy Village Green | 08/2019 | *** | ** | **** | ** |
| Massapequa Center Rehabilitation and Nursing | Current | ** | ** | **** | * |
| Center | 11/2017 | *** | ** | **** | *** |
| Sunset Nursing and Rehab | Current | * | * | *** | * |
| Center | 01/2019 | ** | *** | *** | * |
| Pennsylvania | | | | | |
| Willow Terrace | Current | ** | *** | *** | * |
| Willow Terrace | 05/2018 | ** | * | **** | *** |
| Wyomissing Health And | Current | *** | *** | **** | * |
| Rehabilitation Center | 05/2016 | **** | *** | **** | *** |
| Pleasant Acres Nursing And | Current | * | * | ** | * |
| Rehabilitation Center † | 10/2018 | ** | * | *** | **** |
| Maryland | | | | | |
| Sterling Care At South | Current | ** | ** | **** | ** |
| Mountain | 11/2018 | ** | ** | ** | ** |

| Facility | Ownership Since | Overall | Health Inspection | Quality Measures | Staffing |
|---|--------------------|---------|----------------------|---------------------|----------|
| Sterling Care At Frostburg | Current | ** | ** | **** | * |
| Village | 11/2018 | * | * | *** | *** |
| Florida | | | | | |
| Manatee Springs Rehab and Nursing Center | Current | **** | *** | **** | *** |
| | 04/2017 | * | * | *** | *** |
| Page Rehabilitation and | Current | ** | * | **** | *** |
| Healthcare Center | 01/2019 | ** | * | **** | **** |

Data as of: 09/2022

Enforcement History

Page Rehabilitation and Healthcare Center (Florida):

- The facility was assessed federal CMP's on 4/18/2022 in the amount of \$3,618
- The facility was assessed federal CMP's on 4/11/2022 in the amount of \$3,289
- The facility was assessed federal CMP's on 4/4/2022 in the amount of \$2,960
- The facility was assessed federal CMP's on 3/28/2022 in the amount of \$2,631
- The facility was assessed federal CMP's on 3/21/2022 in the amount of \$3,542
- The facility was assessed federal CMP's on 3/14/2022 in the amount of \$1,973
- The facility was assessed federal CMP's on 3/7/2022 in the amount of \$1,645
- The facility was assessed federal CMP's on 2/28/2022 in the amount of \$1,316
- The facility was assessed federal CMP's on 2/28/2022 in the amount of \$987
- The facility was assessed federal CMP's on 2/14/2022 in the amount of \$658
- The facility was assessed federal CMPs on 01/30/2020 in the amount of \$92,563 and \$92,564 for failing to honor the residents' right to request, refuse and or discontinue treatment and administer the facility in a manner that enables it to use its resources effectively and efficiently respectively.

Willow Terrace Nursing and Rehabilitation Center (Pennsylvania):

- The facility was assessed federal CMP's on 6/28/2021 in the amount of \$650
- The facility was assessed federal CMP's on 4/28/2021 in the amount of \$9,750
- The facility was assessed federal CMPs of \$143,579 on 09/20/19 for not providing appropriate treatment and care according to orders, resident's preferences, and goals; and \$16,544 on 10/31/18 for not ensuring food and drink are palatable, attractive, and at a safe and appetizing temperature.
- They also received a G level tag on 06/19/19 for not ensuring that a nursing home area is free from accident hazards and provides adequate supervision to prevent accidents.

Pleasant Acres (Pennsylvania):

- The facility was assessed a federal CMP of \$111,813 on 09/03/21 for not developing and implementing a complete care plan that meets all the resident's needs, with timetables and actions that can be measured and protecting each resident from all types of abuse such as physical, mental, sexual abuse, physical punishment, and neglect by anybody. The latter of these resulted in physical harm for one of three residents reviewed.
- The facility was assessed federal CMP's on 7/19/2021 in the amount of \$650
- The facility was assessed federal CMP's on 3/30/2021 in the amount of \$15,289
- The facility was assessed federal CMP's on 10/29/2020 in the amount of \$22,750
- The facility was assessed federal CMP's on 7/15/2020 in the amount of \$13,000
- The facility received a G tag on 02/01/19 for not ensuring that a nursing home area is free from accident hazards and provides adequate supervision to prevent accidents

• K tag on 08/29/19 for not providing appropriate treatment and care according to orders, resident's preferences and goals.

Sterling Care at Forstburg Village (Maryland):

- The facility was assessed federal CMP's on 4/11/2022 in the amount of \$658
- They received a J level tag on 06/06/2019 for not providing appropriate treatment and care according to orders, residents' preferences, and goals.

Massapequa Center Rehabilitation and Nursing (New York):

- The facility was assessed a federal CMP on 2/21/2022 in the amount of \$658.
- The facility was assessed a federal CMP on 5/4/2021 in the amount of \$5,000 on 5/4/2021
- The facility was assessed a federal CMP of \$7,036 on 03/01/19 for not protecting each resident from all types of abuse such as physical, mental, sexual abuse, physical punishment, and neglect by anybody.
- The facility was fined \$2,000 pursuant to Stipulation and Order NH 20-041 issued on 9/14/2020 for surveillance findings on 8/14/2020. Deficiencies were found under 10 NYCRR 415.19 (a) (1), (a)(2), and (b)(1) Isolation/social distancing.
- The facility was fined \$10,000 pursuant to Stipulation and Order NH19-027 issued on 7/3/2019 for surveillance findings on 3/1/2018

Sunset Nursing and Rehab Center (New York):

- The facility was fined \$2,000 pursuant to Stipulation and Order NH-21-206 issued on 11/17/2021 for surveillance findings on 7/21/2021. Deficiencies were found under 10 NYCRR sections 415.19 (a) and 415.19(b)(4) Infection control.
- The facility was assessed a federal CMP of \$6,923 on 07/21/21 for not ensuring that a nursing home area is free from accident hazards and provides adequate supervision to prevent accidents, and not protecting each resident from all types of abuse such as physical, mental, sexual abuse, physical punishment, and neglect by anybody.

Highfield Gardens Care Center of Great Neck (New York):

- The facility was fined \$2,000 pursuant to Stipulation and Order NH-21-222 issued on 11/23/2021 for surveillance findings on 9/21/2021. Deficiencies were found under 10 NYCRR 415.19(a) Infection Control
- The facility was fined \$8,000 pursuant to Stipulation and Order NH21-050 issued on 3/13/2021 for surveillance findings on 1/7/2021. Deficiencies were found under 10 NYCRR sections 415.19(a) (1-2), 415.19 (b)(4), and 400.2 and Governors Executive Order 202.11. Deficiencies are for Infection Control, PPE, and Handwashing.
- The facility was fined \$2,000 pursuant to Stipulation and Order NH20-071 issued on 9/15/2020 for surveillance findings on 8/13/2020. Deficiencies were found under 10NYCRR sections 419.19(a)(1), 415.19(a)(2) Infection Control – Facemask.

Conclusion

The individual background review indicates the applicants have met the standard for approval as set forth in Public Health Law §2801-a(3). There will be no changes to beds or services as a result of this project.

Financial Analysis

Operating Budget

The applicant has provided an operating budget, in 2022 dollars, for the first and third years after the change of ownership. The budget is summarized below:

| | Current Year | | | | Year Three | |
|----------------------|--------------|-----------------------------|----------|------------------|------------|------------------|
| | | <u>(2020)</u> <u>(2023)</u> | | | 025) | |
| | Per Diem | <u>Total</u> | Per Diem | <u>Total</u> | Per Diem | <u>Total</u> |
| Inpatient Revenues | | | | | | |
| Commercial FFS | \$310.00 | \$17,360 | \$312.15 | \$1,936,900 | \$355.83 | \$2,207,900 |
| Medicare FFS | \$742.15 | 3,140,759 | \$728.32 | 4,039,268 | \$860.11 | 4,770,185 |
| Medicare MC | \$712.43 | 1,077,196 | \$728.28 | 1,383,732 | \$742.85 | 1,411,415 |
| Medicaid FFS | \$225.41 | 6,238,562 | \$239.83 | 6,094,942 | \$385.42 | 11,725,416 |
| Medicaid MC | \$225.41 | 2,135,084 | \$239.89 | 4,323,058 | \$23.90 | 430,684 |
| Private Pay | \$390.78 | 1,404,865 | \$390.19 | 1,936,900 | \$395.19 | 2,207,900 |
| Other* | | 278 | | 1,200 | | 1,200 |
| Medicare Part B | | <u>0</u> | | <u>249,600</u> | | <u>255,500</u> |
| Total Inpatient Rev. | | \$14,014,104 | | \$19,965,600 | | \$23,010,200 |
| | | | | | | |
| ADHCP Revenues | | | | | | |
| Commercial FFS | \$153.11 | \$23,732 | | | | |
| Medicaid FFS | \$152.47 | 128,071 | | | | |
| Private Pay | \$128.00 | <u>1,024</u> | | | | |
| Total Outpt Rev. | | \$152,827 | | | | |
| | | | | | | |
| Non-Oper. Rev. | | <u>3,352,235</u> | | | | |
| Total Revenues | | \$17,519,166 | | \$19,965,600 | | \$23,010,200 |
| <u>Expenses</u> | | | | | | |
| Operating Exp. | | \$17,526,520 | | \$14,039,397 | | \$16,254,298 |
| Capital Exp. | | 1,089,774 | | 5,672,532 | | 6,273,131 |
| Total Exp. | | \$18,616,194 | | \$19,711,929 | | \$22,427,429 |
| Total Exp! | | Ψ10,010,101 | | ψ.ο,: ::,o2o | | Ψ22, 121, 120 |
| Net Income/(Loss) | | (\$1,097,028) | | <u>\$253,671</u> | | <u>\$582,771</u> |
| Total Patient Days | | 46,543 | | 62,050 | | 69,350 |
| Total ADHCP Visits | | 1,003 | | 0 | | 0 |
| Occupancy (RHCF) | | 63.76% | | 85.00% | | 94.94% |

^{*}Other revenue is Investment income, contributed services, and general contributions.

The following is noted concerning the submitted budget:

- The Medicare and Private Pay rates are projected based on current market rates.
- ADCHP revenue and expenses are not included in Years One and Three as this will not be part of the future operation of the RHCF.
- Medicare utilization is expected to increase significantly in Years One and Three as the applicant plans to provide short-term rehabilitation resident service.
- The current year's Medicaid rate is based on the facility's current Medicaid experience.
- The budget indicates a plan to increase occupancy by working with hospitals, and community-based organizations and implementing a 24-hour-per-day admissions protocol to ensure easy access for discharge planners.

- The current year's occupancy is 63.76% due to the negative effects of COVID-19, but the facility is taking steps to increase occupancy. Pre-COVID-19 the facility's occupancy was at 83.2%, and the average occupancy for Westchester County was 84.6% as of 6/1/22.
- The applicant will add experienced staff to the facility to stabilize operations. The new operator will invest significant resources to market the facility effectively. This proposed marketing campaign will focus on communication and relationship building with area doctors, hospitals, and residents' family members regarding improvements made at the facility. The applicant states that similar marketing plans have been successful at the applicant's members' affiliated facilities.

Utilization by payor source is as follows:

| | RHCF | RHCF | RHCF |
|----------------|--------------|--------------|--------------|
| <u>Payor</u> | Current Yr. | Year 1 | Year 3 |
| Commercial FFS | .12% | 10.00% | 8.95% |
| Medicare FFS | 9.09% | 8.94% | 8.00% |
| Medicare MC | 3.25% | 3.06% | 2.74% |
| Medicaid FFS | 59.46% | 40.96% | 47.17% |
| Medicaid MC | 20.35% | 29.04% | 25.99% |
| Private Pay | <u>7.72%</u> | <u>8.00%</u> | <u>7.16%</u> |
| Total | 100% | 100% | 100% |

Asset Purchase Agreement

The applicant has submitted a draft Asset Purchase Agreement (APA) for the RHCF's operating interest. The terms of the agreement are summarized below:

| Date: | October 30, 2020 |
|--|--|
| Seller: | The Bethel Springvale Nursing Home, Inc. (Operations) |
| Buyer: | The Premier Center for Rehabilitation of Westchester, LLC (Operations) |
| Rate: | 6% Letter of interest has been submitted from Capital Funding, LLC |
| Purchased Assets: | Operational Assets: Operations seller's rights, title, and interest in every kind, nature, and description owned or leased in connection with the business; sellers rights to deposits relating to prepayments or prepaid expenses; complete copies of all personnel records and payroll information; any insurance claims and rights concerning injury, damage or loss related or arising from the Purchased Assets; rights, title, and interest in regards to providing services and proprietary information agreements related to the business; all the seller's books and records relating to the operations of the business and medical records; any funds held in trust by the seller in connection with the resident's funds. |
| Excluded Assets: (Operational & Real Property) | Contracts of Seller that are not assigned or assumed; Seller's Medicaid provider number or provider status; the Adult Day Care Program operated by Seller; Vehicles that the seller currently owns; retroactive reimbursements concerning Medicaid, or settlements and or adjustments. |
| Purchase Price: | \$8,000,000 for the operations. |
| Payment of Purchase Price: | The payout period is 36 months amortized over 25 years. A letter of interest has been provided to the Department for the purchase price. |

The applicant submitted a Medicaid affidavit, acceptable to the Department, where the applicant agrees, notwithstanding any agreement, arrangement, or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor under Article 28 of the Public Health Law concerning the period before the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of June 5, 2022, the facility has outstanding Medicaid liabilities totaling \$18,561, which will be added to working capital and, per the pro forma, paid out of operations.

Purchase and Sale Agreement (Realty)

The applicant has submitted an executed (Purchase and Sale Agreement) for the RHCF's Realty Purchase Agreement. The terms of the agreement are summarized below:

| Seller: | The Bethel Springvale Nursing Home, Inc. |
|----------------------------|--|
| Buyer: | 67 Springvale Nursing Home, LLC |
| Purchase Price: | \$32,000,000 |
| Rate: | 6% |
| Term: | 25 years. |
| Payment of Purchase Price: | Capital Funding, LLC has submitted a letter of interest. |
| Provisions: | Expected to be permanently refinanced through HUD 232/223F. If |
| | funding is not favorable, Sorah Bleier has provided an affidavit stating |
| | she will provide a balloon payment for the residual amount owed. |

This is a non-arm's length agreement between the parties as listed above in the narrative.

Lease Agreement

The applicant submitted a draft lease agreement for the RHCF, the terms are summarized as follows:

| Date: | To-Be-Determined |
|-------------|---|
| Premises: | 200-bed RHCF 67 Springvale Road, Croton-On-Hudson (Westchester County). |
| Landlord: | 67 Springvale Road, LLC |
| Tenant: | The Premier Center for Rehabilitation of Westchester, LLC |
| Term: | 10-year term |
| Rental: | \$4,500,000 annually, subject to an increase of 2% of the prior year's base rent, on each |
| | anniversary of the commencement date. |
| Provisions: | Lessee at its sole cost and expense will maintain, repair, or replace and restore the |
| | property to its original condition if necessary. Lessee shall not make alterations in the |
| | demised premises without the permission of Lessor. |

The Premier Center for rehabilitation of Westchester (Operations) has entered into a non-arm's length agreement with 67 Springfield Road, LLC (Realty), and The Premier Center for Rehabilitation of Westchester, LLC does have common ownership.

Capability and Feasibility

There are no project costs associated with this application. The total purchase price for the operating interest and realty acquisition is \$40,000,000; \$32,000,000 for the Real Estate, and \$8,000,000 for the operations. The Real Estate portion of the transaction will be met with a loan of \$32,000,000 over 25 years at a 6% interest rate, for which Capital Funding, LLC provided a letter of interest. The purchase price for acquiring the operating interests is \$8,000,000. The applicant submitted a draft APA for the purchase price of the facility operations at a rate of 6% for a 36-month term amortized over 25 years.

The working capital requirement is \$3,627,738, based on two months of first-year expenses. BFA Attachment A shows that the members have sufficient funds via member equity to satisfy the funding requirement. In addition, Sorah Bleier has submitted a disproportionate share affidavit to any member of The Premier Center for Rehabilitation of Westchester, LLC that cannot meet the equity requirements.

BFA Attachment B is the 2019-2020 certified financial statements and the November 30, 2021 Internal financial statements for the facility. The facility experienced a negative working capital and equity position for both periods. The facility showed an operating loss of \$1,776,120 in 2019 and \$1,097,028, in 2020. The internal financial statements show negative working capital, net asset positions, and an operating loss of \$161,708. These losses were driven by the negative effects of the COVID-19 pandemic. Before the pandemic, the facility planned to increase occupancy by working with providers seeking facility admissions, a robust marketing program that will also work with local hospitals, and a dedicated admissions team who will work with physician groups and groups to coordinate the continuation of patient care.

The submitted budget shows a projected net income of \$253,671 and \$582,771 for the first and third years. The budget appears reasonable. BFA Attachment C is the pro forma to the financial position on the first day of operations showing members' equity of \$3,657,000.

Attachment D is a financial summary using the certified financial statements for the affiliated facilities. Massapequa Center for Rehabilitation and Nursing (2021); Wedgewood Care Center, Inc (2020); and Leroy Village Green Residential Health Care Facility (2021) had positive working capital, working capital, and net income position. Sunset Nursing and Rehabilitation (2020) had negative working capital and net asset position and incurred an operating loss of \$1,250,219 due to the COVID-19 pandemic and increasing operating expenses.

Conclusion

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

Attachments

| LTCOP Attachment A | Long Term Care Ombudsman Program Recommendation |
|--------------------|--|
| BFA Attachment A | Net Worth-Operations - The Premier Center for Rehabilitation of Westchester |
| | Net Worth- Realty- 67 Springvale Road, LLC, (Realty Interest) |
| BFA Attachment B | Bethel Springvale Nursing Home Inc. 2019-2020 Certified Financial Statements |
| | and 2021 Internal Financial Statement |
| BFA Attachment C | Pro Forma Balance Sheet |
| BFA Attachment D | Affiliated Residential Health Care Facilities. |

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 8th day of December 2022, 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 The Premier Center for Rehabilitation of Westchester, LLC as the new operator of Bethel Nursing and Rehabilitation Center, a 200-bed residential health care facility located at 67 Springvale Road, Croton-On-Hudson, 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:

211087 E The Premier Center for Rehabilitation of

Westchester, LLC d/b/a Springvale Nursing and

Rehabilitation Center

APPROVAL CONTINGENT UPON:

- 1. Submission of an executed commitment for the purchase of the realty, acceptable to the Department of Health. [BFA]
- 2. Submission of an executed commitment for the purchase of the operations, acceptable to the Department of Health. [BFA]
- 3. Submission of an executed lease agreement acceptable to the Department. [BFA]
- 4. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR].
- 5. Submission of a plan to continue to enhance access to Medicaid residents. At a minimum, the plan should include, but not necessarily be limited to, ways in which the facility will: a. Reach out to hospital discharge planners to make them aware of the facility's Medicaid Access Program; b. Communicate with local hospital discharge planners on a regular basis regarding bed availability at the nursing facility; and identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility and inform them about the facility's Medicaid Access policy, and c. Identify community resources that serve the low-income and frail elderly population who may eventually use the nursing facility and inform them about the facility's Medicaid Access policy. [RNR]
- 6. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]
- 7. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of Bethel Op Holdings LLC, acceptable to the Department. [CSL]
- 8. Submission of a photocopy of an executed Certificate of Amendment of the Articles of Organization of JSB Bethel Holdings LLC, acceptable to the Department. [CSL]
- 9. Submission of photocopy of an amended and executed Second Amendment of the Operating Agreement of The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]
- 10. Submission of an executed Lease Agreement between 67 Springvale Road LLC and The Premier Center for Rehabilitation of Westchester, LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by one year from the date of the recommendation letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [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*.