

State of New York
Public Health and Health Planning Council

Minutes
August 8, 2019

The meeting of the Public Health and Health Planning Council was held on Thursday, August 8, 2019 at the New York State Department of Health Offices, 90 Church Street, 4th Floor CR 4 A/B, NYC. Chairman Jeffrey Kraut presided.

COUNCIL MEMBERS PRESENT

Ms. Judy Baumgartner – via video Buffalo	Dr. Glenn Martin
Dr. Howard Berliner	Ms. Ann Monroe
Dr. Jo Ivey Boufford	Dr. Mario Ortiz
Dr. Lawrence Brown	Mr. Peter Robinson
Ms. Carver-Cheney – via video Albany	Dr. John Ruge
Dr. Angel Gutiérrez	Mr. Hugh Thomas – via video Rochester
Dr. Gary Kalkut	Dr. Anderson Torres
Mr. Jeffrey Kraut	Dr. Kevin Watkins
Mr. Scott La Rue	Dr. Patsy Yang
Mr. Harvey Lawrence	Ms. Sally Dreslin – Ex-officio

DEPARTMENT OF HEALTH STAFF PRESENT

Ms. Deirdre Astin – via video Albany	Ms. Marthe Ngwashi
Ms. Barbara DelCogliano – via video Albany	Mr. Mark Noe – via video Albany
Ms. Alejandra Diaz	Ms. Laura Palmer
Ms. Shelly Glock	Ms. Tracy Raleigh
Mr. Mark Furnish – via video Albany	Ms. Laura Santilli
Mr. Brad Hutton – via video Albany	Ms. Lisa Thomson
Mr. Mark Kissinger – via video Albany	Mr. John Walters – via video Albany
Ms. Colleen Leonard	Ms. Kristin Wheeler
Mr. George Macko – via video Albany	
Mr. Nicholas Mestoik	

INTRODUCTION

Mr. Kraut called the meeting to order and welcomed Council members, Ms. Dreslin, meeting participants and observers.

WELCOME NEW MEMBERS MS. MONROE AND DR. ORTIZ

Mr. Kraut announced Ms. Monroe and Dr. Ortiz have been appointed as new members of the Council and introduced and welcomed them to the Council. See pages 2 through 4 of the transcript.

APPROVAL OF THE MINUTES OF JUNE 6, 2019

Mr. Kraut asked for a motion to approve the June 6, 2019 Minutes of the Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval which was seconded by Dr. Kalkut. The minutes were unanimously adopted. Please refer to page 5 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Mr. Kraut introduced Ms. Dreslin who was participating from Albany to give a report on the Department of Health report

Measles

Ms. Dreslin began her report by stating the public health response to measles remains a priority for the Department and continues to manage the outbreak in the lower Hudson Valley. As of August 2, 2019, the Department confirmed the following numbers of measles cases in New York, outside of New York City in New York State. 290 in Rockland County, 55 in Orange County, 18 in Westchester County, and 14 in Sullivan County. Although this has been the State's largest and longest lasting measles outbreak in decades, the Department is starting to see a light at the end of the tunnel. Since the beginning of the outbreak last fall, local providers have administered more than 65,000 doses of MMR vaccine in Rockland, Orange, Westchester, and Sullivan Counties. That is a 70 percent increase in MMR vaccine administration in those counties over the same timeframe from last year. As of August 1, 2019, the CDC reported that 30 states had confirmed more than 1100 cases of measles. Inadequate levels of vaccination have become a nationwide problem that states do need to address. Governor Cuomo signed legislation in June to improve New York's already high immunization rates to prevent the kinds of outbreaks that we are seeing in the lower Hudson Valley, and in New York City. The legislation eliminates all non-medical exemptions for childhood vaccinations that are required for public, private, and parochial schools and daycares. Under the new law, children who were not previously vaccinated will have 14 days from the first day of school or daycare to receive the first age appropriate dose and each immunization and then they will have 30 days from the first day of school to schedule their follow up appointments and then the series are expected to be administered according to the guidelines from CDC. The scheduled appointments need to happen. In addition, in light of national immunization awareness month, the Department has just launched a new public service announcement, a set of campaigns to help promote vaccination as school starts next month. It is a big push not just for MMR, but also for immunizations against human papilloma virus, HPV. While HPV is not required for school attendance. Is highly recommended to protect adolescents in New York State against certain cancers. Students also

need the Tetanus, Diphtheria, Whooping Cough, the Tdap and meningitis vaccines. And anyone living in crowded quarters such as college dormitories, military quarters, should certainly consider receiving a meningitis vaccine. And with flu season right around the corner, we're recommending that fall is a perfect time to start getting your 19-20 flu vaccine.

Maternal Mortality

Ms. Dreslin stated the Department continues to focus on maternal mortality. In the Budget there is a \$8 million investment over two years to fund initiatives to combat maternal mortality. Governor Cuomo expanded on this key component of his women's agenda by signing legislation to create the Maternal Mortality Review Board. The Board will review the cause of each maternal death in New York State and made recommendations to the Department on strategies for preventing future deaths and improving overall health outcomes. This oversight and data analysis will help us address racial disparities in our society that can all too often lead to tragedy. In addition, there is momentum nationally to standardize maternal mortality data from state to state and to share both data and insights. With this new Board, New York State will be very involved in that effort.

Drinking Water Quality

Ms. Dreslin advised that in August, the Department took another significant step forward in addressing drinking water quality when Commissioner Zucker accepted the New York State Drinking Water Quality Council's recommendations for maximum contaminant levels in drinking water for three emerging contaminants; PFOA, PFOS, and 1-4 Dioxane. The levels of 10 parts per trillion for PFOA, 10 parts per trillion for PFOS, and 1 part per billion for 1-4 Dioxane is the nation's ... the 1-4 Dioxane level is the nation's first ever level set for that contaminant. Ensuring the delivery of clean drinking water is critical to the public health and well-being of all New Yorkers and has been a primary focus of the Department's work. The regulatory process for adopting these enforceable standards is underway and the Department is in the process of receiving public comments. The Department looks forward to working with PHHPC on this important process in the coming months to ensure that we are regularly testing water systems before there is ever a public health risk in any part of the state.

Ms. Dreslin also stated that the Governor also announced that \$350 million is now available through the Water Infrastructure Improvement Act and the IntraMunicipal Water Infrastructure grant program for municipalities with infrastructure project that protect the public health or improve water quality. To compliment these initiatives, the Department of Health and the Department of Environmental Conservation just last week launched a new map-based website. It's called "Know your New York water." It will provide information about the State's public drinking water and health of its lakes, rivers, and streams and other water bodies that are used for recreation and habitat protection. This valuable service derives from the work of the statewide water quality rapid response team and was created in partnership with the state Office of Information Technology Services. With this interactive site, New Yorkers can find the nearest large public drinking water system and view their localities and drinking water quality report and

contact information. New Yorkers on public water supplies will continue to receive the annual drinking water quality reports that their water suppliers provide. This online tool will make it easier to access that information and have it all in one place.

Statewide Healthcare Facility Transformation Program

Ms. Dreslin informed the Council members that in July, the Governor announced \$187 million in funding to support 25 statewide projects that will protect and transform New York State's healthcare system. This funding from the statewide healthcare facility transformation program will improve patient care into the development of high-quality medical facilities and programs serving inpatient primary care, substance abuse disorder and long term care needs of communities throughout the state. The 2019-20 state budget amendment to the statewide healthcare facility transformation program authorized the Department to allocated funds to support project applications that had not been awarded during the previous round of funding that was announced in February 2019. This is an initial round of new funding and we're going to be announcing some additional works in the coming weeks.

Affordable Care Act

Ms. Dreslin noted that one of the most important items in the 19-20 state budget was the codification of key provisions of the affordable care act and the New York State of Health, New York's health insurance marketplace, into New York State law to protect New Yorkers essential health benefits and prohibit the denial of insurance coverage for those with preexisting conditions. This summer the Department has been vigilant in fending off any threats to these protections from Washington while continuing to educate New Yorkers on their options including New York State of Health. The Department joined other state agencies in submitting comments in opposition to the US Department of Health and Health and Human Services proposed rollback of healthcare protections for transgender and gender non-conforming individuals by limiting the types of insurance that must comply with the affordable care act's non-discrimination protections. This spring, New York celebrated legislation protecting the rights of the LGBT community including passage of the gender expression non-discrimination act agenda banning conversion therapy and eliminating the gay and trans panic defense. Defending the healthcare rights of transgender and gender non-conforming individuals is an extension of our commitment to justice for all.

Ms. Dreslin stated the Governor announced a plan to benefit children throughout the state with complex health needs. This proposal for a new Medicaid model care for such children has been approved by the federal CMS. The new streamline care model will improve access to Medicaid services and expand Medicaid coverage for home community-based care for more than 6000 youth under age 21 who are faced with an array of serious health problems.

Ms. Dreslin noted that the Department is reaching out to New Yorkers at summer fun spots like free learn to swim programs, and farmers markets to inform and educate them about low-cost, high-quality healthcare coverage. At the end of this year's open enrollment in January,

data showed the enrollment across the marketplace programs all of the marketplace programs increased by more than 435,000 people from 2018 and we aim to do even better in 2020. This summer has seen a lot of positive movement in public health protections that the Department has had as priorities for some time now, and we're excited about the progress and we look forward to updating you on other new legislation and the new initiatives preceding in the months ahead.

Ms. Dreslin concluded her report. To read the complete report and questions from the Members, please see pages 5 through 15 of the attached transcript.

Office of Public Health Activities

Mr. Kraut introduced Mr. Hutton to give the Office of Public Health report.

Mr. Hutton began his report by giving an update on lead poisoning prevention. The Department recently submitted proposed amendments to New York State regulations that would lower the definition of an elevated blood lead level in a child from 10 to 5, and we recently completed our public comment period, received 20 comments on the proposed regulations from local health departments, different advocacy organizations and elected officials, and we're right in the midst of reviewing all those comments and preparing our assessment of public comment. The Lead Poisoning Prevention Advisory Council met. The Department is working hard to implement this new legislation which lowers the blood lead level, and there are lots of different trainings and webinars, guidance for healthcare providers, lots of activity here in the coming months because the effective date of the legislation is October 1, 2019 when we will begin having children identified at lowered levels, with blood lead levels and enrolled in environmental management and case management to try and address those levels.

Mr. Hutton reported that the Department recently announced awards for the second round of lead service line replacement program. This is unique program in state health departments whereby we were providing in this case \$10 million to 18 municipalities around the state. The awards are approximately a half million dollars for each municipality and it allows them to go to residents that have leaded lines that could be contributing to those lead exposures and essentially replace the lines for them. This is made possible through the New York's Clean Water Infrastructure Act which is now \$3 billion in capital funding to provide safe drinking water and other clean waste water.

Mr. Hutton advised that recently there was a cyclophorias outbreak in the Capital District, but also in New York and other parts of the nation. This is a good example of the hard work that goes on to protect our food supply. And in this instance, we were seeing a pretty dramatic increase in cases of cyclophorias in New York and identified through some great collaboration with four local health departments and New York State Agriculture and Markets identified some commonalities as a result of the disease interviews that happen among people who have been infected, and then through some environmental detective work that identifies commonalities in the invoices among restaurants. Ultimately identified a highly suspect food item. In this case it was imported basil, and along with the work at the federal level and other states, it resulted in the announcement of FDA a couple of weeks ago of the voluntary recall of

specific basil that was made in a specific vendor across the border. The Department always has several food investigations that they are participating in along with colleagues in other states.

Lastly, Mr. Hutton shared that the Department continues to have meetings of the Health Across All Policies Workgroup. This is a group that Dr. Boufford has been passionate about. It's an interagency group with colleagues in our colleague agencies, Dr. Zucker and Mr. Francis, the Deputy Secretary for Health are very well engaged. There was another interagency meeting at the end of July to continue moving that work forward.

Mr. Hutton concluded his report, to view the members discussion please see pages 15 through 29 of the attached transcript.

REGULATION

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

Report of the Committee on Codes, Regulation and Legislation

For Adoption

18-24 Amendment of Sections 415.2 and 415.3 of Title 10 NYCRR (Residents' Rights)

Dr. Gutiérrez described for adoption the proposed Amendment of Sections 415.2 and 415.3 of Title 10 NYCRR (Residents' Rights) and motioned for approval. Dr. Watkins seconded the motion. The motion to adopt carried. Please see pages 29 and 30 of the attached transcript.

For Information

19-07 Amendment of Sections 405.7 and 751.9 of Title 10 NYCRR
(Patients' Bill of Rights)

19-18 Amendment of Sections 405.5 and 405.19 of Title 10 NYCRR (Registered Nurses in the
Emergency Department)

19-04 Amendment of Subpart 5-1 of Title 10 NYCRR (Maximum Contaminant Levels (MCLs))

Dr. Gutiérrez described for information Amendment of Sections 405.7 and 751.9 of Title 10 NYCRR (Patients' Bill of Rights), Amendment of Sections 405.5 and 405.19 of Title 10 NYCRR (Registered Nurses in the Emergency Department), and Amendment of Subpart 5-1 of Title 10 NYCRR (Maximum Contaminant Levels (MCLs)). Please see pages 30 through 32 of the transcript.

HEALTH POLICY

Mr. Kraut then moved to the next item on the agenda and introduced Dr. Ruge to give the activities Report of the Committee on Health Planning.

Dr. Ruge concluded his report. To review the complete report, see pages 32 through 75 of the attached transcript.

Mr. Kraut then moved to the next item on the agenda and 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

Dr. Gary Kalkut, Vice Chair, Establishment and Project Review Committee

A. APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Residential Health Care Facilities - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191132 C	Canterbury Woods (Erie County)	Contingent Approval

Dr. Kalkut called application 191132 and motioned for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 75 of the 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

Acute Care Services - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191174 C	Memorial Hospital for Cancer and Allied Diseases (Westchester County) Mr. Kraut - Interest	Contingent Approval

Ambulatory Surgery Centers - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191215 C	Syracuse Surgery Center (Onondaga County) Mr. Kraut - Interest	Contingent Approval

Diagnostic and Treatment Centers - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191147 C	New York Hotel Trades Council and Hotel Association of New York City Health Center (Kings County) Mr. Kraut - Interest	Contingent Approval

Dr. Kalkut calls application 191174, 191215, and 191147 and notes for the record that Mr. Kraut has declared an interest on both applications. Dr. Kalkut motions for approval, Dr. Gutiérrez seconds the motion. The motion carried with Mr. Kraut’s noted interests. Please see pages 75 and 76 of the transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

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

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

B. APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Ambulatory Surgery Centers – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
182236 B	Precision SC, LLC d/b/a PrecisionCare Surgery Center (Suffolk County)	Contingent Approval
191095 B	Hauppauge SC, LLC d/b/a The Center for Advanced Spine and Joint Surgery (Suffolk County)	Contingent Approval
191237 E	PBGS, LLC (Kings County)	Contingent Approval

Dr. Kalkut called applications 182236, 191095, and 191237 and motioned for approval. Dr. Gutiérrez seconded the motion. The motion to approved carried. Please see pages 77 and 78 of the transcript.

Dialysis Services – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
182296 B	Novo Dialysis Flatlands, LLC (Kings County)	Contingent Approval
191077 B	Cobble Hill Dialysis (Kings County)	Contingent Approval

Dr. Kalkut introduced applications 182296 and 191077 and motioned for approval. Dr. Torres seconded the motion. The motion to approve carried. See pages 79 and 80 of the attached transcript.

Certificates

Certificate of Dissolution

<u>Applicant</u>	<u>Council Action</u>
Jewish Care Services of Long Island, Inc.	Approval

Certificate of Amendment of the Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
The Eastern Long Island Hospital Association	Approval
Rochester Primary Care Network, Inc.	Approval
Columbia-Greene Hospital Foundation	Approval

Restated Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
Carthage Area Hospital, Inc.	Approval

Amended and Restate Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
HealthCare Choices NY, Inc.	Approval

Dr. Kalkut called for consent to file certificates for the above listed entities and motioned for approval. Dr. Gutiérrez seconded the motion. The motion to approve passed. Please see pages 80 through 82 of the 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>	<u>Applicant/Facility</u>	<u>Council Action</u>
191189 B	UWS ASC, LLC (New York County) Dr. Martin - Recusal	Contingent Approval

Next, Dr. Kalkut called application 191189 and noted for the record that Dr. Martin has a conflict and has exited the meeting room. Dr. Kalkut motioned for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried with Dr. Martin’s recusal. Dr. Martin returned to the meeting room. See pages 82 and 83 of the attached transcript.t

CATEGORY 3: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

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

CON Applications

Dialysis Services – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191136 E	Cowley Dialysis, LLC d/b/a Hutchinson River Dialysis (Bronx County) Mr. Kraut – Interest Dr. Gutiérrez - Opposed	Contingent Approval

Dr. Kalkut introduced application 191136 and noted for the record that Mr. Kraut has an interest. Dr. Kalkut motions for approval, Dr. Boufford seconds the motion. The motion to approve carried with one member opposing the application. Please see pages 83 through 85 of the attached transcript.

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

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

CON Applications

HOME HEALTH AGENCY LICENSURES

Affiliated with Assisted Living Program (ALPs)

182301 E	Brookhaven Home Care, LLC (Suffolk County)	Contingent Approval
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191097 E	Oyster Bay Manor Home Care, Inc. (Nassau County)	Contingent Approval
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Changes in Ownership with Consolidation

191210 E	Supportive Home Care, LLC d/b/a Care365 Homecare (Kings County)	Approval
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Lastly, Dr. Kalkut called applications 182301, 191097, and 191210 and motioned for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. See pages 85 through 87 of the transcript.

Dr. Kalkut concluded his report.

ADJOURNMENT:

Mr. Kraut announced the upcoming PHHPC meetings and adjourned the meeting.

1 NEW YORK STATE DEPARTMENT OF HEALTH
2 PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
3 AUGUST 8, 2019
4 FULL COUNCIL TRANSCRIPT
5 90 CHURCH STREET, 4TH FLOOR CR 4A/B, NYC
6

7 JEFF KRAUT: Is this to follow?

8 So we can start the reports. I think I'll start the meeting
9 out of deference to some travel plans for people in the
10 afternoon. And what's my quorum number? And how many do I have?
11 Sally, you there? And so, and I just.... Let me just open the
12 meeting then I'll acknowledge who's in the remote rooms and
13 stuff like that.

14 Good morning. I'm Jeff Kraut and I have the privilege to
15 call to order the meeting of the health and health planning
16 council and welcome members, executive deputy commissioner
17 Dreslin, participants and observers. I'd like to remind the
18 council members, staff, and the audience, the meeting is subject
19 to the open meetings law and is broadcast over the internet. The
20 webcast can be accessible from <http://www.nyhealth.gov>. these
21 online demand webcasts will be available no later than seven
22 days after the meeting for a minimum of 30 days and then a copy
23 will be retained in the Department for up to four months. Just
24 some ground rules that you should all be aware of. We do

1 synchronized captioning. You can't speak over each other. It's
2 hard to do that when two people speak at the same time. The
3 first time you speak, if you could state your name and briefly
4 identify yourself as a council member, a DOH staff. This will
5 be helpful. And note that the microphones are hot, as you can
6 hear in Albany. They pick up every sound and try to avoid the
7 rustling of papers next to the microphone and be sensitive about
8 side personal conversations. They will pick that up. As a
9 reminder to our audience, there's a form that needs to be filled
10 out before you enter the meeting room which records your
11 attendance at meetings. It's required by the joint commission on
12 public ethics in accordance with executive law section 166. The
13 form is also posted on the Department of Health's website under
14 nyhealth.gov under the certificate of need tab. So in the future
15 you could fill out the form prior to attending the council
16 meeting, so appreciate your cooperation in fulfilling our
17 duties. Today, we have joining us in, I guess Rochester - Thomas
18 and in Buffalo is Judy Baumgartner. And is anybody in the
19 Albany office? Albany is Kathleen Carver-Cheney along with
20 members of the staff. Before we begin today's meeting I just
21 want to announce that Governor Cuomo has appointed Ann Monroe
22 and Dr. Mario Ortiz to serve as members of the council. I'll
23 talk a little about them in a minute. Ms. Monroe is going to be
24 serving on the establishment and project review committee and

1 the public health committee. Dr. Ortiz is going to be serving
2 on the health planning committee, the public health committee,
3 and the committee on health personnel and interprofessional
4 relationships. Now, we're so fortunate that you guys have both
5 been accepted, that you've accepted the invitation to join and
6 you've made it through the gauntlet that gets you into this room
7 as each one of us know it's quite daunting. And Dr. Ortiz is
8 Dean and professor of Nursing at Binghamton's Decker School of
9 Nursing. He's the Executive Director of the Kresky Center for
10 nursing research. He's board certified in community and public
11 health nursing as his specialty, and he's a family nurse
12 practitioner. He's a recognized expert in nursing research,
13 practice, and health policy, and I think that background will
14 add a lot to our conversations and thoughts and the dean of my
15 nursing school said be sure to also tell everybody that in 2018
16 he received the best article award in the Nursing Science
17 Quarterly. So, a required... so we thank you for that. And Ann
18 Monroe has kind of been active in the state in a lot of - you,
19 could you hold off? We're picking up your side conversations.
20 No, we were just picking up your side conversation. And Ann,
21 thank you. Ann has so many activities. She serves on the AARP
22 executive committee, she was formerly the head of the Health
23 Foundation of Western New York. Started her life in quality
24 initiatives at the California Healthcare Foundation. She serves

1 on the Medicare Resign [sic] team, the oversight board of DSRIP,
 2 and I serve with Ann on the New York E-Health collaborative for
 3 the interoperability of data. She's on the national coalition to
 4 transform advance care, and the board of grant makers in aging.
 5 Ann has just kind of a boots on the ground community-based
 6 advocacy perspective that were so glad that you're going to join
 7 us and we know both you and Dr. Ortiz are going to add a lot of
 8 conversation and perspective to the council's deliberations, and
 9 I think the expertise, both of you have are really going to be
 10 very helpful. And again, most thankful - I hope everybody
 11 afterwards has an opportunity to introduce themselves to get to
 12 know, and we're going to have a more formal kind of orientation
 13 session. We did a quick one over the phone; we'll do a little
 14 more detailed one in October 10. Right? So we'll go through
 15 some of the... but by that time you'll be fully up to speed. You
 16 won't need it. So on behalf of the council I welcome you and
 17 look forward, we all look forward to working with you and thank
 18 you again.

19 Today we're going to hear from executive deputy
 20 commissioner Dreslin, who will provide a report on the
 21 Department of Health. Mr. Hutton is going to give us an update
 22 on the Office of Public Health. Mr. Sheppard was called away, is
 23 not going to be able to join us, but between Sally and Brad
 24 we'll have opportunities to hear about what's happening up at

1 Department. And then Dr. Gutierrez will present regulations for
2 information and adoption followed by Dr. Rugge giving us an
3 update on the planning committee, and then we'll move to the
4 establishment and project review committee with Dr. Kalkut and
5 Mr. Robinson providing some things.

6 So members of the council and most of our guests who
7 regularly attend the meetings are now familiar with the
8 organization of the agenda. We've organized these by topics and
9 categories which capture our roles and responsibilities, and as
10 a consequence, we've batched the CON applications prior to us
11 calling those applications. Take time. Take a look at how we
12 batch them. If there's any specific project you'd like to remove
13 from a batch, let us know before we get rolling, and just let
14 Colleen know and she'll let us know. The next agenda item is,
15 I'm going to ask for adoption of the minutes. Can I have a
16 motion to adopt the minutes of the June 6, 2019 PHHPC minutes? I
17 have a motion by Dr. Brown. I have second, Dr. Kalkut. All those
18 in favor?

19

20 [Aye]

21 Ok. And now I'm going to turn it over to Ms. Dreslin who is
22 going to update us about the Department's activities since our
23 last meeting.

24

1 SALLY DRESLIN: I'm very glad to be here with you today. On
2 behalf of Dr. Zucker and apologies for not being able to be in
3 New York City today with the bulk of the members, but I have a
4 member with me so that's excellent. I'll get right to updating
5 you on the activities since we last met in June. Our public
6 health response to measles remains a priority for the Department
7 as we continue to manage the outbreak in the lower Hudson
8 Valley. As of August 2, the Department confirmed the following
9 numbers of measles cases in New York, outside of New York City
10 in New York State. So, 290 in Rockland County, 55 in Orange
11 County, 18 in Westchester County, and 14 in Sullivan County. And
12 although this has been the State's largest and longest lasting
13 measles outbreak in decades, it think we're starting to see a
14 light at the end of the tunnel. So a lot of hard work.

15 Since the beginning of the outbreak last fall, local
16 providers have administered more than 65,000 doses of MMR
17 vaccine in Rockland, Orange, Westchester, and Sullivan Counties.
18 That's a 70 percent increase in MMR vaccine administration in
19 those counties over the same timeframe from last year. As of
20 August 1, the CDC reported that 30 states had confirmed more
21 than 1100 cases of measles. Inadequate levels of vaccination has
22 become a nationwide problem that states do need to address.
23 We've learned a lot from this 10-month experience including an
24 idea of returning to the status quo after the resolution of the

1 outbreak is no longer tenable. And that's why Governor Cuomo
 2 signed the legislation in June to improve New York's already
 3 high immunization rates to prevent the kinds of outbreaks that
 4 we're seeing in the lower Hudson Valley, and in New York City.
 5 The legislation eliminates all non-medical exemptions for
 6 childhood vaccinations that are required for public, private,
 7 and parochial schools and daycares. Under the new law, children
 8 who were not previously vaccinated will have 14 days from the
 9 first day of school or daycare to receive the first age
 10 appropriate dose and each immunization and then they'll
 11 have 30 days from the first day of school to schedule their
 12 follow up appointments and then the series are expected to be
 13 administered according to the guidelines from CDC. But those
 14 scheduled appointments need to happen. In addition, in light of
 15 national immunization awareness month, the Department has just
 16 launched a new public service announcement, a set of campaigns
 17 to help promote vaccination as school starts next month. It's a
 18 big push not just for MMR, but also for immunizations against
 19 human papilloma virus, HPV. While HPV is not required for school
 20 attendance, the two (inaudible)
 21 Is highly recommended to protect adolescents in New York State
 22 against certain cancers. Students also need the Tetanus,
 23 Diphtheria, Whooping Cough, the Tdap and meningitis vaccines.
 24 And anyone living in crowded quarters such as college

1 dormitories, military quarters, should certainly consider
2 receiving a meningitis vaccine. And with flu season right around
3 the corner, we're recommending that fall is a perfect time to
4 start getting your 19-20 flu vaccine.

5 As you know, the Department works to address racial
6 disparities and health outcomes, and one of the most significant
7 disparate outcomes we're focused on is maternal mortality. Under
8 the budget highlights I mentioned in April is an \$8 million
9 investment over two years to fund initiatives to combat maternal
10 mortality. Just last week, Governor Cuomo expanded on this key
11 component of his women's agenda by signing legislation to create
12 the maternal mortality review board. The board will review the
13 cause of each maternal death in New York State and made
14 recommendations to the Department on strategies for preventing
15 future deaths and improving overall health outcomes. This
16 oversight and data analysis will help us address racial
17 disparities in our society that can all too often lead to
18 tragedy. In addition, there's momentum nationally to standardize
19 maternal mortality data from state to state and to share both
20 data and insights. And with this new board New York State will
21 be very involved in that effort.

22 Last month, the Department took another significant step
23 forward in addressing drinking water quality when Commissioner
24 Zucker accepted the New York State Drinking Water Quality

1 Council's recommendations for maximum contaminant levels in
2 drinking water for three emerging contaminants; PFOA, PFOS, and
3 1-4 Dioxane. The levels of 10 parts per trillion for PFOA, 10
4 parts per trillion for PFOS, and 1 part per billion for 1-4
5 Dioxane is the nation's ... the 1-4 Dioxane level is the nation's
6 first ever level set for that contaminant. Ensuring the delivery
7 of clean drinking water is critical to the public health and
8 well-being of all New Yorkers and has been a primary focus of
9 the Department's work in all (inaudible)
10 The regulatory process for adopting these enforceable standards
11 is underway and we're in the process of receiving public
12 comments. We look forward to working with PHHPC on this
13 important process in the coming months to ensure that we are
14 regularly testing water systems before there is ever a public
15 health risk in any part of the state. The Governor also
16 announced that \$350 million is now available through the Water
17 Infrastructure Improvement Act and the IntraMunicipal Water
18 Infrastructure grant program for municipalities with
19 infrastructure project that protect the public health or improve
20 water quality. To compliment these initiatives, the Department
21 of Health and the Department of Environmental Conservation just
22 last week launched a new map-based website. It's called "Know
23 your New York water." And it's going to provide - it provides
24 information about the state's public drinking water and health

1 of it's lakes, rivers, and streams and other water bodies that
2 are used for recreation and habitat protection. This valuable
3 service derives from the work of the statewide water quality
4 rapid response team and was created in partnership with the
5 state Office of Information Technology Services. With this
6 interactive site, New Yorkers can find the nearest large public
7 drinking water system and view their localities and drinking
8 water quality report and contact information. New Yorkers on
9 public water supplies will continue to receive the annual
10 drinking water quality reports that their water suppliers
11 provide. This online tool will make it easier to access that
12 information and have it all in one place.

13 In July the Governor announced \$187 million in funding to
14 support 25 statewide projects that will protect and transform
15 New York State's healthcare system. This funding from the
16 statewide healthcare facility transformation program will
17 improve patient care into the development of high quality
18 medical facilities and programs serving inpatient primary care
19 (inaudible) substance abuse disorder and long term care needs of
20 communities throughout the state. The 2019-20 state budget
21 amendment to the statewide healthcare facility transformation
22 program authorized the Department to allocated funds to support
23 project applications that had not been awarded during the
24 previous round of funding that was announced in February 2019.

1 This is an initial round of new funding and we're going to be
2 announcing some additional works in the coming weeks.

3 One of the most important items in the 19-20 state budget
4 was the codification of key provisions of the affordable care
5 act and the New York State of Health, New York's health
6 insurance marketplace, into New York State law to protect New
7 Yorkers essential health benefits and prohibit the denial of
8 insurance coverage for those with preexisting conditions. This
9 summer the Department has been vigilant in fending off any
10 threats to these protections from Washington while continuing to
11 educate New Yorkers on their options including New York State of
12 Health. This week the Department joined other state agencies in
13 submitting comments in opposition to the US Department of Health
14 and Health and Human Services proposed rollback of healthcare
15 protections for transgender and gender non-conforming
16 individuals by limiting the types of insurance that must comply
17 with the affordable care act's non-discrimination protections.
18 This spring, New York celebrated legislation protecting the
19 rights of the LGBT community including passage of the gender
20 expression non-discrimination act agenda banning conversion
21 therapy and eliminating the gay and trans panic defense.
22 Defending the healthcare rights of transgender and gender non-
23 conforming individuals is an extension of our commitment to
24 justice for all.

1 Also this week, the Governor announced a plan to benefit
2 children throughout the state with complex health needs. This
3 proposal for a new Medicaid model care for such children has
4 been approved by the federal CMS. The new streamline care model
5 will improve access to Medicaid services and expand Medicaid
6 coverage for home community-based care for more than 6000 youth
7 under age 21 who are faced with an array of serious health
8 problems.

9 And finally, while the 2019 open enrollment period for
10 qualified health plan has ended, we have been using the vacation
11 months - for some I hear there's vacation - to reach out to New
12 Yorkers at summer fun spots like free learn to swim programs,
13 and farmers markets to inform and educate them about low-cost,
14 high-quality healthcare coverage. We're planning for next year's
15 open enrollment and we want New Yorkers to do the same. At the
16 end of this year's open enrollment in January, data showed the
17 enrollment across the marketplace programs all of the
18 marketplace programs increased by more than 435,000 people from
19 2018 and we aim to do even better in 2020. So this summer has
20 seen a lot of positive movement in public health protections
21 that the Department has had as priorities for some time now, and
22 we're excited about the progress and we look forward to updating
23 you on other new legislation and the new initiatives preceding
24 in the months ahead. Thank you.

1

2 JEFF KRAUT: Thank you. Are there questions? Howard.

3

4 HOWARD BERLINER: Commissioner, can you tell us any
5 progress that's been made on DSRIP 2.0 and where that's going
6 hopefully?

7

8 SALLY DRESLIN: ... we certainly are proud and recognize the
9 of DSRIP and are working to understand the best way to move
10 forward with that. And there will ultimately be an engagement
11 process, obviously, that's how we did DSRIP originally. We're
12 still in the development phases at this point.

13

14 HOWARD BERLINER: Would it be possible for us to get a
15 presentation maybe in the fall or when you've got, when you're
16 closer to an actual proposal?

17

18 SALLY DRESLIN: Absolutely.

19

20 JEFF KRAUT: Ok, so, just to remember to put that on the
21 agenda list for the fall. Yes, Dr. Brown.

22

23 LAWRENCE BROWN: Lawrence Brown, Council member.
24 Commissioner, can you provide us at some point some information

1 that we've heard some, there's been some reports at the federal
2 level that there's been the first time a drop in the number of
3 overdoses nationally. There's some evidence to suggest that. Can
4 you share with us what's happened in New York State, I guess, in
5 consultation with OASAS about how that has been, any reflection
6 in New York State given the fact there's been some expansion
7 naloxone and I certainly would encourage more expansion of that,
8 since there's virtually very little, any reports of any adverse
9 event associated with that. So, it'd be useful, can we hear more
10 about how the Department of Health has actually collaborated
11 with OASAS to in fact continue to address the opiate overdose?

12

13 SALLY DRESLIN: I think I got most of the question. But I'll
14 just start by saying there is a tremendous amount of
15 collaboration between the Department of Health and OASAS. And we
16 have -- so the first part of your question had to do with what
17 we're seeing as nationwide decline in the number of overdoses I
18 believe and we have seen that as well in New York State. We post
19 both our annual overdose reports but we post quarterly reports
20 as well. I believe that last quarterly report might've been in
21 the very beginning of July. Now, that's now final data, and
22 we've put a lot of cautionary words around that data because
23 it's sort of initial non-confirmed because it's coming out so
24 quickly. We much more rely on the annual reports that come out

1 to show us the firm trends, but we are seeing as well, what
2 looks like a reduction which is fantastic, and I think it's a
3 demonstration of the (inaudible) that we had with OASAS and the
4 public health programs here in the Department focus mostly in
5 the AIDS Institute and the Office of Drug User Health. We come
6 at the issue from multiple aspects with our drug user health
7 hubs, with expanding access to naloxone with increasing our
8 training for providers to administer medication assisted
9 therapy, and then obviously working in tandem with OASAS on
10 their treatment beds and work that they do. So, I don't know if
11 you've had a chance to look at the quarterly report. It is
12 posted on the website. I can make sure you have a link to it,
13 because sometimes it is a challenge to find things on our
14 website. I understand that. And then we'd be happy to talk more
15 about all of the different activities that are going on and
16 addressing the opioid crisis here in New York.

17

18 JEFF KRAUT: Thank you. Any other questions?
19 Commissioner, thank you very much. I'll now turn to Brad Hutton
20 to give us an update on the Office of Public Health.

21

22 BRAD HUTTON: Good morning. Just moving a little closer
23 here. I did want to provide three additional updates in addition
24 to those that Sally had shared in the area of public health. The

1 first relates to lead poisoning prevention. The Department
2 recently submitted proposed amendments to New York State
3 regulations that would lower the definition of an elevated blood
4 lead level in a child from 10 to 5, and we recently completed
5 our public comment period, received 20 comments on the proposed
6 regulations from local health departments, different advocacy
7 organizations and elected officials, and we're right in the
8 midst of reviewing all those comments and preparing our
9 assessment of public comment. So, look forward to hopefully
10 moving forward with those regulations very soon. We actually
11 have an advisory council meeting for our lead poisoning
12 prevention advisory council in two weeks, I believe. We're
13 working really hard to implement this new legislation which
14 lowers the blood lead level, and there are lots of different
15 trainings and webinars, guidance for healthcare providers, lots
16 of activity here in the coming months because the effective date
17 of the legislation is October 1 when we'll begin having children
18 identified at lowered levels, with blood lead levels and
19 enrolled in environmental management and case management to try
20 and address those levels.

21 Also in the area of lead, we're pleased that we recently
22 announced awards for our second round of lead service line
23 replacement program. This is a pretty unique program in state
24 health departments whereby we were providing in this case \$10

1 million to 18 municipalities around the state. The awards are
2 approximately a half million dollars for each municipality and
3 it allows them to go to residents that have leaded lines that
4 could be contributing to those lead exposures and essentially
5 replace the lines for them. It's really, I think again, you need
6 the state health department has this. It's made possible through
7 the New York's Clean Water Infrastructure Act which is now \$3
8 billion in capital funding to provide safe drinking water and
9 other clean waste water.

10 The third thing I wanted to share which is maybe something
11 that we often don't share a lot but just goes on behind the
12 scenes, we recently had a cyclophorias outbreak in the capital
13 district, but also in New York and other parts of the nation,
14 and I wanted to just sort of feature it because it think it's a
15 good example of the hard work that goes on to protect our food
16 supply. And in this instance, we were seeing a pretty dramatic
17 increase in cases of cyclophorias in New York and identified
18 through some great collaboration with four local health
19 departments and our state agriculture, department for ag and
20 markets, identified some commonalities as a result of the
21 disease interviews that happen among people who have been
22 infected, and then through some environmental detective work
23 that identifies commonalities in the invoices among restaurants.
24 Ultimately identified a highly suspect food item. In this case

1 It was imported basil, and along with the work at the federal
2 level and other states, it resulted in the announcement of FDA a
3 couple of weeks ago of the voluntary recall of specific basil
4 that was made in a specific vendor across the border. So this
5 goes on all the time, and we have any number of food
6 investigations that we're participating in along with colleagues
7 in other states, and I just wanted to sort of feature it as an
8 example of the good public health work that's going on to
9 prevent instances of disease and give that example.

10 Finally I did want to also share that we continue to have
11 meetings of our health across all policies workgroup. This is a
12 group that I know Jo has been really passionate about. It's an
13 interagency group with colleagues in our colleague agencies, Dr.
14 Zucker and Paul Francis, our deputy secretary for health are
15 really still very well engaged, and we had another interagency
16 meeting at the end of July to continue moving that work forward.
17 I think it's another example of how in New York we're really a
18 model for many other state agencies.

19 And that's it.

20

21 JEFF KRAUT: Thank you. And thank you for the pesto
22 alert. I know, if it's heated up it's less problem.

23

1 ANGEL GUTIERREZ: I have a question; so, earlier on here
2 in the codes committee discussion I learned that this water is
3 not tested, is not included in what we were addressing. But
4 pesto is? Basil is? So tests this water? How does the health
5 department check this water?

6

7 JEFF KRAUT: Dr. Hutton, he's holding up a bottled water.
8 OK. Specifically Poland Spring.

9

10 BRAD HUTTON: Yeah. I missed the earlier conversation, but
11 I'll tell you in New York, one of the few states that actually
12 certified bottled water operators. So there's testing that goes
13 on for water that's sold in New York that doesn't go on in any
14 other state. But we're not yet to the point where we're testing
15 for emerging contaminants in bottled water, but maybe that's
16 what the discussion was about.

17

18 JEFF KRAUT: Mr. Lawrence.

19 Sorry, go ahead.

20

21 KATHLEEN CARVER-CHENEY: I just had a question about tick-
22 borne illnesses? We all know about Lyme disease, but now
23 there's that scarier encephalitis that can be spread by ticks

1 and there's been a death in New York State. Is there anything
2 going on about that?

3

4 BRAD HUTTON: So what you're referring to is Powassan
5 virus. So we do see anywhere from two to six cases a year of
6 Powassan. It's unfortunately it has a really short incubation
7 period so and often times can be more deadly. I think we're
8 seeing, we're not really seeing an increased incidents, but I
9 think we are seeing increased coverage of those few cases that
10 we have seen. A couple of years ago we had an interesting
11 clustering in one county of three cases which I think really had
12 us do a lot of focused tick surveillance in the area, but right
13 now I think we're seeing pretty constant small numbers of
14 Powassan.

15

16 SALLY DRESLIN: We actually have some new resources of the
17 website on our health data, New York Health Data which helps to
18 visualize the tick detections and the diseases associated from
19 year to year on a county by county basis. So it's an interesting
20 tool just to.

21

22 BRAD HUTTON: But, tick-borne disease in general continues
23 to be a real increasing concern. Both we see continued migration
24 of certain pathogens northward and westward which is sort of

1 related to climate change and just continued slow migration of
2 ticks that carry the pathogen. We're seeing increases of other
3 tick-borne diseases like Babesia and Anaplasma along with out
4 migration associated with climate change and other things. We
5 have a new workgroup that we've convened and new legislation
6 that sort of codifies that workgroup and so we have a lot of
7 activity going on in this area.

8

9 JEFF KRAUT: Mr. Harvey, Dr. Boufford, then Dr. Berliner.

10

11 HARVEY LAWRENCE: Harvey Lawrence of the council. You
12 know, this past I guess two weeks we were shocked by a number of
13 mass shootings in our country, and I know Dr. Boufford with the
14 prevention agenda we've been talking a lot about gun violence
15 and how to prevent gun violence, reduce violence overall in the
16 state. And I guess and most recently in the neighborhood in
17 which I work, Brownsville, New York, there were at least two or
18 three killings. There were - one death and about I guess 12
19 other people wounded as a result of gun violence. And I'm
20 wondering whether in light of what's happening with violence
21 overall, gun violence across the country, whether the state is
22 considering a red flag laws or any other interventions at the
23 state level to minimize and to prevent gun violence.

24

1 SALLY DRESLIN: Yeah, I'll take that. And I think we share
2 your great concern with what's happening around gun violence,
3 and I don't know if you've had an opportunity but yesterday the
4 Governor made an announcement about, he's calling it the Make
5 America Safer Pledge, and it's sort of a four-faceted
6 legislative approach that has all been implemented in New York
7 State and he's calling on other states to adopt these four types
8 of laws whether they are increase background checks, red flag
9 laws, better data collection and just tighter access in general
10 to address the problem from a legislative perspective, but Dr.
11 Boufford has been a tremendous champion as have the other
12 members involved in developing prevention agenda on recognizing
13 the whole constellation of issues that can go into gun violence
14 from a public health and social determinants perspective. So, I
15 think from the legislative perspective, we feel that New York
16 State is an example for other states to follow. Sort of a public
17 health and social determinants of health perspective, though I
18 think we always see that there's work to do and we really
19 welcome your leadership as we move forward together in
20 addressing this.

21

22 JO BOUFFORD: Thanks for the question. I was just going to
23 - I'm uncharacteristically quiet this morning from the public
24 health committee, but just quickly, we did report at the last

1 council meeting I think our public health committee meeting,
 2 first meeting to get ourselves organized on the issue that we
 3 agreed to take on which was violence prevention as part of the
 4 prevention agenda, and I think we went through the legislative -
 5 I was saying to Laura Santilli who is sitting over there who is
 6 doing a fabulous job coordinating the staff work that's going to
 7 go into our next meetings. And we're actually actively preparing
 8 not only reviewing the minutes of that meeting which I think
 9 went through pretty robust. I think New York has got pretty much
 10 every legal thing on the books one can do. But the other issues
 11 we were going to try to see what other strategies were available
 12 to look at those notes. And then have a proposal for the public
 13 health committee about to discuss at the next time vote on
 14 strategies we would specifically take up in the work on that
 15 issue. And similarly we've also been, we're getting ready for
 16 another ad-hoc committee, the prevention agenda, and continuing
 17 work on the prevention agenda reporting, especially involving
 18 the other agencies, which is extremely terrific response that
 19 Brad mentioned in, I think it's October or early November. I'm
 20 sorry? I can't remember the dates of all these meetings, but
 21 anyway,

22 [I think you weren't available in October.]

23 No I meant for the meeting that the council would have.

24 [The ad-hoc group (inaudible)]

1 Yeah, for the September another meeting of the public
2 health committee to make proposals to you about advancing the
3 work in that area.

4 And the only other thing I wanted to mention is that while
5 Sally mentioned the maternal mortality commission, this is an
6 example of this council really started focusing on maternal
7 mortality about 4.5, 5 years ago, reported to the council, the
8 council adopted a set of actions they wanted to see advanced,
9 and so now this legislation, the committee that's been
10 established as one of the areas that was part of that proposal,
11 and I think as I reported at the last council meeting we still
12 want to keep looking at the prehospital organization of prenatal
13 care, which is one of the concerns of the Department and another
14 one that the council was concerned about. But we're very
15 grateful for that. But hopefully we'll advance the violence work
16 to really formally address some of these issues as we deal with
17 maternal mortality.

18

19 HOWARD BERLINER: Two questions about lead. The first is,
20 is New York City covered by the New York legislation or is it
21 just the rest of the state?

22

23 BRAD HUTTON: Statewide including New York City.

24

1 HOWARD BERLINER: Second question, this is actually very
2 concerning and quite frightening. The lead pipe identification
3 program - do we have a sense of what percentage of the state or
4 what percentage of the population might have lead pipes?

5
6 BRAD HUTTON: I don't have that at my fingertips, but
7 certainly in the northeast where we have much older housing
8 stock, we unfortunately have not just homes that have peeling
9 and chipping paint, but also homes that still have pipes that at
10 least connect to the water mains that are often leaded. Still,
11 lead paint is still maybe thought to be responsible for about 80
12 percent of elevated blood lead levels. Drinking water and many
13 other different causes, dietary, occupational, are also
14 contribute as well. As far as the water mains, most municipal
15 water systems have long ago replaced their public pipes so that
16 they're no longer lead. They're much larger pipes. But it's the
17 pipes that connect a residence to the public main that are often
18 still leaded.

19
20 SALLY DRESLIN: One of the interesting things about the lead
21 surface (inaudible) that we do is that these are applications
22 that come in. the state, based on the information that we have
23 about the age of the housing stock, the weights of elevated
24 blood lead levels among children, the average income in the

1 area, and then there's one more - so that's the three. So we
2 combine all that information and make the awards to the
3 municipalities. So we're trying to take a approach
4 to addressing that challenge of what comes from the municipal
5 line into the house. So this is, Brad mentioned, the second
6 round of funding. So we've been making good progress and we're
7 seeing the first round which was the \$20 million round, really
8 be implemented pretty aggressively.

9

10 HOWARD BERLINER: So just to follow up, I don't want to
11 spend too much time on this, and maybe we can have a
12 presentation on just lead and lead poisoning and what we're
13 doing about it. But you know, In New York City at least we've
14 had laws against lead paint in housing since, what? Since '68.
15 So how does '68... So 50 years. I mean how do we still have lead
16 paint in apartments, at least in New York City? And the second
17 part is, so it's up to the municipality? It's up to the
18 homeowner to find out if they have a leaded pipe connecting to
19 the municipal line? Or it's up to the municipality to do checks?
20 Anyway, I don't want to dwell on this now, but I mean, maybe we
21 could go into some detail on it at a later date.

22

23 BRAD HUTTON: Yeah, I think we'd be happy to do that. I
24 think just very briefly, residents often paint coat after coat

1 after coat over that leaded paint and if it goes in disrepair as
2 often, housing stock can, that remains a source that well, it
3 might've been well maintained for a long time, can still become
4 a potential hazard. Residents and municipalities work together
5 to try and identify whether or not their pipe is lead. You can
6 actually go down in your basement and scratch it to do that, and
7 we do try to do some public education on the simple way to check
8 and see whether or not your service line is leaded. But the
9 municipality award, often times one of the initial steps they
10 have to do is undertake an inventory if they haven't already, to
11 identify where their leaded lines are. Most public water systems
12 have a very good sense of the neighborhoods that are of concern.

13

14 JEFF KRAUT: So I'm going to go Dr. Watkins, Mr.
15 Lawrence, then Dr. Boufford.

16

17 KEVIN WATKINS: Brad, this is Kevin Watkins. I'm on the
18 council. I just want to see if you can give us an update on the
19 PPB shortage and where local health departments can possibly
20 obtain resources from the state for those local health
21 departments that may be experiencing those shortages.

22

23 BRAD HUTTON: I think I got that. An update on the PPB
24 shortage. I think it continues. I think that's the most

1 important point. We are taking a look at our existing
2 regulations related to testing of healthcare workers to see
3 whether or not there's something that we can do there to help
4 alleviate the shortage. So I think that's something we might be
5 bringing too soon. And I know (inaudible)
6 Doing a lot of work and having discussions with their colleagues
7 in New York City and other places. There's been recommendations
8 to take a look at that.

9

10 HARVEY LAWRENCE: I appreciate all of the work that's
11 being done on violence and gun prevention. So, it would be
12 really helpful to hear maybe a presentation in the fall from the
13 Department on exactly what is, it's approach, and what
14 strategies it's putting in place to assist some of these inner-
15 city neighborhoods or communities with prevention, gun violence
16 and violence prevention.

17

18 JO BOUFFORD: We, for the public health committee, we can
19 include a broader, as part of the meeting we were planning in
20 September, and then bring it forward to the council or add
21 things to it if the committee is not satisfied.

22

23 HARVEY LAWRENCE: I was addressing it to the Department
24 of Health.

1

2 JO BOUFFORD: Sorry.

3

4 JEFF KRAUT: Any other questions? Thank you so much for
5 that report, and I think these conversations are healthy and
6 whether or not the Department brings up an issue or not, when
7 you come into this room, if you've heard about something or read
8 about something, it would be nice to let the Department know
9 you're interested in it before we walk in here, but if not, this
10 is the time. It's kind of like in Parliament, ask the Prime
11 Minister. And it's a unique opportunity I think we have in
12 discharging our responsibilities and raising awareness. So I'll
13 tell our two members, you've seen a little example of it today,
14 and we hope you participate as well.

15 I'll now turn it over to Dr. Gutierrez to give us a report
16 of the Codes and Regulations Committee.

17

18 ANGEL GUTIERREZ: Good morning, again. I'm Angel
19 Gutierrez. I chair the Codes, Regulations, and Legislation
20 Committee, and today's meeting of the committee will review four
21 proposals; one for adoption, and three for information. For
22 adoption was the item titled Residents' Rights. This proposal
23 will amend part 415 of Title 10, Nursing Home Minimum Standards
24 to specify upon admission information regarding discharge rights

1 including information on home and community-based services, and
2 community transition programs. The Committee voted to recommend
3 adoption to the full council, and I so move.

4

5 JEFF KRAUT: I have a motion. Do I have a second? Second,
6 Dr. Watkins. Any questions? Discussion? Hearing none, all those
7 in favor aye?

8

9 [Aye]

10 Opposed? The motion carries.

11

12 ANGEL GUTIERREZ: The following three items are for
13 information only. There will be no voting required. This patient
14 bill of rights, this proposal will amend section 405.7 to
15 reflect the correct name of the educational materials referred
16 to in paragraph 10 of subdivision C of section 405.7 and will
17 amend section 751.9 to clarify the rights afforded to patients
18 by the surprise bill law. If we need clarification on this, Ms.
19 Astin from the Department is available.

20 The next for information is registered nurses in the
21 emergency department. This proposal will strike language from
22 405.19 D2 requiring emergency department nurses to have one year
23 of clinical experience and add language that the nurses must
24 meet competency requirements found in a new subsection 7 of

1 405.5. This new subsection would require nurses in specialty
2 areas including but not limited to the emergency department to
3 complete training and education to establish competencies
4 specific to the specialty area. There was no vote on this. And
5 Ms. Astin from the Department is also available to answer any
6 questions from the council members.

7 Last,...

8

9 HOWARD BERLINER: Can we ask Dr. Ortiz about this? From
10 the perspective of a nursing educator?

11

12 MARIO ORTIZ: I had commented in the earlier and my
13 concern was that I wanted some information if they could use the
14 competencies from the emergency nurses association standard
15 scope of practice to outline how the benchmarks will be
16 established, because right now it reads that each hospital would
17 have the ability to establish their own, because we have both
18 American Nurses Association and DNA standards and scope, it
19 makes sense just to comply with those and then create rubric
20 based off that for it. So they said they would look into that.

21

22 ANGEL GUTIERREZ: Thank you. Maximum contaminant levels.
23 This proposal will amend subpart 5-1 to incorporate maximum
24 contaminant levels for three emerging drinking water

1 contaminants. Perfluorooctanoic Acid (PFOA), and
2 Perfluorooctanoic Sulfonic Acid PFOS, and 1-4 Dioxane. Since
3 this proposal was presented for information, there was no vote
4 and we have Ms. Wheeler available from the department to answer
5 questions. This concludes my report.

6

7 JEFF KRAUT: Thank you very much Dr. Gutierrez. There any
8 other questions? I'll now turn to Dr. Ruge who is going to
9 provide an update on the activities of the health planning
10 committee and have a little presentation.

11

12 JOHN RUGGE: Thank you. Last month the planning committee
13 together with the establishment committee met to consider
14 refining the policy for ambulatory surgical center
15 establishment, especially in rural areas where sole community
16 hospitals can be placed in jeopardy by new competition. I always
17 like to try to put these discussions in context. Last month it
18 was CON going all the way back to WWII and the twist and turns.
19 For hospitals it goes back a little further to the 19th century,
20 where hospitals were basically places for the insane to be
21 housed and for poor people to die. But what transpired with the
22 explosion of new technologies and new science was hospitals
23 becoming the really indispensable place of care. So in 1966, 50
24 years ago, the (Millis Commission) on behalf of the AMA reported

1 that "the hospital rather than the home or the office has become
2 the preferred and frequently the only practical place for
3 treatment and diagnosis." How times change. I'd like to point -
4 Is this better? I'd like to point out that when I started
5 medical practice, patients following cataract surgery required a
6 week in the hospital with their head in blocks. It is now a 15
7 minute procedure. Gall bladder surgery, cholecystectomy,
8 required another week in the hospital and is now done as
9 outpatient. Hip surgery, likewise. A week or 10 days now is down
10 to one overnight stay and we're fast approaching outpatient
11 surgery. So with this, enormous transfer of care to the
12 ambulatory setting. Really a redefinition of hospitals. I think
13 of our oversight challenge as being one of helping to guide and
14 direct the transformation of care to the most setting,
15 but also without jeopardizing really essential operations in the
16 communities that we have. So last month the planning committee
17 and the establishment committee tried to help, but also note
18 that planning activities, council activities have their own
19 history. So before the PHHPC was the SHRPC. The State Hospital
20 Review and Planning Council. We've broadened the scope from
21 hospital really to healthcare. Before SHRPC there were a whole
22 series of councils going all the way back to 1912 when New York
23 established for the first time a state hospital commission. Of
24 interest, it was not a new commission. That commission was

1 renamed from a commission housed at the Department of Social
 2 Welfare. The previous commission being, the commission on
 3 lunacy. How far we've come. So with that. With that Tracy is
 4 prepared to do - I hope that the Department found the discussion
 5 by PHHPC members last month to be helpful and constructive in
 6 terms of reviewing really very careful work that's been done,
 7 but also added perspective that comes from around the table and
 8 by extension around the state from so many communities where we
 9 can each have our own experiences to bring to bear. And I think
 10 that we've helped to do this next iteration of a policy, which
 11 no doubt we will be coming back to - our successors will be
 12 coming back to in only a few years. So with that, Tracy.

13

14 TRACY RALEIGH: Thank you Dr. Ruge. This is - I really
 15 appreciate that history lesson, and I think it brings great
 16 value as we take on challenges in terms of how healthcare is
 17 evolving. So, the planning committee met both in May and most
 18 recently in July, and we took up a rather, more narrow issue
 19 which is how our current policies address for establishing
 20 ambulatory surgery centers in new areas consider the impact
 21 those ASCs will have on the local hospitals in the area. And the
 22 last planning committee in July was, the Department came forth
 23 with a revised policy proposal and really sought the endorsement
 24 of the PHHPC planning committee on it, which we received. And

1 just to help frame what the problem was we were trying to solve
2 is as Dr. Rugge said, our current policies and procedures with
3 respect to new ASCs establishment really does lean forward in
4 terms of approval of new ambulatory surgery centers in areas
5 because they do hit the triple aim. We recognize that they
6 deliver safe services and lower cost setting and is the
7 consumers preference in many cases for delivery of that care.
8 However, current policies don't allow us to differentiate how
9 that new ASC coming into an area could be different in different
10 geographies in New York State, particularly upstate. So, in
11 rural areas of the state our problem statement was that these
12 areas are characterized by perhaps one sole community hospital
13 or critical access hospitals in those areas. And when we look at
14 the impact of an ASC coming into that area our revised policy
15 was saying we should take a broader look because it does impact
16 not only surgical services but the broader array of essential
17 services provided to those communities. So we generally receive
18 the endorsement of PHHPC in these policies, and we're bringing
19 back today our final set of policies that we'll be implementing
20 going forward.

21 So, what we heard from the discussion at the planning
22 committee was that we wanted to acknowledge that when a new
23 ambulatory surgery center comes to an area, it could be either
24 freestanding, meaning that it doesn't have a hospital partner as

1 part of it's ownership, or it could be owned by a hospital and
2 being proposed in a rural area. So, regardless of whether it's
3 freestanding or owned by a hospital, our policies are going to
4 still require outreach to area hospitals and demonstration of
5 the area hospitals if they are opposing that new ASC coming in,
6 to demonstrate the financial impact that it'll have on the local
7 hospital services. The Department is still going to verify that.
8 But if it is in an area in upstate where there is sole community
9 providers and critical access hospitals, our first position is
10 going to start with a general disapproval of that application if
11 there is significant harm shown for the reasons that I
12 mentioned, because it is basically going to threaten the
13 essential services in the area. The discussion brought out that
14 we shouldn't just stop there though, we need to not have a hard
15 stop but also consider other factors and those are factors such
16 as the efforts of the area hospital in collaboration with the
17 physicians in the community. Good points were raised about we
18 need to make sure that we're not prohibiting the entrance of new
19 technologies in certain areas or the retention of surgeons if
20 that becomes an issue in that rural community. So collaboration
21 was a big point that we took away from those discussions as a
22 factor. In addition, there were also comments about quality
23 metrics. So if we're going to say a new ASC will not be allowed
24 to enter an area and there's a hospital opposing, we would want

1 to look at, is the quality metrics of the surgical services
2 being delivered where they need to be before we limit and say no
3 one can enter. That was a very good point raised and we're
4 taking that into consideration. Other factors would be the type
5 of surgical specialty and in general where the reimbursement
6 trends are going. So, we appreciated that feedback. We
7 incorporated that into our policy. The second change and
8 discussion point was that that we often, this body often gets
9 applications that are not for new ASC establishment, but may be
10 expansion of an existing ASC from a single specialty to a
11 multispecialty. And that was also raised in some of the public
12 comments we received. And so our current policies really only do
13 the outreach to the area hospitals in terms of impact when it's
14 a new ASC coming in. But we are suggesting here that we're going
15 to change our procedures and if there is a construction which we
16 call a non-establishment application that is going to expand
17 from single to multispecialty, we're going to do that outreach
18 as well. So that's what the second bullet represents. And then
19 finally there are applications that have come before PHHPC for
20 new establishment and our current policies do require us to put
21 a limited life which means that the applicant, the new ASC can
22 operate for, we use a period of five years and during that five
23 years you'll, and at the end of the five years, you'll see these
24 applications come back, and we're asking for them to demonstrate

1 that they are providing the services to the uninsured and
2 Medicaid populations to make sure that it's access to all. And
3 in that policy we're acknowledging that it doesn't today address
4 when there is a complete change of owner. So it, the limitation
5 if put only when it's a brand new establishment ASC. Not when
6 it's a proposed change of ownership. So our policy going,
7 revised policy going forward will be to apply the limited life
8 not only at initial establishment, but also when there is a
9 change of ownership of 50 percent or greater. And there were
10 questions raised about how we can implement this considering
11 that there can be changes over time. So we're going to be
12 looking at that over a period of time. We're going to measure
13 that over time and apply that limited life.

14 That really concludes my presentation. We really appreciate
15 that robust discussion that we had at both planning committee
16 meetings, and welcome any comments or questions.

17

18 JOHN RUGGE: Dr. Gutierrez.

19

20 ANGEL GUTIERREZ: Thank you. Listening to what Dr. Ruge
21 said and flawless presentation plus a side conversation Dr.
22 Kalkut and I have had over the past 10, 15 minutes, it seems to
23 me as though as council we are contemplating this specific
24 issue; what is the effect of an ambulatory surgical center on

1 the hospital? And here links with what John was saying. Why do
 2 hospitals close? Why are hospitals continuing to close? It began
 3 with women that would deliver children and stay in the hospital
 4 several days. That doesn't happen anymore. We've got rid of
 5 polio, we got rid of rheumatic fever, tuberculosis is not an
 6 issue. This is my concern: we are not immune to a catastrophe of
 7 public health or to a sudden epidemic of something that we did
 8 not anticipate. What are we - how are we doing in anticipating
 9 that and having the hospital beds that will be necessary to cope
 10 with that kind of crisis, independent of this small issue in
 11 reality, when you're talking a major public health catastrophe,
 12 you're talking about something similar to the flu pandemic back
 13 in the '20s. Should we be talking perhaps to a national guard or
 14 the army so they can have in some place in the state tents and
 15 beds because if we get hit, I don't think we have the bed
 16 capacity to cope with it.

17

18 JEFF KRAUT: So we have - first of all, you're right. And
 19 there's, this policy, there's an affirmative responsibility of
 20 the state and by extension this council to ensure the critical
 21 access of sole community hospitals. So we recognize there's a
 22 need for that for all the reasons you've said, and then for
 23 other things. And part of the struggle here is, and I'll come
 24 back to the policy and I'll answer your question. So there are

1 in the event of a disaster, there are through HHS there's
2 funding and there's national nest teams if you will, of disaster
3 - my organization is one of them for the New York region. We
4 have in a warehouse a 100-bed hospital we can deploy in six
5 hours. It's military-grade portable hospital plus equipment,
6 beds, cots, IV poles, all kinds of equipment that we can deploy
7 in the event of an emergency, and I think the last time we
8 deployed it was, or deployed a portion of it was in 2009 during
9 the avian flu, H1N1. So there is that capability, but it is a
10 short term solution. It's not a long term solution. And we were
11 just talking fever, the things that are happening around
12 the world, you've got to be really anxious about this in
13 capacity. I think another aspect of it is the Department in my
14 opinion, maybe not the Department's opinion, we've been less
15 focused on beds, beds, give up beds, close beds, there's been a
16 flexibility with the Department on not being crazy about
17 contracting the bed supply too much. Although market forces are
18 doing that separate and apart from other opportunities here. And
19 I think all the hospitals are confronted with the ability - they
20 all, many of them have surge capacity. They may not have funding
21 to surge, but we do have surge plans in almost every place
22 because we have to do that as part of our emergency preparedness
23 and disas - and if there's a federal emergency the Feds will
24 fund it. HANYS, Greater New York, Hospital Association, we drill

1 on this opportunity. We've never had a broad scale test of it
2 and I hope to god we don't, but I do know the capability exists.
3 And I think also the national guard has similar, somewhat
4 similar resources and you know, I think there's an opportunity.
5 Just ask the question. But I want to come back to the policy. So
6 that introduction that this is a policy that's basically saying
7 we're trying to figure out how to protect what we see as vital
8 resources to communities and this is primarily focusing in,
9 let's in hard to reach rural communities. We're not talking
10 about Brooklyn; we're not talking Long Island or Westchester,
11 highly populated areas. So that's what we're trying to do. And I
12 would almost, I would love to have a, we need to have a
13 discussion because we need to make sure that we have consensus
14 on this because we're going to apply it and it's important that
15 we're not second guessing it as we apply it. But believe me, we
16 haven't figured out the situation that's going to confront us,
17 because there'll be some variation on this and one of the things
18 is it's being used in a protectionist way where the hospitals
19 say hey, you know, I'm protected, I don't have to do things, I
20 don't have to invest. That came up in some of the discussion.
21 What if they're not investing in technology that's contemporary
22 and here's a new group that is. And also hospitals that may
23 become part of bigger systems that refuse to and the consequence
24 are they're weak and this thing would harm them, but if they

1 were to collaborate with other hospitals, they wouldn't be as
2 weak. And they refuse to do it. And they use this as a
3 protectionary thing. Those are variations. I don't have answers
4 for any of that. But that's it. So let's start the discussion.
5 Dr. Brown and then Dr. Kalkut and then Mr. Robinson and then Mr.
6 Lawrence.

7

8 LAWRENCE BROWN: I want to in fact, commend the
9 Department for the work they've done on this. I do understand
10 and appreciate that this is not been an easy lift for you. I
11 realize though in reading the third bullet, I have actually two
12 questions, and the second question may no longer be relevant
13 depending on the answer to the first. So, I guess I'm asking,
14 what has been the experience of the Department with respect to
15 hospitals seeking to have an ASC in a different community or
16 similar community. What has been the number of applications from
17 hospitals seeking to establish an ASC somewhere else?

18

19 TRACY RALEIGH: Thank you Dr. Brown. That's a great
20 question. I don't - I can tell you trend-wise and we can get
21 back to you with specific numbers, but in fact, I think the
22 agenda today that you'll see from the projects reflects an
23 increasing trend of hospitals actually partnering with
24 physicians in their community. Happy to - so we are seeing more

1 and more in the last I'd say going back three to five years that
2 trend of hospitals partnering with the doctors in their
3 community.

4
5 LAWRENCE BROWN: First of all, I'm glad to hear about
6 that partnership. We often don't receive a lot of experience of
7 that partnership actually happening as frequently as we'd like
8 to. I guess the reason why I posed that first question because
9 it gives on the face value of this third bullet. A sense that
10 hospitals are going to get a favored treatment because it's only
11 the non-hospital ASCs that is getting the requirement to have a
12 limited life. So it gives the impression that hospitals who do
13 this may not have unlimited life. I don't know if that was the
14 intent.

15
16 TRACY RALEIGH: We actually spent much time talking about
17 this and it's a very astute point that you point out. We landed
18 on, you know, this policy with an intent to promote
19 collaboration so there is an incentive if you are a hospital-
20 owned ASC, incentive for collaboration in the area with the
21 local physicians. So as a hospital-owned there would not be a
22 limited life. It also has a history in the purpose of the
23 limited life which goes back to the concept that an ASC when
24 these first were coming as a new mode of care was going to be

1 cherry-picking certain payer classes and not serving access to
2 all. So, by nature, a hospital-owned ASC given the requirements
3 on hospitals is generally treating everyone walking in the
4 emergency department has a broader access. But we did debate
5 that point and this is where we landed.

6

7 GARY KALKUT: Tracy, I also want to applaud the Department
8 for their thoughtfulness and balance in this proposal. Two
9 questions; prior to this, hospitals could object or objected to
10 ASCs in the community and provided data or sometimes provided
11 data about it. Can you talk a little bit about the verification
12 process, which I assume is new in the kind of detail that you
13 alluded to in here in terms of what the impact would be on the
14 hospital? What sort of process is that?

15

16 TRACY RALEIGH: Sure, and just to clarify, it's not new. It
17 has been in our procedures. So, when we initially get opposition
18 we require the opposing hospital to provide us with a first of
19 all, where are the cases that are going to be - where are the
20 cases currently performed? And they have to document pretty much
21 by physician level that the cases that are going to be in the
22 proposed ASC are currently being done in the hospital. And then
23 they have to document for us both the revenue, the net revenue
24 from that and the expense portion of that and come down to what

1 is the contribution of those cases - it gets very specific - of
2 those cases that will leave and what will that harm be if those
3 cases leave? The Department can verify that through our cost
4 report data. We can look at that ambulatory surgery service
5 contribution in total. Sometimes it gets more detailed for us to
6 drill down to the certain surgical specialty, but we have a
7 general sense and can verify the reasonableness of that
8 assessment of harm. And so, we get to that point where we verify
9 that; is it reasonable or not? And that's a back and forth with
10 the opposing hospital, and sometimes the applicant because the
11 applicant is proposing certain projected utilization of cases.
12 We're verifying where they're coming from.

13

14 GARY KALKUT: So, it's the current process.

15

16 TRACY RALEIGH: That is the current process. Yep. And that's
17 not changing.

18

19 GARY KALKUT: Understood. And the second question is how
20 many counties will this affect? We know the location of these
21 critical access hospitals.

22

23 TRACY RALEIGH: Sure, do we have that? We had the map. Yes.
24 I could count.

1

2 GARY KALKUT: I can look at the map.

3

4 TRACY RALEIGH: We provided the map -

5

6 JEFF KRAUT: We had sent a map around as part of the
7 committee meeting and maybe Colleen, if you could just please
8 circulate it to the rest of the council to see and they've
9 identified the potential areas where these issues may arise.

10

11 TRACY RALEIGH: There's roughly - I want to say 16

12

13 JEFF KRAUT: 16 counties, 22 places.

14

15 GARY KALKUT: 23 hospitals.

16

17 JEFF KRAUT: Mr. Lawrence, then Dr. Berliner.

18 After Mr. Lawrence it'll be Mr. Robinson then Dr. Berliner.

19

20 HARVEY LAWRENCE: Thank you. As a member on the council
21 we've struggled and I'm happy to see this come to some sort of a
22 policy because we've always struggled with do no harm to the
23 critical access hospitals, which I support. I guess first would
24 be sort of some wordsmithing. When you say "negative", anything

1 negative is a cause for action, I would suggest maybe "adverse
2 financial" because as to higher standard, especially given what
3 Dr. Rugge has said about the reduction from a week stay to
4 inpatient for a couple minutes. So we want to promote I think
5 innovation and competition so if it's going to be an adverse, a
6 higher standard I believe for the hospital so I think that would
7 be helpful. The other comment is I understand with bullet three
8 that the intent is to encourage collaboration. Is there another
9 more affirming way to encourage collaboration maybe if there is
10 going to be an adverse impact to have the hospital and the ASC
11 offer, come together and have some sort of a joint proposal that
12 would mitigate some of the adverse impact in one area, but might
13 be beneficial to the hospital in some other areas. So, promoting
14 that. And I'm assuming that in bullet three that it's all that
15 we're only referring to critical access hospitals and that this
16 is not generalized. It's all hospitals.

17

18 JEFF KRAUT: And Mr. Lawrence, I can reasonably guarantee
19 you that if we adopt this as a policy that entities that are
20 seeking to develop am-surg centers in these communities will
21 collaborate with the hospitals for fear of coming into this room
22 and wasting their time.

23 [That's good to know]

1 I think that's part of the intent of the policy. It'll
2 effect the market somewhat.

3

4 JOHN RUGGE: Harvey, just as a point of information, in
5 addition to critical access hospitals, sole community hospitals
6 would be in the ballpark as well.

7

8 HARVEY LAWRENCE: And the last, Mr. Kraut indicated that
9 this would not apply to Brooklyn but we do have a number of
10 struggling critical access hospitals in Brooklyn. I don't know
11 if they need some other type of protection but...

12

13 JEFF KRAUT: But if you look at where all the am-surg
14 centers have been developed, it's nowhere near our critical
15 access hospitals. But I would agree. If there's a case to be
16 made, we'll see.

17

18 PETER ROBINSON: A couple of comments, but thank you for
19 I think an elegant solution to I think a fairly complex problem,
20 and I commend the Department and the committee for the work that
21 they've done to come up with this.

22 A couple of comments; one is that in addition to critical
23 access hospitals and sole community providers there are other
24 hospitals that sort of fall slightly outside of the boundaries

1 of that that have actually seen state funding intervention
 2 through various programs like (VAP) and the like that would
 3 actually kind of fall into the same category of risk and so I
 4 would ask the Department to be flexible and say that certainly
 5 critical access and sole community provider hospitals should be
 6 there, but there may be others that can get kind of called into
 7 this on a case by case basis. Because I do think that there are
 8 some second - this is a critical issue for recruiting and
 9 retention of physicians in areas where it is very difficult to
 10 do that. And hospitals can often times in those communities
 11 actually get held up by members of their own medical staff who
 12 decide that they're retirement program is going to be funded
 13 essentially by taking their practice out of the hospital,
 14 forming an independent ambulatory surgery center, and diverting
 15 those dollars away. So the fact that this creates an incentive
 16 for hospitals and physicians to work together is actually an
 17 added plus. So I just want to thank you again for that and just
 18 offer those thoughts. Thank you.

19 JEFF KRAUT: Dr. Berliner then Ms. Monroe.

20 HOWARD BERLINER: Perhaps this is more of a possibility
 21 than a reality. So what happens if a hospital joins with a
 22 physician group in another area, an area in which there is a
 23 critical access hospital to start an ASC that cuts out the
 24 critical access hospital? I thought that's where Dr. Brown was

1 going? I guess the closest we've come recently was in Albany
2 with Albany Medical Center and Ellis a couple of months ago. I
3 mean, a similar maybe not quite the level of critical access but
4 a wealthier hospital moving into the territory of less wealthy
5 hospital if you will.

6

7 JEFF KRAUT: Let's not call it territory. It's serving
8 patients. OK. I'll defer to Dr. Berliner. Service area.

9

10 TRACY RALEIGH: OK, so let me take a stab at addressing Dr.
11 Berliner's question. So, the reason we went back and said it's
12 not just freestanding ASCs, it's also regardless if the hospital
13 is participating or not. So, our policy is limited. We have to
14 have policies that we can implement and we took all this
15 consideration into effect, but we are limiting it to sole
16 community and critical access areas. So, in your example, where
17 we had the application with Albany Med and Ellis I believe it
18 was opposing, we did do our same procedures. We looked at the
19 impact and at the end of the day it wasn't if we would put this
20 lens on it, it wasn't a critical access or sole community
21 hospital. We did the validation of the data and we had
22 determined that the impact had already been absorbed. And so we
23 came out with our favorable recommendation. But to your prior
24 point, we are able to use this revised policy when a hospital is

1 going to be, regardless of whether it's hospital participation.
2 So if a hospital and area physicians are going to come into an
3 area where there is a sole community or critical access
4 hospital, we are going to apply this policy. And if I can, I
5 just wanted to address Mr. Lawrence's point just quickly. And I
6 appreciate really appreciate this positive feedback. I just want
7 to clarify on the third bullet which is the limited life, your
8 question I believe was is this limited to just areas where
9 there's sole community and critical access? And the answer is,
10 no. This is a separate thought and policy and it has come up in
11 applications where we see a proposed ambulatory surgery center
12 changing 100 percent ownership. So it's an existing ASC that has
13 completely different members. And our policies today do not
14 allow us to apply a limited life. This would be applicable not
15 only in areas where there's sole community or critical access,
16 but applicable in all areas.

17

18 ANN MONROE: Thank you. I'll try this, it's my first day
19 but...

20

21 JEFF KRAUT: Dive into the deep end.

22

23 ANN MONROE: I am. Don't worry. When you say solicit
24 feedback from surrounding hospitals, when you open in the first

1 paragraph beyond negative financial impact to look at all of
2 those other things, I mean I think we've really come to, it's a
3 judgment call in many cases. So when you solicit feedback from
4 surrounding hospitals, is it related to those items? I mean, and
5 then what do you do with that feedback?

6

7 TRACY RALEIGH: Great question. So as part of what Dr.
8 Kalkut was asking too, what we do is we in our outreach we let
9 the area hospital know that there's a proposed application and
10 if they are opposing, it's what I went through before. There has
11 to be a detailed analysis provided by the hospital as to the
12 harm that that, the movement of the cases will have. And that
13 gets very specific in terms of their documenting harm.

14

15 ANN MONROE: So is that the data then that would lead you
16 to either approval or disapproval and the regular process that
17 you talked about?

18

19 TRACY RALEIGH: Right. So when we go back to the bullet one
20 which I think is what you're asking, how do we incorporate those
21 other factors. That is a dialog that the Department has as the
22 application is getting reviewed. So for example, we will once we
23 receive the written analysis back from the hospital, we'll often
24 engage in discussion about efforts. We ask the questions, have

1 you taken the efforts to talk to the area physicians to
2 collaborate? What we're saying here is we're going to expand
3 that outreach in our revised policies to look at what's the
4 quality, some of the quality metrics at the surgical services
5 being performed in the hospital? We often look at specialty type
6 as well. So in that outreach it's done in a dialog between the
7 opposing hospital and the applicant.

8

9 ANN MONROE: One last clarification. If it's a hospital-
10 owned ASC, and it's not subject to limited life, does it ever
11 get reviewed again?

12

13 TRACY RALEIGH: No. unless the ownership is changing.

14

15 ANN MONROE: So the local hospitals that maybe agreed
16 because this was a good faith and they were working well
17 together, is there a mechanism for them to come back at a later
18 time and say, wait a minute, this didn't follow through. We'd
19 like to see this reviewed again. Tracy Raleigh.

20

21 TRACY RALEIGH: No.

22

23 ANN MONROE: So that makes this decision not a real
24 important one not just for now but forever in a sense.

1

2 TRACY RALEIGH: Right. That's correct.

3

4 ANN MONROE: Ok, thank you.

5

6 JEFF KRAUT: Before I turn it back to Dr. Rugge, any
7 other questions? Dr. Martin.

8

9 GLENN MARTIN: So that's also our current policy, right?

10

11 JEFF KRAUT: Yes.

12

13 GLENN MARTIN: Alright. So we're not changing it
14 necessarily, but I have misgivings about it also. Can somebody
15 affirmatively explain to me why this is good policy though? Why
16 should this exception be there? Because we just heard, it's
17 quite possible that a hospital run ACS [sic] in partnership
18 could be just as good or bad as one operated without in terms of
19 meeting their requirements for one thing or another or whatever
20 they've pledged to us. So why should we do this? I still don't
21 get it.

22

23 TRACY RALEIGH: Sure. Let me try to respond to that concern.

24 So the reason why we're doing this is because our current

1 policies don't allow us - current policy is really a high
 2 threshold. It is basically saying in this particular area, say
 3 it's a critical access hospital opposing or sole community
 4 hospital opposing, they have to prove that this, that the loss
 5 of the surgical cases will essentially close, threaten their
 6 ability to continue. And that has become the bar because to the
 7 point earlier of adverse financial impact, that is really where
 8 we've come to. Because our policies are generally promoting
 9 entrance into markets. So the reason we're doing this is because
 10 financial sustainability in a rural area with a critical access
 11 hospital or sole community means something different because it
 12 has the potential to have a broader impact on the totality of
 13 services delivered in that community. So whereas the financial
 14 impact of the specific surgery cases leaving, may not be enough
 15 to close the hospital. It could threaten the ability to provide.
 16 They're the only source of say, inpatient mental health care in
 17 the community, or maternity services of the community. So that's
 18 - we don't have that flexibility. I don't know if that's your
 19 question.

20

21 JEFF KRAUT: No, He's... could I amplify on that? He's
 22 asking us why don't we have lookbacks and to see the impact of
 23 some of the decisions? And I'll give it to you from a slightly
 24 different perspective. And we need to periodically remind

1 ourselves; when we have deal with establishment, this council
 2 has certain powers. The powers of establishment are above the
 3 commissioner, right? Everything else is recommendation to the
 4 Commissioner, to the Department. We affirm the Department, we
 5 deliberate and do it. Establishment has three criteria and it is
 6 do they have the character and competence to do this? Is it
 7 financially feasible, and is there a community need? Once we
 8 determine that using whatever policies we've adopted, we are not
 9 in the business of oversight of the healthcare delivery system.
 10 Now, we can come back and create policies that force the
 11 Department to do things, but it is the Department's
 12 responsibility to ensure that the intent of our decisions are
 13 followed through, they follow the regs, and if there are
 14 unforeseen circumstances, it's in the Department's power to do
 15 that. Particularly when we do establishment. If we've -- we are
 16 not permitted and we haven't been able to revoke a certificate,
 17 that is the Department's responsibility. That doesn't mean you
 18 can't come in here and have a situation and discuss policy and
 19 see how that gets applied during establishment, which is
 20 essentially what we're trying to do. But once we vote, it moves
 21 into the regulatory and oversight. But I understand. We have
 22 lookbacks on Medicaid, on am-surg to see the impact of our rules
 23 and policies which is appropriate, but no, we can't act. As a
 24 council.

1

2 GLENN MARTIN: I understood, but now I'm totally confused,
3 because basically that's what we're doing, it seems to me, with
4 the non-hospital based ambulatory surgery centers. We give them
5 a five year limited to force it to come back here.

6

7 JEFF KRAUT: But it's a policy because we decided that's
8 what we created limited life for that category.

9

10 GLENN MARTIN: And im asking again, and my question is very
11 focused is, we did that and I'm asking, I don't still understand
12 the rationale for not doing it for hospitals. I just don't
13 understand what that rationale is.

14

15 [ASCs]

16 JEFF KRAUT: For hospital ASCs. Hospitals are already
17 established.

18

19 GLENN MARTIN: Alright, so you're saying that it's not a
20 question that you think it's good policy or bad policy -

21

22 JEFF KRAUT: It's they're established providers.

23

1 GLENN MARTIN: It is policy so there's nothing we can do
2 about it.

3

4 JEFF KRAUT: Well...

5

6 GLENN MARTIN: Because we can't treat them the same way
7 because they've already been established.

8

9 JEFF KRAUT: That's correct. If the hospital is the owner
10 of the am-surg center - they're not coming as, they're coming as
11 a satellite or a DNTC.

12

13 GLENN MARTIN: They're just expanding it so I can argue
14 about the expansion. Argue about the owner. I got it. But if
15 they do it in partnership with somebody it's treated the same
16 way even though it's really a different entity, depending on how
17 you (set it up.)

18

19 JEFF KRAUT: Well, it depends on what they're asking.
20 Certain, you've got to look at it, certain hospitals are
21 establishing because they may have a different ownership
22 percentage. So just because the hospital's name is on it,
23 doesn't mean the hospital owns it.

24

1 GLENN MARTIN: Oh, I'm fully aware of that. That's the
2 point is that different things that look the same are going to
3 be treated differently because of the stuff three levels behind
4 which I don't understand, which doesn't seem right as an end
5 point.

6

7 LAWRENCE BROWN: So I can certainly understand the
8 overarching purpose of this. I guess the thing that I have a
9 concern about is, and I appreciate Jeff, that explanation you
10 gave but it does appear on the surface that a hospital, I know
11 they have to come back if they're going to expand and if they in
12 fact establish an ASC as part of an expansion, so it seems to me
13 that if they do, then I'm not sure I understand why they are not
14 also expected to have limited life for that expansion portion,
15 not the rest of the hospital because they're coming to expand,
16 so I don't understand that policy. Why they would have unlimited
17 life and someone who is not a hospital would have a limited
18 life.

19

20 JEFF KRAUT: That goes back to the history of how we
21 established the policies of limited life. The policies of
22 limited life were not, were to be concerned of new providers
23 that had no track record in treating and access to Medicaid
24 patients. Every hospital-based provider came into this room with

1 a track record and we applied that track record to their new
2 activity. And every ASC that was approved has fulfilled, we've
3 never - with one or two exceptions, every one that the
4 Department looks at whether they're hospital owned or
5 freestanding have met the criteria. So this is the policy that
6 was done years ago in the ad-hoc committee chaired by Mr.
7 Robinson and we resolved that issue years ago as a policy. That
8 has been the policy here. There's no rationale to revisit it
9 other than because it's proven to be true. Right?

10

11 LAWRENCE BROWN: Well, Jeff, I do appreciate that
12 policies should not be reversed on trivial basis, but when we
13 look at things that happen going forward that we didn't consider
14 in the past, it does make sense to in fact consider that. For
15 example, --

16

17 JEFF KRAUT: We did consider it.

18

19 LAWRENCE BROWN: If I could do one more thing, I
20 apologize. So let's say there's an entity that's also an article
21 28 facility, non-hospital that comes and decides that I want to
22 establish and work with an organization locally to establish an
23 ASC in a community then I'm going to have to have a limited life
24 as opposed to a hospital if they do the same thing, they have no

1 limitation. So that to me seems a little difficult to entirely
2 ingest.

3

4 PETER ROBINSON: So, let me just maybe provide a little
5 clarification again, the Department can correct me if I'm wrong.
6 The main purpose behind limited life was access. And particular,
7 access to services by Medicaid recipients and people who are
8 uninsured. And so as Mr. Kraut was saying, when we look at
9 unexperienced or new applicants coming in without any evidence
10 that they've done that, we want to see evidence. That's what the
11 five year limited life allows us to do. And then we have a
12 choice at the end of that period to provide permanent
13 establishment or not. In this case, what we're talking about
14 here is looking at the ensuring the continued sustainability of
15 scarce and very important community resources in a generally
16 underserved communities. And so I think the issue that we're
17 addressing with this particular policy is different than the one
18 we were trying to address with limited life. And so I think
19 that's the reason why we're taking a different approach. In
20 other words, the purpose is to actually sustain the viability of
21 the existing article 28 provider and to ensure that a new
22 entrant that comes in doesn't undermine that. I think that's
23 where we're going with this.

24

1 JEFF KRAUT: There's a way to deal with this just to
2 answer the question so we're not just talking on policy. Why
3 don't we on that particular question just bring in the data? So
4 you can see it to do the issue? And then if the data doesn't
5 bear that out and we want to have discussion, we'll bring this
6 back to address that concern. So I think just so we have the
7 information in the room so we're not dealing with hypotheticals.

8

9 GARY KALKUT: And the data, Jeff, is the Medicaid and
10 uninsured?

11

12 JEFF KRAUT: Yeah, I mean, for all the am-surg centers be
13 it hospital based or freestanding, and we do that anyway so we
14 generate that report, I just don't have - if I had my computer I
15 could pull it right up, but we don't - why don't we just do
16 that. That would be yet a fourth bullet if we choose to do it.
17 OK? But what I'd like to get closure on today -

18

19 ANN MONROE: Would you articulate that bullet again
20 please?

21

22 JEFF KRAUT: Well, what Dr. Brown and Dr. Martin have
23 been saying is we treat hospital ownership of joint venture
24 activities and I'll separate it, it's hospitals where they join

1 venture with physicians in communities don't have the same
2 limited life application to them. And what is questioning is why
3 not? Now, it's a policy we developed many years ago. It's been
4 fine. There's been no issue with it. But it's being raised in
5 the context of the discussion of the third bullet and we can
6 come back and we can have that conversation. Yes, Mr. Lawrence.

7

8 TRACY RALEIGH: And Jeff, we're happy to bring back data.
9 Data always helps. So, but I just want to make one
10 clarification. So, and this gets very technical and granular so
11 bear with me, but our policy today, if there is a new
12 corporation established where the hospital creates a subsidiary
13 and it's joint venturing with physicians, they get, that entity
14 gets a limited life applied. So I think that's something that
15 should be level set.

16

17 JEFF KRAUT: We're differentiating between a hospital
18 opening an am-surg center, doesn't get a limited life. If
19 they're joint venturing and we're setting up a new corporation,
20 they do. They're treated identical to the others.

21

22 TRACY RALEIGH: It's the direct ownership. It's when the
23 hospital directly owns the ASC.

24

1 JEFF KRAUT: And which is uses it's Medicaid, it uses the
2 entity's payer mix. That's it.

3
4 GLENN MARTIN: (inaudible) That information strikes me as
5 useful in the report that you're going to be giving us. Is how
6 they've set it up. Because it's sort of like looking at this 100
7 percent ownership and you alluded to it is why don't I do a
8 40/20 switch. One month I come in with 40 and then the next
9 month I come in and I switch the other 20 percent, I never get
10 reviewed because it's under 50 percent.

11
12 JEFF KRAUT: That's why we're trying to do that.

13
14 GLENN MARTIN: So I'm wondering, I just want to when we get
15 the report, do hospitals game the system the same way that they
16 didn't do things which they should've to avoid this sort of
17 thing. Probably not, ...

18
19 JEFF KRAUT: The problem has not been with the hospital
20 based. The problem has been with 100 percent physician
21 ownership. That's where that issue came up.

22
23 GLENN MARTIN: That's what the data will show. Hopefully.
24 Or not.

1

2 JEFF KRAUT: So what I'd like to do is just get an
3 understanding. We had a pretty robust conversation - Mr.
4 Lawrence.

5

6 HARVEY LAWRENCE: I think if we're going to look at the
7 data and also revisit the policy, then if other issues have
8 evolved over time, maybe we should also look at what else we
9 should be asking of hospitals. Prospectively. And so, and maybe
10 the data can inform that as well.

11

12 JEFF KRAUT: I think it's fine. We'll see where that
13 conversation goes. But what I do want to do is I just want ot be
14 clear on the three bullets that we did discuss and there seems
15 to be general agreement. Is there anybody that - because this is
16 going to be a policy that will be adopted by the Department in
17 the analysis of CON applications that will be brought here, and
18 then we will apply this criteria in this room when we read the
19 department's recommendations.

20

21 LAWRENCE BROWN: Jeff, I would, I might offer an
22 amendment but I don't want to do it now to take up time. I'm OK
23 with bullets one and two. It's just the wording in bullet number

1 three is where I have some concern and I'd like to see that
2 data.

3

4 JEFF KRAUT: Well, the issue with three is what we're
5 saying, is we're applying it to non-hospital because that's
6 where we've had an issue and we are saying we will bring back a
7 discussion about hospital owned. They're mutually exclusive in
8 my mind. They're not linked necessarily. Because you wouldn't
9 not do one and not - you're suggesting do another. We're saying
10 we gotta do this one. This is the one that has presented
11 problems for us that got in the room. So now we'll say, I said,
12 we'll bring back the data. We'll talk about hospital ones.
13 That'll be a fourth bullet one day. But we shouldn't wait to if
14 we've discussed this, because it's a different version of the
15 issue you just said.

16

17 LAWRENCE BROWN: I understand, and I'm not trying to be
18 difficult. I just have a concern with that phrase, "non-hospital
19 owned." If we say hospital or non-hospital...

20

21 JEFF KRAUT: We're saying we're not going to do that
22 today because...

23

1 LAWRENCE BROWN: But you're asking us to accept this
2 bullet, are you not?

3
4 JEFF KRAUT: Because this is the issue you asked us to
5 review. The council asked the committee to review this issue
6 because it was a problem. Nobody complained about the other
7 issue until today. And I'm saying, we will bring that back to
8 the committee. What I want to do is I want to be able to create
9 policy here that we can move forward and review - there's
10 applications in the line that are affected by this policy. And
11 we want to bring those applications through, but we had to be
12 clear, I held those applications from coming into the room until
13 we had the policy conversation. That's all I'm trying to do.

14
15 ANN MONROE: If I could ask, how is our what you say we
16 need to do impacted if we only approve the first two policy
17 points? Is there anything then at risk with what's either before
18 the council or the Department? The limited life is at risk?

19
20 JEFF KRAUT: Sure. You will - there's a change in
21 ownership, you won't be able to review it. You're not going to
22 be able to apply limited life. If they hit the limited life and
23 there's a change in ownership, you're not going to be able to do
24 a thing about it if they meet the criteria.

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TRACY RALEIGH: And I'll confirm that. There's really two distinct policy issues here that we're putting on the piece of paper. The first two deal with the issue of looking at the areas of the state where we need to have a broader look at the impact of ASCs on a broader array of services. That's what the first two policies do. The second is, as Jeff said, we bring to you because you raised it to us and we didn't want to have it in the discussion on an application. But it was brought up for this type of planning committee which is when there is a not direct hospital ownership proposed new ASC, and they are proposing to change, they come to us and they seek PHHPC approval to change the ownership. So it's been operating, it's been subject to limited life, it's not proposing to completely change ownership. Say the limited life had already expired, we are saying it should reset the clock. If there is a complete new set of ownership or 50 percent or greater and we want to measure that over time because those issues were raised, we think that that should get a limited life applied, and that is not our current policy.

JEFF KRAUT: Yea, Dr. Berliner.

1 HOWARD BERLINER: So, why couldn't we also add to that
2 same third point that if a place changes, wants to change from
3 single specialty to multispecialty that we also give it a new
4 limited life?

5
6 TRACY RALEIGH: We took that point about that expansion
7 because that was a very, we had a robust discussion about
8 expansion from single to multi and where our second bullet
9 really addresses that which is in our procedures today, we do
10 not currently require those types of applicants if an ASC is
11 expanding. It's only when a new ASC is coming in for
12 establishment. So what we're saying is, we would prefer to deal
13 with that as part of our outreach. So if there is an application
14 which is currently operating, doesn't need establishment but is
15 going to expand from single to multi, we're going to require as
16 part of that we're going to outreach to the area hospitals that
17 are going to be impacted by that which is not currently part of
18 our procedure. And we're going to assess and have the ability
19 to verify the financial impact that that might have.

20
21 HOWARD BERLINER: Ok, but the other part of that is, and
22 we've seen this in a couple of applications recently, single
23 specialties in which the nature of the specialty is such that
24 they don't provider much charity care converting to

1 multispecialties and then you know, they could still be at zero
2 and we would have nothing to say because it hasn't happened yet
3 so we don't know if it's going to be zero. But if it is, there's
4 nothing we can do about it.

5

6 JEFF KRAUT: So why don't we take that issue and the
7 hospital - I mean we discussed this at the planning committee.
8 We discussed the multispecialty, so we're willing, I'll send
9 both issues back to the planning committee to come back and have
10 another discussion. OK. So we'll do that as well. We' do the
11 single to multispecialty conversion and we'll do the hospital-
12 based ownership.

13

14 PETER ROBINSON: So what we're saying is the possibility
15 of "and" to these policies, not "or." In other words, what we
16 seem to be coming to as a consensus to support what's here but
17 there are two incremental issues that we want clarification on
18 that we should move forward on. Is that correct?

19

20 JEFF KRAUT: So, with that caveat, I'm looking, we're not
21 asking for a vote but I'm looking to see, does anybody have any
22 other concern that needs to be expressed, because this was the
23 unanimous recommendation of the planning committee to the
24 council. We've now discussed it and we'll direct the Department

1 of Health to adopt this into policy in their review of the
2 applications. Is that clear? Anybody have a concern? And we will
3 bring the other two issues back to the planning committee to
4 come back up for us. OK. Great. Dr. Rugge. Just closing remarks.

5

6 JOHN RUGGE: Just as an editorial comment, I think that
7 this Tracy, staff, represents a very nuanced and effective
8 policy response to the age old question about what degree is
9 healthcare? A marketplace? A functioning market? And to what
10 extent is it a utility that we need to protect? And we have a
11 very complex state environment and this is our way of coping. As
12 just a preliminary question, what is next by way of promulgating
13 this as a policy, Tracy? Would this be put on the web and all
14 that?

15

16 TRACY RALEIGH: Yes, we have the, we'll be posting this as a
17 revised policy following this PHHPC meeting. I think that just
18 from Jeff's point I want clarification. I think that the third
19 bullet, are we agreeing to go forward with that, but come back...

20

21 PETER ROBINSON: It's a question of "and." The first
22 three are fine but there are two potential ands, maybe bullets
23 four and five.

24

1 TRACY RALEIGH: That's right. So yes, the answer is yes,
2 we'll be posting this.

3

4 JOHN RUGGE: So thanks to this meeting we have an
5 expanded agenda for the planning committee, and in addition,
6 coming up as I understand it, soon, probably in the next cycle,
7 is consideration that was begun with the RMI repertory
8 modernization initiative discussion two years ago regarding the
9 integration of behavioral health with primary and other medical
10 services. One that is not only potentially a policy issue, but
11 one that could become regulatory or even statutory in terms of
12 how do we create better value by assuring effective coordination
13 and integration of those service? So this will be the next beast
14 to slaughter and we will be looking at that in the next cycle.

15

16 JEFF KRAUT: And Colleen, I would ask that everybody on
17 the council be invited to the planning committee and be aware of
18 the agenda when these issues are discussed so they can
19 participate as well, because it'll be helpful if you have the
20 extended discussion and it's tough to do policy on the fly as a
21 full council, but for those thoughts to be incorporated into the
22 conversation. Everybody's made aware of it. Dr. Gutierrez.

23

1 ANGEL GUTIERREZ: Just a comment in general about the
2 discussion. What we are experiencing is having to deal with the
3 pace of change. And I don't know if we can deal well with that
4 if we become rigid rather than pliant.

5

6 JEFF KRAUT: I agree. Look, the changes that we're
7 dealing with a section of our industry that's highly regulated
8 when most of the change is occurring outside of this section.
9 When you actually get data into some of these issues, I mean
10 we're trying to do the best we can and this is, the safety net
11 conversation and sole community providers are intertwined with
12 major Medicaid health policy issue of how do we keep and support
13 these critical institutions and it's more complex than this
14 room. And that's why I'm always advocating take a bigger view of
15 issues, but it's beyond just regulation. Regulation is not
16 always the right answer. But it is the only, you know, got the
17 hammer everything looks like a nail. So we have to figure out
18 how to do that. And it's time for another kind of retreat to
19 plan. Because we have a whole host of issues that probably would
20 benefit from a more robust discussion what we spend four or five
21 hours going through them then just trying to do this within a
22 hour or two within a committee report.

23

1 JOHN RUGGE: I think it's fascinating how individual
2 discussions of individual applications leads to the
3 understanding or more general issue that we as a council in turn
4 are addressing. So, very interesting back and forth in terms of
5 coming to understand what are the issues that we can deal with.
6 We can't deal with everything.

7
8 JEFF KRAUT: Dr. Boufford, and then we're going to talk
9 to Dr. Kalkut...

10
11 JO BOUFFORD: Just to reinforce the need to have a further
12 discussion because I think a subtext of this discussion which I
13 think Jeff characterized well is with these sweeping changes
14 most of the bulk of the regulatory and legal frameworks have to
15 do with hospitals. And what we've been doing is taking up bits
16 and pieces on various ambulatory based entities, long term care
17 mechanisms, etc., and they're all just out there in a stovepipe
18 in some ways around the way they're being handled. They haven't
19 been handled historically and I think the point that's been
20 brought up today I think there's a need for thinking
21 contextually about the changes in the system and are there
22 things that need to be flexed or further looked at. And we
23 probably don't have the vehicle to do that in a holistic way

1 that we might looking at the hospital industry, because of the
2 history.

3

4 JEFF KRAUT: Dr. Kalkut. The report on project review and
5 establishment actions please.

6

7 GARY KALKUT: Thank you. I'd like to start with 191132C,
8 Canterbury Woods in Erie County. This is to certify two
9 additional residential healthcare facility beds to an existing
10 continuing care retirement community and construct in addition
11 to the first floor of the northwest wing. Both the Department
12 and the establishment committee have approved and with
13 conditions and contingencies as a recommendation and I so move.

14

15 JEFF KRAUT: I have a motion, I have a second Dr.
16 Gutierrez. Any comment from the Department. Any questions for
17 the Department? Hearing none, I'll call for a vote. All those
18 in favor aye?

19

20 [Aye]

21 Opposed? Abstention? Motion carries.

22

23 GARY KALKUT: there are two applications for construction.
24 First is 191174C, Memorial Hospital for Cancer and Allied

1 Diseases in Westchester County. Mr. Kraut declared an interest.
2 This is to establish observation services at the existing cancer
3 care hospital extension clinic located at 500 Westchester Avenue
4 in Harrison. This is part of an observation demonstration
5 project. Both the Department and establishment review committee
6 approve with conditions and contingencies with an expiration of
7 the services five years from the date of final approval as their
8 recommendation. Second is 191215C. Syracuse Surgery Center in
9 Onondaga County. Again, an interest by Mr. Kraut. This is to
10 renovate space to change from a single specialty ambulatory
11 surgery center to a multispecialty ambulatory surgery center.
12 Both the Department and review committee approved with
13 conditions and - recommended approval with conditions and
14 contingencies. And I so move.

15

16 JEFF KRAUT: I have a second, Dr. Gutierrez. Any
17 questions for the Department? All those in favor, aye?

18

19 [Aye]

20 Opposed? The motion carries.

21

22 GARY KALKUT: Next, 191147C. New York Hotel Trades Council
23 and Hotel Association of New York City in Kings County. An
24 interest by Mr. Kraut. This is to relocate existing extension

1 clinic from 6880 Shermahorn Street in Brooklyn to 265 Ashton
2 Place in Brooklyn. Both the Department and the committee
3 recommended approval with conditions and contingencies, and I so
4 move.

5

6 JEFF KRAUT: Second, Dr. Gutierrez. Any questions? All
7 those in favor, aye?

8

9 [Aye]

10 Opposed? Abstentions? The motion carries.

11

12 GARY KALKUT: Next is applications for establishment and
13 construction of ambulatory surgery centers. First, 182236B,
14 Precision SC LLC d/b/a Precision Care Surgery Center in Suffolk
15 County. To establish and construct a single specialty article 28
16 freestanding ambulatory surgery center to be located at 28
17 research way in East Setauket. The freestanding ambulatory
18 surgery center will specialize in orthopedics including spine
19 procedures. Both the committee and the Department recommend
20 approval with conditions and contingencies. Next is 191095B,
21 Hauppauge SC LLC d/b/a the Center for Advanced Spine and Joint
22 Surgery in Suffolk County. To establish and construct a new
23 multispecialty ambulatory surgery center to be located at 526
24 route 111 in Hauppauge. The committee and the Department both

1 recommend approval with condition and contingencies. And then
2 191237E, PBGS LLC in Kings County. This is a request for
3 indefinite life for CON 112032. The Department and the committee
4 recommended approval with conditions and contingencies. And I so
5 move.

6

7 JEFF KRAUT: I have a second by Dr. Gutierrez. Any
8 questions on any one of these items? All those in favor, aye?

9

10 [Aye]

11 Opposed? Abstentions? The motion carries.

12

13 GARY KALKUT: Next is applications for D&TC establishment
14 and construction. First 191196B. Shakespeare operating LLC d/b/a
15 Bronx Treatment Center in Bronx County. This is to establish and
16 construct a diagnostic and treatment center to be located at
17 1250 Shakespeare Avenue in the Bronx. The Department and the
18 committee recommend approval with conditions and contingencies.
19 Next is 191245E, Planned Parenthood of New York City Inc. To be
20 known as Planned Parenthood of Greater New York Inc., in New
21 York County. This is the merger of five Planned Parenthood
22 corporations. New York City, Mid-Hudson Valley, Mohawk Hudson,
23 Nassau County and Southern Finger Lakes with Planned Parenthood
24 of New York City with a corporate name change. Both the

1 Department and the committee recommend approval with conditions
2 and contingencies, and I so move.

3

4 JEFF KRAUT: I have second Dr. Torres. Just to change
5 off. Any questions? All those in favor, aye?

6

7 [Aye]

8 Opposed? Abstentions? The motion carries.

9

10 GARY KALKUT: Next is applications for establishment and
11 construction of dialysis services. First, 182296B, Novo Dialysis
12 Flatlands LLC in Kings County. To establish and construct a new
13 27 station chronic renal dialysis center and home training
14 program to be located at 2306 Nostrand Avenue in Brooklyn.
15 Department and the Committee recommend approval with conditions
16 and contingencies. And then 191077B. Cobble Hill Dialysis in
17 Kings County. Establish and construct a new 12 station renal
18 dialysis center to be located at 380 Henry Street Brooklyn
19 within the Cobble Hill Nursing Home. Again, the Department
20 recommends approval with conditions and contingencies, and I so
21 move.

22

23 JEFF KRAUT: Second Dr. Gutierrez. Any questions on any
24 of these? Yes, Ms. Monroe.

1

2 ANN MONROE: I'm just curious, for the two that are both
3 going to be in Kings County, how close are they to each other?
4 Do we know?

5

6 JEFF KRAUT: Cobble Hill is on the eastern, north eastern
7 part and Flatlands is probably central Brooklyn.

8

9 ANN MONROE: So they're pretty far away. Thank you.

10

11 JEFF KRAUT: I mean, from a time distance, 20 minutes.
12 More. 30.

13 So it's all the way out.

14 Any other questions? All those in favor, aye?

15

16 [Aye]

17 Opposed? Abstentions? The motion carries. That's why I
18 never dated anybody in Brooklyn.

19

20 GARY KALKUT: Next is certificates. First, certificate of
21 dissolution. Jewish Care Services of Long Island. Next is
22 certificate of amendment of the certificate of incorporation for
23 the Eastern Long Island Hospital Association. This is change of
24 corporate purposes. Rochester Primary Care Network Inc., a

1 corporate name change. Columbia Greene Hospital Foundation,
2 again, a corporate name change. And then restated certificates
3 of incorporations, Carthage Area Hospital, a corporate name
4 change, and update of corporate purposes. And then finally an
5 amended and restated certificate of incorporation Health Care
6 Choices of New York incorporated to expand corporate purposes.
7 The Department and committee recommend approval, and I so move.

8

9 JEFF KRAUT: I have a motion and a second, Dr. Gutierrez.
10 Any questions?

11

12 JO BOUFFORD: Maybe two quick words on corporate purposes
13 if there, just for the one that has corporate purpose changes if
14 they had anything remarkable.

15

16 GARY KALKUT: Tracy, do you want to comment on corporate
17 purposes. Expand corporate purposes, Health Care Choices of New
18 York. Update is Carthage Area Hospital. I think those are the
19 two that Dr. Boufford is referring to.

20

21 TRACY RALEIGH: I think it's just amending certificates of
22 incorporation to acknowledge additional services.

23

24 GARY KALKUT: We'll get the book.

1 Carthage and Healthcare Choices.

2

3 MARTHE NGWASHI: Marthe Ngwashi, Department of Health
4 legal. Carthage changed it's corporate purposes to comply with a
5 grant it is seeking to get from the US Department of
6 Agriculture. So it wasn't anything related to services that it's
7 being offered. And the other one I'll get to you right now I'll
8 look at it.

9

10 PETER ROBINSON: So the one for Health Care Choices,
11 which I think is the other one you mentioned, indicates to add
12 to it's corporate purposes the explicit authorization to own and
13 operate a diagnostic and treatment center and one or more dually
14 authorized extension clinics within the meaning of article 28.
15 So that's the added purpose.

16

17 JEFF KRAUT: Any other questions? Hearing none, I'll call
18 for a vote. All those in favor, aye.

19

20 [Aye]

21 Opposed? Abstentions? The motion carries.

22

23 GARY KALKUT: Next is establishment and construction of
24 ambulatory surgery center 191189B, EWSA SC LLC in New York

1 County. Conflict and recusal by Dr. Martin who is leaving the
2 room. This is to establish and construct a single specialty
3 ambulatory surgery center to be located at 2101 to 2115 Broadway
4 in New York providing gastroenterology services. The Department
5 recommends approval with conditions and contingencies with
6 expiration of the operating certificate five years from the date
7 of issuance. And the committee recommends the same, and I so
8 move.

9

10 JEFF KRAUT: We have a second Dr. Gutierrez. Any
11 questions? Any member of the committee wants to comment on this
12 application? I believe there was dissent at the project review?
13 Just because of the recusal. All those in favor, aye?

14

15 [Aye]

16 Opposed? Abstentions? The motion carries. You can ask Dr.
17 Martin to return.

18

19 GARY KALKUT: Next is 191136E, Cowley Dialysis LLC d/b/a
20 Hutchison River Dialysis in Bronx County. An interest by Mr.
21 Kraut. This is to certify Cowley Dialysis LLC as the new
22 operator of a 19 station chronic renal dialysis center located
23 at 2331 East Chester Road in the Bronx, currently operated as an
24 extension clinic of Bronx Dialysis Center. The Department

1 recommends approval with conditions and contingencies and the
2 committee recommends the same with one member opposing. And I so
3 move.

4
5 JEFF KRAUT: I have a motion may I have a second. Second
6 Dr. Boufford. Any questions or discussions? Dr. Gutierrez.

7
8 ANGEL GUTIERREZ: I was the opposing vote. I continue to
9 be concerned about the fact that there have been no word from
10 DaVita who is the owner of Knickerbocker dialysis about an
11 explanation as for forgivens for examples of clear breaches on
12 character which is historically documented. So that was the
13 reason for my negative vote.

14
15 JEFF KRAUT: So Dr. Gutierrez was quite expressive at the
16 establishment and project review committee. And just to be sure,
17 did anybody reach out after he made those public statements from
18 DaVita to the Department that you're aware of? I don't think so.
19 Just to acknowledge his point.

20
21 TRACY RALEIGH: During the discussion, representatives from
22 DaVita were present. There was comment that they provided to
23 address that. They subsequently prior to the meeting to keep us
24 updated, they disclosed - first I want to point out that the

1 applicant does disclose, and I would put these as compliance
2 issues, in their application to us that we do take into
3 consideration. Many of these issues do apply broadly to other
4 large corporately owned dialysis centers. But there was no
5 specific follow up that we received.

6

7 JEFF KRAUT: Yes, Dr. Brown.

8

9 LAWRENCE BROWN: I also want to acknowledge a good
10 colleague's comments. And from the standpoint and transparency
11 for the rest of the members of the council who were not involved
12 in that conversation, it was a very difficult issue even for me,
13 because on the one hand there clearly is a need for the care. On
14 the other hand there is certainly questions about the provider,
15 even though the amount of their ownership was dropped there was
16 still a concern that how we would be able to make sure that need
17 for the care in that community for kidney dialysis is adequately
18 going to be overseen and not be having any further consequences
19 about what have been DaVita's prior history.

20

21 JEFF KRAUT: And the partners in that affirmed they had
22 no such concerns and had a very positive relationship. And the
23 physician, the medical director was clear that he had

1 responsibility for the thing. So we're clear. OK. All those in
2 favor, aye?

3

4 [Aye]

5 Opposed? Abstentions? The motion carries.

6

7

8

9 [Aye]

10 Opposed? Dr. Gutierrez. Abstentions? The motion carries.

11

12 GARY KALKUT: Next is home health agency licensures. First
13 affiliated with assisted living programs. That is 182301D
14 Brookhaven Homecare LLC in Suffolk County. 191097E, Oyster Bay
15 Manor Home Care in Nassau County. And then changes of ownership
16 with consolidation. 191210E, Supportive Homecare LLC d/b/a Care
17 365 Homecare in Kings County. The Department recommends approval
18 as does the committee with conditions and contingencies and I so
19 move.

20

21 JEFF KRAUT: Second by Dr. Gutierrez. Any questions? All
22 those in favor, aye?

23

24 [Aye]

1 Opposed? Abstentions? The motion carries.

2

3 GRAY KALKUT: With that I adjourn the report of the --
4 that's the end of the report for the establishment and project
5 review committee, pardon me.

6

7 [we're done before noon!]

8

9 JEFF KRAUT: Shhhh. Thank you all. Thank you for the
10 conversation today. Really appreciate it. Thank you to our new
11 members for jumping in and participating. Appreciate it. Dr.
12 Gutierrez.

13

14 ANGEL GUTIERREZ: At least one county in New York State
15 has no search planning.

16

17 JEFF KRAUT: I'm not suggesting everyone does.

18

19 ANGEL GUTIERREZ: IS the search planning you referred to
20 something local applying to New York City? Is it a county thing?
21 Is it a state thing? And if it's not a state thing? Should it
22 be?

23

1 JEFF KRAUT: I think there is - let's do this because I
2 know what I know; I don't know what I don't know. As my father
3 constantly reminded me. A discussion at some point about the
4 kind of emergency response in the event of a broad scale public
5 health incident, what would be, maybe somebody could give us a
6 brief presentation at one of the full meetings and we can
7 discuss search capacity in particular.

8
9 [it used to be a federal system]

10

11 Well, the federal system is still in place.

12

13 SALLY DRESLIN: We're happy to do that. The Department of
14 Health has a very robust Office of Emergency Preparedness. And
15 we work very closely with many of our partner agencies and we
16 have many many plans, many many efforts that are ongoing,
17 supplies and efforts that respond to natural disasters obviously
18 to disease outbreaks, to environmental situations, so we're
19 happy to give a presentation on how that process works here in
20 the state and who are partners are.

21

22 JEFF KRAUT: Thank you very much. I think that would be
23 very helpful. Dr. Kalkut.

24

1 GARY KALKUT: And in 2012 I think there was a need for
2 surge based on supply not demand with hurricane Sandy where more
3 than 1000 beds were taken out of the system abruptly.

4
5 JEFF KRAUT: Abruptly, but everybody got into a bed.

6
7 ANGEL GUTIERREZ: The problem with an epidemic is that
8 you won't even have the ambulance capacity to move people
9 around.

10
11 JEFF KRAUT: I'm well aware. We had this with Ebola and
12 we were concerned.

13 So we'll do that. Again, thank everybody. Our next meeting
14 the project committee day is on September 26. Our full council
15 meeting will be on October 10. The new members will also have an
16 orientation following the meeting. So with that I have a motion
17 to adjourn. So moved. We are adjourned. Thank you very much.

18
19
20
21
22

State of New York
Public Health and Health Planning Council

Minutes
October 10, 2019

The meeting of the Public Health and Health Planning Council was held on Thursday, October 10, 2019 at the New York State Department of Health Offices, 90 Church Street, 4th Floor CR 4 A/B, NYC. Chairman Jeffrey Kraut presided.

COUNCIL MEMBERS PRESENT

Ms. Judy Baumgartner	Dr. Ms. Ann Monroe
Dr. Howard Berliner	Mario Ortiz
Dr. Jo Ivey Boufford	Ms. Ellen Rautenberg
Dr. Lawrence Brown	Mr. Peter Robinson
Ms. Carver-Cheney	Dr. John Ruge
Dr. Angel Gutiérrez	Ms. Nilda Soto
Mr. Thomas Holt	Dt. Theodore Strange
Dr. Gary Kalkut	Mr. Hugh Thomas
Mr. Jeffrey Kraut	Dr. Anderson Torres
Mr. Scott La Rue	Dr. Kevin Watkins
Mr. Harvey Lawrence	Dr. Patsy Yang
Dr. Glenn Martin	Dr. Howard Zucker – Ex-officio

DEPARTMENT OF HEALTH STAFF PRESENT

Mr. Gregory Allen	Mr. George Macko – via video Albany
Ms. Deirdre Astin	Mr. Nicholas Mestoik
Ms. Barbara DelCogliano – via video Albany	Ms. Marthe Ngwashi
Ms. Alejandra Diaz	Mr. Mark Noe – via video Albany
Ms. Valerie Deetz	Ms. Tracy Raleigh
Ms. Shelly Glock	Mr. Dan Sheppard
Mr. Mark Furnish – via video Albany	Ms. Laura Santilli
Mr. Mark Hennessey	Ms. Lauren Tobias – via video Albany
Mr. Brad Hutton – via video Albany	Ms. Jennifer Treacy
Mr. Brian Gallagher – via video Albany	Mr. John Walters – via video Albany
Ms. Colleen Leonard	Mr. Richard Zahnleuter

INTRODUCTION

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

APPROVAL OF THE MINUTES OF SEPTEMBER 12, 2019 AND SEPTEMBER 17, 2019

Mr. Kraut asked for a motion to approve the September 12, 2019 Minutes of the Special Public Health and Health Planning Council meeting. Dr. Gutiérrez motioned for approval which was seconded by Dr. Brown. The minutes were unanimously adopted. Please refer to page 3 of the attached transcript.

Mr. Kraut asked for a motion to approve the September 17, 2019 Minutes of the Special Public Health and Health Planning Council meeting. Dr. Brown motioned for approval which was seconded by Mr. Holt. The minutes were unanimously adopted. Please refer to pages 3 and 4 of the attached transcript.

REGULATION

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

Report of the Committee on Codes, Regulation and Legislation

For Emergency Adoption

19-34 Addition of Subpart 9-2 to Title 10 NYCRR
(Required Signage Warning Against the Dangers of Illegal Products)

Dr. Gutiérrez described for emergency adoption the Addition of Subpart 9-2 to Title 10 NYCRR (Required Signage Warning Against the Dangers of Illegal Products) and motioned for adoption. Dr. Torres seconded the motion. The motion carried. Please see pages 4 and 5 of the transcript.

For Adoption

19-18 Amendment of Sections 405.5 and 405.19 of Title 10 NYCRR
(Registered Nurses in the Emergency Department)

Dr. Gutiérrez described for adoption the Amendment of Sections 405.5 and 405.19 of Title 10 NYCRR (Registered Nurses in the Emergency Department) and motioned for adoption. Dr Torres seconded the motion. The motion to adopt carried. Please see page 5 of the transcript.

19-07 Amendment of Sections 405.7 and 751.9 of Title 10 NYCRR
(Patients' Bill of Rights)

Dr. Gutiérrez described for adoption the Amendment of Sections 405.7 and 751.9 of Title 10 NYCRR (Patients' Bill of Rights) and motioned for adoption. Dr Torres seconded the motion. The motion to adopt carried. Please see page 6 of the transcript.

18-19 Amendment of Parts 69, 400 & 405 and Addition of Part 795 to Title 10 NYCRR
(Midwifery Birth Center Services)

Dr. Gutiérrez described for adoption the Amendment of Parts 69, 400 & 405 and Addition of Part 795 to Title 10 NYCRR (Midwifery Birth Center Services) and motioned for adoption. Dr. Torres seconded the motion. The motion carried. Please see pages 6 and 7 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Office of Primary Care and Health Systems Management Activities

Mr. Kraut introduced Mr. Sheppard to give the Office of Primary Care and Health Systems Management activities report.

Mr. Sheppard stated that the Department announced capital awards for 25 projects totaling \$187 million which are the latest awards from the statewide healthcare transformation program. He also highlighted capital projects from previous years.

Mr. Sheppard advised that Ms. Raleigh's team focuses their work on the Council along with spearheading and managing transformation initiatives from more than 25 hospitals throughout the State and gave an update on the facilities.

Mr. Sheppard lastly reported that there was legislation enacted earlier this year that directed the Department to conduct a study to examine how staffing enhancements and other initiatives can be used to improve patient safety and quality of healthcare service delivery in hospitals and nursing homes.

Mr. Sheppard announced that this was his last PHHPC meeting that he would be attending since he was retiring from State service. Mr. Kraut thanked Mr. Sheppard for his dedication, and it has been a pleasure working with him.

Mr. Sheppard concluded his report. Please see pages 7 through 21 of the transcript.

Department of Health Activities

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

Pulmonary Illness Associated with E-cigarettes

Dr. Zucker began his report by thanking the members for attending the 2 emergency meetings in September as they came forward and helped New York State and the Department with their time and advice on the issues related to vaping. New York State physicians are seeing severe pulmonary illness associated with e-cigarettes and vaping in patients ranging from about 14 years of age to 69 years of age and who have used at least one vape product prior to becoming ill. On October 4, 2019, there was New York's first vaping related death and that tragically was a 17 years old male in New York City and he had been hospitalized in early September with a vaping associated respiratory illness and he was readmitted later in the month. The CDC last update data on this illness on October 1, 2019 and at that time it reported 1080 cases and 18 confirmed deaths in 15 states but since that time the recent update will show that Massachusetts has unfortunately a death as do we so the toll continues to rise. Vaping remains a priority for the Department.

Dr. Zucker stated that this is a public health emergency. It does demand immediate attention. The Department has worked extremely hard on this issue. The State's decision to ban the sale of flavored e-cigarettes was a direct response to the growing threat that no defend of public health could afford to ignore and the vaping industry is using the flavored e-cigarettes to get young people hooked on potentially dangerous and deadly products. We need to help ensure the well-being of our children. The Department is confident that once the courts hear our argument they will agree as well. While the courts' ruling temporarily delays our schedule of enforcement of this ban, it will not deter us. The Department will continue to use every tool at our disposal to address this crisis. The Department remains the leader in nationwide research into vaping products. The Wadsworth Center has determined that the thickening agent used in the black market vaping products are nearly pure vitamin E acetate oil. The Department will continue to investigate the high levels of vitamin E acetate in the samples of taint, and that is one possibility we recognize and there could be others.

Measles

Dr. Zucker noted that October, the Department marked the passage of more than 42 days and that is the equivalent of two incubation periods without any new cases of measles reported. Sullivan County, Orange County, since the outbreak began in October 2018, and Rockland County passed that threshold in September. The threat of vaccine-preventable diseases remains and the Department is not letting down its guard. With the Rockland partners, the Department is currently investigating a case who has contracted measles internationally and then travelled to Rockland County. The Department has some active public health responses underway in Nassau County, two cases, one in Monroe County, one in Putnam County that are related to measles exposures, again from international travel, but they are not affiliated with the 2018 outbreak. Between October 1, 2018 and October 3, 2019, 406 people were infected with measles in Rockland, Orange, and Sullivan, and Westchester Counties, as a result of initial exposures from international travel. With the Department's partners, 85,000 MMR vaccines were administered in those counties during that timeframe. New York State is taking strong measures in 2019 to ensure school eligible students are vaccinated and will remain vigilant in protecting New Yorkers from measles and other dangerous vaccine-preventable illnesses.

Flu

Dr. Zucker reported on the flu season. The flu season begins in October. The Department is aligning its extensive outreach and awareness efforts with the CDC's recommendations that people get the 2019/2020 influenza vaccine by the end of October. In September, unfortunately a four-year-old in California died after testing positive for influenza. The Department has already seen the tragic potential even before the season typically gets underway. This is why the Department aggressively pushes to encourage all New Yorkers to get their shots in October to protect them and their families.

Organ Donation Enrollment Day

Dr. Zucker noted that October 10, 2019 is the fifth annual organ donation enrollment day in New York state. This is the day in which the registry goes all out to enroll as many new donors as possible during the 24-hour window. The Department and registry had been working to increase the state's organ donation rate of 35 percent. Every 18 hours another New Yorker tragically dies waiting for a donated organ. We know that 92 percent of New Yorkers support organ and tissue donation, so the willingness is obviously there. The State and the registry have done a lot in the past few years to harness that willingness. New York has changed the driver's license applications and renewal process and lowered the age of organ donor consent to 16 and 17 year olds who apply for learners permits and drivers licenses, and pursued enrollment avenues outside the DMV such as the New York State of Health, the marketplace. Since this new route to donation began April 2017, 200,000 New Yorkers had elected to enroll in organ donation through the marketplace.

Health Insurance Coverage

Dr. Zucker announced that in October, the new United States Census Bureau data revealed that the rate of uninsured New Yorkers declined in more than half of New York's counties in 2018. Last year New York was one of only three states in the nation to see a decrease in its uninsured population reducing the number of uninsured individuals by 1.2 million since 2010 and one million of those New Yorkers acquired their insurance since the New York State of Health marketplace opened in 2013. New York's annual open enrollment period for enrollment is, begins on November 1, 2019 and will run through January 31, 2020.

Breast Cancer Awareness Month

Dr. Zucker stated that October breast cancer awareness month and New York State continues to promote vigilant breast cancer screening to save lives. Each year almost 16,000 New York women are diagnosed with breast cancer and over 2500 unfortunately die from the disease. Breast Cancer became New York State's most frequently diagnosed cancer in 2013 and the Department and Governor Cuomo have responded to that threat with legislation and programs focused on early detection which is obviously the best possible treatment. This spring the Governor signed legislation requiring large group insurance to cover medically necessary

mammograms for women ages 35-39. The Department has made 3D mammography available to more New Yorkers by mobile mammography vans and 3D mammography makes it easier for doctors to catch more types of cancer, which is especially helpful for women with dense breast tissue. Nearly half of all women 40 and older have dense breasts. The Department is seeing positive results from the statewide measures, dating from the behavioral risk factors surveillance system shows that the number one screen for breast cancer in New York state increased from 80.3 percent in 2017 up to 82.1 percent in 2018 in just a year. Being that approximately 50,000 more women were screened in 2018 compared to the year before.

HIV

Dr. Zucker announced that new data showed that 2018 had the largest decrease in new HIV diagnoses in New York State since the launch of the ending the epidemic initiative began in 2014. We are on track to end the AIDS epidemic by the end of 2020. A new diagnoses for last year reached an all time low of 2481, an 11 percent drop from 2017 and 28 percent drop since 2014. These advances place the state in an idea position to contribute to the national goal of ending the AIDS epidemic by 2030. Governor Cuomo has designated October 20-26 as a week to raise awareness about preexposure prophylaxis of HIV known as PREP as we know, and this medication is a way for those who do not have HIV but who are at substantial risk of getting it to prevent HIV infection by taking the pill every day. PREP reduces the risk of getting HIV from sex by 99 percent. New York leads the nation with the largest percentage of individuals on PREP medication and new data shows that almost 32,000 New Yorkers took PREP in 2018 and again, that's an increase from 2017 by 32 percent. The Department has been incredibly busy focused throughout this eventful year. The Commissioner thanked his entire team who work unbelievably hard and 24-hours a day, 7-days a week and they get calls on the weekends and evenings. He also thanked the Council for all they do to help us move the initiatives forward that the Department feel are best for the state of New York.

Dr. Zucker concluded her report. To read the complete report and questions from the Members, please see pages 21 through 35 of the attached transcript.

Office of Health Insurance Programs Activities

Mr. Kraut introduced Mr. Allen to give the Office of Health Insurance Programs activities report.

Mr. Allen began report by stating the State has a six year waiver for healthcare transformation using Medicaid resources, this waiver expires in April 2020.

Mr. Allen also noted that DSRIP is a performance based program and the Department continues to focus on performance measures that will be used for value based payment and payment contracts. The Department continues the State's effort to health essential community providers.

Mr. Allen concluded her report. To read the complete report and questions from the Members, please see pages 35 through 58 of the attached transcript.

Office of Public Health Activities

Mr. Kraut introduced Mr. Hutton to give the Office of Public Health report.

Mr. Hutton began his report by advising the lower blood lead level rulemaking went into effect on October 1, 2019. The Department issued guidance to healthcare providers on the lower level and provided training. The Department has modified the software system used for tracking children with elevated blood lead levels and the activities they receive to lower the levels.

Mr. Hutton next shared an update on the activities in the area of drinking water. The public comment period ended for the contaminant levels for PFOA and PFOS and 1-4 dioxane. The Department received thousands of comments and staff is assessing the comments.

Mr. Hutton noted that the Department received two federal grants. First the Department in collaboration with the University of Albany School of Public Health is one of seven grantees that have been awarded it's prestigious multistate health study. The second grant is by way of the environmental protection agency, EPA. We're one of eight grantees who have been awarded a special grant. In this instance we'll be studying landfills across New York state and constructing a database of the PFOS contamination that arises from landfill contamination and better understanding the sources and potential strategies to respond to that type of contamination.

Lastly Mr. Hutton stated that there will be a presentation on violence prevention at the next Public Health Committee as well as looking forward to the Public Health Committee continuing it's work on maternal mortality.

Mr. Hutton concluded his report, to view the members discussion please see pages 51 through 58 of the attached transcript.

Mr. Kraut then moved to the next item on the agenda and introduced Mr. Robinson 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

Peter Robinson, Chair, Establishment and Project Review Committee

A. APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Residential Health Care Facilities - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191203 C	St. Anns Community (Monroe County)	Contingent Approval

Mr. Robinson calls application 1912303 and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see page 59 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

Acute Care Services - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191344 C	North Central Bronx Hospital (Bronx County) Ms. Soto – Interest/Abstaining Dr. Yang – Recusal	Contingent Approval

Mr. Robinson calls application 191344 and notes for the record that Dr Yang has a conflict and has let the meeting room. He also noted for the record that Ms. Soto has declared an interest and will be abstaining. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with the noted recusal and abstention. Dr. Yang returns to the meeting room. Please see pages 59 and 60 of the attached transcript.

182232 C	NYU Winthrop Hospital (Nassau County) Dr. Kalkut – Recusal	Contingent Approval
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Mr. Robinson calls application 182232 and notes for the record that Dr. Kalkut has declared a conflict and has left the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with the noted recusal. Dr. Kalkut returns to the meeting room. Please see pages 60 and 61 of the attached transcript.

192002 C Highland Hospital Contingent Approval
(Monroe County)
Mr. Robinson – Recusal
Mr. Thomas – Interest

Dr. Kalkut calls application 192002 and notes for the record that Mr. Robison has declared a conflict and has left the meeting room. Dr. Kalkut also notes for the record that Mr. Thomas has declared an interest. Dr. Gutiérrez motions for approval. Dr. Kalkut seconds the motion. The motion to approve carries with the noted recusal and interest. Mr. Robinson returns to the meeting room. Please see page 61 of the attached transcript.

191280 C Maimonides Medical Center Contingent Approval
(Kings County)
Mr. Kraut – Recusal
Dr. Strange – Recusal

Mr. Robinson calls application 191280 and notes for the record that Mr. Kraut, Mr. Lawrence and Dr. Strange have declared a conflict and have left the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with the noted recusals. Mr. Lawrence returns to the meeting room. Please see page 62 of the attached transcript.

192019 C Southside Hospital Contingent Approval
(Suffolk County)
Mr. Kraut – Recusal
Dr. Strange – Recusal

192020 C Southside Hospital Contingent Approval
(Suffolk County)
Mr. Kraut – Recusal
Dr. Strange – Recusal

Mr. Robinson calls applications 192019 and 192020 and notes for the record that Mr. Kraut and Dr. Strange have declared a conflict and have remained outside the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with the noted recusals. Mr. Lawrence returns to the meeting room. Please see pages 62 and 63 of the attached transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

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

CON Applications

Residential Health Care Facilities – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
182117 E	TCPRNC LLC d/b/a New Riverdale Nursing Home (Bronx County) Mr. LaRue – Recusal	Contingent Approval

Mr. Robinson calls application 182117 and notes for the record that Mr. LaRue has declared a conflict and has exited the meeting room.. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with the noted recusals. Mr. LaRue returns to the meeting room. Please see pages 63 and 64of the attached transcript.

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. APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Residential Health Care Facilities – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191263 E	Schoellkopf Health Center (Niagara County)	Contingent Approval

191270 E	Troy Diamond Operations, LLC d/b/a The Diamond Hill Nursing and Rehabilitation Center (Rensselaer County)	Contingent Approval
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Certified Home Health Agencies – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191341 E	Marquis Certified Home Care, LLC (Albany County)	Contingent Approval

Ambulatory Surgery Centers – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191137 B	Binghamton ASC, LLC d/b/a Greater Binghamton Eye Surgery Center (Broome County)	Contingent Approval
191314 B	Staten Island ASC, LLC d/b/a Specialty Surgery Center of Staten Island (Richmond County)	Contingent Approval

Diagnostic and Treatment Centers – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191170 B	AIDS Healthcare Foundation (Bronx County)	Contingent Approval
191326 B	Sunrise Med Plus, LLC (Suffolk County)	Contingent Approval
192007 B	Cayuga Community Services (Tompkins County)	Contingent Approval
192012 B	Hollis AK, LLC d/b/a Hollis Diagnostic & Treatment Center (Queens County)	Contingent Approval

Mr. Robinson calls applications 191263, 191270, 191341, 191137, 191314, 191170, 191326, 192007, and 192012 and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 64 through 67 of the attached transcript.

CATEGORY 4: Applications Recommended for Approval with the following:

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

CON Applications

Residential Health Care Facilities - Construction

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
182120 C	The Plaza Rehab and Nursing Center (Bronx County) Mr. LaRue - Recusal	Contingent Approval

Mr. Robinson calls applications 182120 and notes for the record that Mr. LaRue has declared a conflict and has left the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. LaRue’s recusal. Mr. LaRue returns to the meeting room. Please see page 67 of the attached transcript.

Dialysis Services – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191284 E	Citadel Renal Center LLC (Bronx County)	Contingent Approval
191264 E	Freedom Center of Troy, LLC d/b/a Fresenius Kidney Care – Troy (Rensselaer County)	Contingent Approval
191288 E	Freedom Center of Rockland County, LLC d/b/a Fresenius Kidney Care Valley Cottage (Rockland County)	Contingent Approval

Mr. Robinson calls applications 191284, 191264, and 191288 and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 68 and 69 of the attached transcript.

Certificates

Certificate of Amendment of the Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
Hemophilia Center of Western New York, Inc.	Approval
WMC Health Network – Ulster, Inc.	Approval
HealthAlliance, Inc.	Approval
Northwest Buffalo Community Health Care Center, Inc.	Approval

Certificate of Amendment of the Restated Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
Catskill Regional Medical Center	Approval
Greater Hudson Valley Health System, Inc.	Approval
Orange Regional Medical Center	Approval

Mr. Robinson calls the above listed certificates for approval for consent to file. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 69 and 70 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

Residential Health Care Facility – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
192001 E	St. Joseph's Hospital - Skilled Nursing Facility (Chemung County) Mr. Robinson - Recusal	Contingent Approval

Mr. Kraut describes application 192001 and notes for the record that Mr. Robinson had declared a conflict and has left the meeting room. Mr. Kraut motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. Robinson’s recusal. Mr. Robinson returns to the meeting room. Please see pages 70 and 71 of the attached transcript

Acute Care Services – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
192030 E	Unity Hospital of Rochester (Monroe County) Mr. Thomas – Recusal Mr. Robinson - Interest	Contingent Approval

Mr. Robinson describes application 192030 and notes for the record that Mr. Thomas had declared a conflict and has left the meeting room. Mr. Robinson declared an interest in the application. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Mr. Thomas’ recusal. Mr. Thomas returns to the meeting room. Please see page 71 of the attached transcript

Ambulatory Surgery Centers – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
191164 B	Harlem Road Ventures, LLC t/b/k/a Harlem Ambulatory Surgery Center, LLC (Erie County) Ms. Baumgartner - Recusal	Contingent Approval

Mr. Robinson describes application 191164 and notes for the record that Mr. Baumgartner has declared a conflict and has left the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries with Ms. Baumgartner’s recusal. Ms. Baumgartner returns to the meeting room. Please see page 72 of the attached transcript

Certificates

Certificate of Amendment of the Certificate of Incorporation

<u>Applicant</u>	<u>Council Action</u>
Southside Hospital Mr. Kraut – Recusal Dr. Strange - Recusal	Approval

Mr. Robinson calls Southside Hospital's Certificate of Amendment of the Certificate of Incorporation and notes for the record that Mr. Kraut and Dr. Strange have declared a conflict and have left the meeting room. Mr. Robinson motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries the noted recusals. Mr. Kraut and Dr. Strange returns to the meeting room. Please see page 72 of the attached transcript

CATEGORY 3: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

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

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

CON Applications

HOME HEALTH AGENCY LICENSURES

Changes in Ownership with Consolidation

191340 E	Marquis Home Care, LLC (Albany County)	Contingent Approval
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Serious Concern/Access

182282 E	BAYADA Home Health Care, Inc. (Queens County)	Contingent Approval
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191104 E	Intrathecal Care Solutions, LLC d/b/a Advanced Nursing Solutions (Sullivan County)	Contingent Approval
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Mr. Robinson calls applications 191340, 192282 and 191104 and motions for approval. Dr. Gutiérrez seconds the motion. The motion to approve carries. Please see pages 73 and 74 of the attached transcript

Mr. Robinson concluded his report.

ADJOURNMENT:

Mr. Kraut announced the upcoming PHHPC meetings and adjourned the public portion of the meeting and noted for the record the Council will go into executive session to consider the Report of the Committee on Health Personnel and Interprofessional Relations.

1 NEW YORK STATE DEPARTMENT OF HEALTH

2 PUBLIC HEALTH AND HEALTH PLANNING COUNCIL MEETING

3 OCTOBER 10, 2019

4 TRANSCRIPT

5
6 JEFF KRAUT: We're going to start the webcast. Great.

7 Good morning. I'm Jeff Kraut and I have the privilege to call to
8 order the meeting of the public health and health planning
9 council. And welcome members. Eventually commissioner Zucker,
10 participants and observers. I'd like to remind the council
11 members, staff and audience this meeting is subject to the open
12 meeting law and is broadcast over the internet where the webcast
13 can be accessed through the Department's website at
14 NYHEALTH.GOV. these on-demand webcasts will be available no
15 later than seven days after the meeting and up for a minimum of
16 30 days, and then a copy is retained in the Department's
17 records. In order to make this meeting successful, there's
18 synchronized captioning so we have to make sure people are not
19 going to speak over each other. We obviously can't do the
20 captioning when two people speak at the same time. The first
21 time we speak we need you to state your name, briefly identify
22 yourself as a council member or a DOH staff. This will be very
23 helpful to us and you'll note, we have new microphones. All of
24 the microphones are hot. These portable microphones without
25 wires can be passed around. You must have the green light on in

1 order to speak and you probably have to have it within six
2 inches of your mouth to be heard effectively. In addition you'll
3 notice there are sound system speakers in the ceiling. These new
4 microphones are extraordinarily sensitive. They will pick up
5 every sound. So be careful about rustling of papers, but
6 particularly be careful of side conversations because we're
7 seeing that recorded as we speak. And as demonstrated by our two
8 council members, thank you for that demonstration. Additionally
9 for the first time we have microphones over the audience. So
10 your sounds also and your side conversations will be captured
11 and preserved for eternity. So just be careful about it. There's
12 a form to fill out before you enter the meeting room which
13 records your attendance here. It's required by the Joint
14 Commission on Public Ethics in accordance with executive law
15 166. This form is also posted on the Department's website at
16 NYHEALTH.GOV under CON, certificate of need, so in the future
17 you could fill out the form before you actually come into the
18 room. Today we're going to hear reports from the commissioner,
19 Mr. Sheppard and the office of primary care and health systems,
20 Mr. Hutton, and unfortunately Mr. Allen who planned to give us
21 an update on DSRIP 2.0 and the DSRIP program had been called
22 away. So we're going to - we'll see what we can do with the
23 staff that are available but I suspect that presentation will
24 have to be put off one more cycle. I'm going to ask Dr.
25 Gutierrez to present regulations for emergency adoption,

1 adoption and for information. Mr. Robinson will provide the
2 report of the establishment and project review committee. I want
3 to remind people before we do Mr. Robinson's report, you know
4 the agenda is organized by topics or categories which captures
5 our roles and responsibilities, as we're going to be batching
6 CON applications. So for the members, just take a look at the
7 agenda and how they've been organized and how we batch them and
8 if you want a project moved from one category to another please
9 let Colleen know prior to us calling those applications, and
10 we'll change the application. My next agenda item is the
11 adoption of the minutes, and may I have a motion for adoption of
12 the September 12, 2019 special PHHPC meeting minutes. I have a
13 motion Dr. Gutierrez, Dr. Brown for being ahead of us. I have a
14 second. Any comments? Any changes to the minutes? Hearing none,
15 I'll call for a vote. All those in favor, aye.

16

17 [Aye]

18 Opposed? Thank you.

19 I know would like to have a motion for the adoption of the
20 September 17, 2019 special PHHPC meeting minutes. May I have a
21 motion for adoption?

22 So moved.

23 I have a motion. Second, Mr. Holt. Any comments about those
24 minutes? Hearing none, I'll call for a vote. All those in favor
25 aye.

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[Aye]

Thank you.

I'm going to move around just to kind of compress the day. We have the full council. I'm going to ask Dr. Gutierrez first to present the report of the Codes committee.

ANGEL GUTIERREZ: Thank you very much. Good morning. And again, at today's meeting of the committee on Codes, Regulation, and Legislation, the committee reviewed four proposals; one for emergency adoption and one for adoption. For emergency adoption required signage warning against the dangers of illegal products. The proposal on subpart 9-2 to Title 10 and requires entities in New York State that sell vaping products to post signage on the dangers of vaping illegal e-cigarettes and e-liquid products. The committee voted to recommend emergency adoption to the full council, and I so move.

JEFF KRAUT: I have a motion. Do I have a second? I have a second, Dr. Torres. Any questions?

ANGEL GUTIERREZ: Brad Hutton is available for questions from council members.

1 JEFF KRAUT: Hearing none, all those in favor aye.

2

3 [Aye]

4 Opposed? Abstention? The motion carries.

5

6 ANGEL GUTIERREZ: For adoption registered nurses in the
7 emergency department. This proposal would strike the language
8 from 405.19 D2 requiring emergency department nurses to have one
9 year of clinical experience and add language that the nurses
10 must meet competency requirements found in new subsection 7 of
11 405.5. This new subsection will require nurses in specialty
12 areas including but not limited to the emergency department to
13 complete training and education to establish competencies
14 specific to the specialty area. Deirdre Astin is available to
15 answer questions from the council, but the committee voted to
16 recommend the adoption to the full council, and I so move.

17

18 JEFF KRAUT: I have a motion from Dr. Gutierrez. May I
19 have a second, Dr. Torres. Any member of the council has
20 questions for the Department? Hearing none, I'll call for a
21 vote. All those in favor, aye.

22

23 [Aye]

24 Opposed? Abstention? The motion carries.

25

1 ANGEL GUTIERREZ: Patients' Bill of Rights is also for
2 adoption. This proposal will amend section 405.7 to reflect the
3 correct name of the educational materials referred to in
4 paragraph 10 of subdivision C, section 405.7 and would amend
5 section 751.9 to clarify the rights afforded to patients by the
6 surprise bill law. The committee voted to recommend adoption to
7 the full council and I so move.

8

9 JEFF KRAUT: I have a motion by Dr. Gutierrez. I have a
10 second by Dr. Torres. Any questions for the Department? Hearing
11 none I'll call for a vote. All those in favor, aye.

12

13 [Aye]

14 Opposed? The motion carries.

15

16 ANGEL GUTIERREZ: Last for adoption is the midwifery
17 birth centers. This proposal will create a new part 795 of Title
18 10 establishing regulations for a midwifery birth centers. The
19 committee voted to recommend adoption to the full council, and I
20 so move.

21

22 JEFF KRAUT: I have a motion from Dr. Gutierrez. A second
23 by Dr. Torres. Any questions for the Department. Hearing none
24 I'll call for a vote. All those in favor, aye.

25

1 [Aye]

2 Opposed? Abstentions? Motion carries.

3

4 ANGEL GUTIERREZ: I'm done.

5

6 JEFF KRAUT: Dr. Gutierrez, thank you very much for that
7 wonderfully succinct presentation. I'll now turn it over to Mr.
8 Sheppard. The Commissioner is in transit and when he arrives
9 here we'll obviously accommodate his schedule.

10

11 DAN SHEPPARD: OK. Thank you very much. I want to start my
12 report with just a couple updates from the Office of Primary
13 Care and Health Systems Management. Since last time I gave a
14 full report to council the Department announced capital awards
15 for 25 projects totaling \$187 million. These are the latest
16 awards from the statewide healthcare transformation program.
17 There are projects in nearly every region in the state
18 reflecting significant investments in inpatient and outpatient
19 mental health and substance use disorder services. FQHC
20 expansion projects, and generally a focus on renovation and
21 expansion projects that integrate primary and behavioral health
22 services. Included in the awards were several debt relief
23 rewards for rural and urban safety net hospitals. Among these
24 were Sienna Memorial Hospital in northcountry and St. John's
25 Riverside Hospital in Yonkers. These awards are critical to

1 implementation of long term strategic transformation and
2 sustainability plans for these facilities. These awards
3 continue, the state's commitment to preserve and expand
4 essential healthcare services in communities throughout the
5 state. And over the past five years the Department has awarded a
6 total of \$3.5 billion of transformation capital across all
7 provider types; hospitals, clinics, of all strikes, 28, 31, 32,
8 as well as clinics for people who have developmental
9 disabilities. They also include community-based and residential-
10 based long term care projects.

11

12 Couple of other highlights on the capital from \$3.5 million
13 just a reminder to the committee, there was a major focus
14 capital investment of \$664 million in central Brooklyn. This was
15 related to the formation of the one Brooklyn Health Systems
16 which is the - council may recall recently created parent of
17 Brookdale, Interfaith, and Kingsbrook, and these dollars
18 included more than \$230 million of the \$664 for community-based
19 ambulatory care projects and those dollars are beginning to flow
20 this year. Also, among the total capital awards we've done over
21 the past five years, there were \$300 million for the new Mohawk
22 Valley Health System Hospital in downtown Utica. There's site
23 preparation beginning for this hospital within the next few
24 weeks and completion is targeted for early 2023. And this

1 project consolidates two obsolete hospitals and the context of
2 doing that reduces total inpatient beds and expands services.

3

4 Finally, just wanted to highlight from the capital projects
5 that what we've done over the past few years, St. James Mercy
6 Hospital in Cornell New York in Steuben County, the state
7 invested more than \$60 million in a replacement hospital and a
8 new medical office building. So similar pattern to many of our
9 other projects in terms of downsizing inpatient capacity,
10 expanding ambulatory services, and securing affiliations with
11 major regional systems to ensure that access to specialty
12 physicians continues and also to create economies of scale.

13

14 Shifting to another area that I want to highlight from the
15 work of OPHSM, while capital is one of the tools that we have to
16 help financially distressed hospitals, and other essential
17 healthcare providers, another is really reflected in the work
18 that Tracy Raleigh and her team do. So when they're not focused
19 on everything that you see from the vantage point of this
20 council, Tracy and her team, her spearheading another major
21 responsibility. Currently actively managing transformation
22 initiatives from more than 25 hospitals throughout the state.
23 These responsibilities include the administration of
24 transitional operating assistance and the oversight of the
25 implementation of these strategic transformation plans which the

1 hospitals must agree to as a condition of the state assistance.
2 These hospitals are in various stages of progress from early
3 progress like (Messina) Memorial Hospital to well underway like
4 the One Brooklyn Health System, Health Alliance in Kingston,
5 Alice Hyde Hospital in North Country, St. Luke's Cornwall
6 hospital in Newburgh, and Nyack Hospital in Rockland County. And
7 then finally there are also a number of hospitals that are
8 either at successful completion or near completion of their
9 transformation; St. James Mercy Hospital as I mentioned, the
10 capital work before was in Ticonderoga, (AL FOX) in Oneonta,
11 Cortland Memorial Hospital as well as Christian Association
12 Hospital our in Jamestown.

13

14 Finally, just an update from the office on a staffing study
15 that we're doing. There was legislation enacted earlier this
16 year that directed the Department to conduct a study to examine
17 how staffing enhancements and other initiatives can be used to
18 improve patient safety and the quality of healthcare service
19 delivery in hospitals and nursing homes. This legislation also
20 directed the Department to analyze the range of potential fiscal
21 impacts of staffing levels as well as other staffing enhancement
22 strategies and patient quality initiatives. On September 20 in
23 Albany, the Department held the first two public stakeholder
24 engagement sessions which invited experts and the general public
25 were provided with an opportunity to present information and

1 make remarks on the subject. Over 60 people attended and 25
2 spoke. The meeting was webcast. It is archived on the
3 Department's website if you're interested. Written testimony and
4 other supporting materials provided by the stakeholders will
5 also be available on the website.

6

7 Second stakeholder engagement session will be held in New
8 York City on October 22, here in this room at 90 Church Street.
9 At the Albany session, while points of view on this topic varied
10 widely, it came through clearly all stakeholders, providers,
11 workers, consumers, everybody who spoke and provided input
12 shared the common goal of improving quality, safety, and patient
13 satisfaction. In addition to the information from the
14 stakeholder sessions and the Department's review of data and
15 literature, we've also engaged Cornell University School of
16 Labor Relations and their college of Human Ecology to conduct
17 research on New York's existing nursing and certified nursing
18 assistant workforce in order to model potential cost and labor
19 supply implications of the various staffing scenarios that are
20 being explored and doing this analysis on both statewide and
21 regional basis. Legislation directs the department to complete
22 this study by December 31 of this year.

23

24 Finally on a personal note I would just like to say that
25 this will be my last PHHPC full council meeting. I recently

1 announced that, to my colleagues at the Department that I will
2 be retiring at the end of the year. The calendar year. It's been
3 a privilege to be a public servant for the past 32 years; last
4 five here at the Department. I will sincerely count as a career
5 highlight working with this council during what I think is
6 probably fair to say is a time of unprecedented change in our
7 healthcare delivery system. On both macro policy issues and the
8 CON specific matters, you've supported and challenged me and my
9 Department colleagues and we've done better work because of it.
10 Together we have made some progress, highlight regulatory
11 modernization, increase focus on quality as the basis for
12 facility licensure, establishment of regionally integrated
13 health systems. There's also still much more we need to do, the
14 Department needs to do and that's more regulatory streamlining,
15 improving access to third party capital, balancing New York
16 State's history of patient access and choice with the
17 imperatives of financial sustainability, balancing the
18 importance of scale and integration with overall cost to
19 consumers, and breaking down the silos between provider types
20 created more patient-centered experience. I'm confident that the
21 incredible executive leadership and staff of the Department of
22 Health and this council continue to make progress towards
23 creating a high quality cost effective nimble future oriented
24 and sustainable healthcare system for all New Yorkers. So thank
25 you.

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JEFF KRAUT: We can ask him questions in a minute.

Alright. But let me just start at the end and we'll work our way backwards. There's probably not enough time to thank you for what you've accomplished during your five years in the position you had. You know, you came to us as an industry, knowing a little about us and having spent 30 years you can't avoid us if we're dealing in the state between Medicaid, budget, and the like, but you know, I was struck by how you came, you listened, you learned, you schooled yourself diligently and in an enormously short period of time you mastered an understanding of a complex industry that effectively touches every life in the state of New York, and it's such a tribute to the content of your character of what you did, the team you formed, the areas you chose to focus on and how effective of an advocate you were with the team that you brought together to effectively focusing on serving and improving the health of New Yorkers. There's so many adjectives to describe you; intelligent, articulate. I'll just use the two that are the most important. Nice and smart.

And you know, if you hire everybody on a nice and smart 2x2 matrix, I've learned you can teach smart; you can't teach nice.

And it's been personally an absolute pleasure on behalf of the council, me personally, to work with you. Everything you've done is a tribute to the content of your character and on behalf of the council, which we will do a more formal presentation because

1 we were caught a little off guard today, where we'll give you a
2 xerox slip of a thanks. But in a separate meeting, but just on
3 behalf of all of us, we must thank you and wish you well.

4

5 [standing ovation]

6

7 JO BOUFFORD: Can I just, I didn't catch Jeff before he
8 got everybody into a standing ovation, but let me just add, I
9 think the other thing that I really admired about you, Dan, is
10 that you really helped us balance the population health
11 prevention agenda with the healthcare delivery agenda which in
12 many instances can quite overwhelm our conversations. So I
13 appreciate that balance, and I hope your successor will sustain
14 it but you really helped make that signature. I think bring the
15 council's deliberation's together in a much more integrated and
16 holistic way so thank you for that.

17

18 JEFF KRAUT: And Dan, whether you obviously - I'm sorry
19 we'll just continue - if you know it of not, when we wanted to
20 make changes, when we wanted to be more transparent, when we
21 wanted to change some of the ways we dealt with things, you
22 couldn't get a bigger supporter of Dan trying to figure out how
23 to help us do that. Now, having dispensed that, if you want to
24 grill him on anything he just said and question him, please, in
25 all seriousness, are there any questions? And Dan, again, in

1 December we'll do something a little more formal, but you know,
2 not going to be repetitive. But if anybody has any questions for
3 anything that Dan had asked, don't make his last moments here
4 easy. Ann, thank you.

5

6 ANN MONROE: Well, Dan, the only thing I'm disappointed
7 in is I just got on the council, and then you take off, and I
8 will take no responsibility.

9

10 Yes, I hope so. I'm interested in those constituency
11 meetings that you had, and while I appreciate that everyone is
12 interested in quality, patient safety etc., etc., were there any
13 specific things that emerged from that first group that might
14 give us hope that there are some kind of collective ways that
15 people are willing to go about that?

16

17 DAN SHEPPARD: Thank you Ann. You know, I think, there is
18 lots of good information that we received. And I wouldn't want
19 any conclusory remarks from me to indicate that we're really
20 doing any more than just taking in a lot of information right
21 now, and there'll be a lot of good, smart people who are, who
22 will put all that together for the report that the Department's
23 required to submit at the end of the year. But it's all - but
24 everything that was said is all on the website and in a lot of

1 good both testimony as well as supplemental materials that we'll
2 be putting up and everybody can see.

3

4 HARVEY LAWRENCE: Dan, I'm going to miss you. Not only
5 been very nice but you've also been very helpful. And so I want
6 to thank you. I commend the state on expanding access to primary
7 care and it's capital investment in the infrastructure, but my
8 growing concern is around labor force. Primary care physicians
9 are very difficult to recruit, find, and the price tags continue
10 to escalate, and that's true also of nurses, and some level I
11 know we have got those across the state something, grant
12 programs funded to retain and secure doctors, primary care
13 physicians within the state, but this labor force question is
14 one that I think is - it's something that's going to explode
15 because we all are competing for shrinking pool of primary care
16 physicians. And those who are not at the top of the food chain
17 having an increasingly difficult time to secure and retain
18 physicians.

19

20 DAN SHEPPARD: So, actually, and maybe an answer in your
21 question I can do a little more justice to Ann Monroe's
22 question, absolutely, I think one of the I think whether it's
23 generally in working with clinics and long term care facilities
24 workforce, even hospitals and rural hospitals, even large urban
25 hospital have problems attracting physicians specialists like

1 psychiatrists - any folks around here - but I think workforce
2 and probably in my closing remarks should've highlighted that as
3 something else that certainly it should be a huge goal for, it
4 goes beyond the department is workforce. So in the forum that
5 happened on the 20th related to staffing, I think universally
6 even though there's varying degrees of opinion on what to do
7 with staff once they're there, access to workforce is a huge
8 issue. It's a huge issue for LPNs and RNs for primary care
9 physicians, for psychiatrists, for CNAs, Aids and orderlys, and
10 we do need, there are programs that we have that are effective
11 and narrowly focused like Doctors Across New York. There are
12 various loan forgiveness programs, but I think to meet the
13 demand that exists now and will only grow here in the
14 demographics, and our policy goal is to expand primary care, we
15 need much broader Marshall Plan-like efforts to deal with this.
16 And so, it is a critical area. Probably certainly top three or
17 five in what we need to be focused on.

18

19 JEFF KRAUT: Dr. Brown then Mr. LaRue.

20

21 LAWRENCE BROWN: This is Lawrence Brown, member of the
22 council, and Dan I would want to for two reasons take advantage
23 of this opportunity. One is to express my appreciation of your
24 leadership and dedication. It has been phenomenal even for the
25 rather short time I've been on the council compared to the time

1 that you've been doing the great work of this state of New York.
2 I'd like to underscore colleagues comments because while we are
3 fighting more and more the value of behavioral health with
4 respect to dealing with the public health issues that we have in
5 society, and certainly in the state of New York, that is also
6 had an impact with respect to the workforce, and I think it's
7 interesting to hear at some point probably by your successor and
8 hopefully you'll come back to give us an opportunity to
9 appreciate you again. The, because I find that the issue about
10 recruitment is certainly different than the issue about
11 retention, and also the issue with respect to the credentials
12 that many societies and certainly that governments and certainly
13 the state of New York has with respect to those are key, and the
14 role of the State in terms of the pipeline I think is really
15 going to be critical as we talk about the ways in which we
16 respond to this continuing challenge, and is something that I've
17 come to appreciate during the time that I've been a physician
18 that has been a constant issue about what do we do with the
19 workforce? How do we encourage persons in a society where we're
20 talking about procedures and other types of interventions as
21 opposed to primary care. And we still have to also have deal
22 with professionals who deal with behavioral health side because
23 they tend to not get the attention - I mean, that's improving
24 recognizing healthcare - but we still have much way to go if
25 we're going to actually take advantage of the causes of the

1 excess morbidity and mortality that we have that often
2 associated with behaviors as opposed to in fact any disease
3 whether chronic or acute. We look at it, we can see some
4 behavioral, which we could intervene even more effectively. So,
5 again, it'd be interesting to hear from the Department about the
6 results of that particular part of the conversation, because I
7 think we would be really interested in finding out more about
8 how we can help to further provide more information about it.
9 And again, thank you for your service.

10

11 SCOTT LARUE: Yes, Dan, I also want to thank you and
12 especially for making sure everyone's voice was always heard in
13 value. Often conflicting voices. Going back to the staffing,
14 could you describe the process, so after this next meeting, and
15 then there's a report that's being put together. How is this
16 playing out?

17

18 DAN SHEPPARD: So the statute requires that the Department
19 produces report by December 31, 2019, and so we have one more
20 scheduled stakeholder engagement session [no mic]

21

22 [no audio]

23

24 JEFF KRAUT: Lost Albany? There is goes. Ok. Go ahead.
25 Just keep going. Just walk loud I guess.

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DAN SHEPPARD: It's not hard.

[no audio]

DAN SHEPPARD: It informs further discussion and decision making.

JEFF KRAUT: Dr. Kalkut and then Mr. Robinson.

GARY KALKUT: Dan, I also want to thank you for your leadership, your smarts, and your sense of humor with this, and very nice reading glasses through the years.

(inaudible)

And specifically for your support in getting information related to DSRIP in front of this council, notwithstanding something that I think over the past few years has been important here rather inflection point now, and in the program, and in all the infrastructure that has been built. But certainly and also for the council to have really driven that and made it possible to hear what was gone on in the state related to this crucial program. So thank you.

1 PETER ROBINSON: May I pile on and say thank you. Yes.
2 Dan, can you speak a little bit more about healthcare capital?
3 Obviously the announcement was for about \$187 million. There's
4 about \$350 that I recall in the pool, so the question is what's
5 happening with the balance of the pool, and the second part of
6 the question is, is the State or the Department considering for
7 next year's budget a new tranche of health care capital?

8
9 DAN SHEPPARD: So with respect to the next steps with
10 currently authorized capital, there's a request for applications
11 that we expect will be going out within the next 30-45 days, and
12 that will kick off another round overview and awards. With
13 respect to next year's budget, I think it's premature to, we're
14 in the very early phases of that so I think it's a little
15 premature to try to anticipate that.

16
17 JEFF KRAUT: Thank you. Thanks Mr. Sheppard and Dan will
18 be back. You won't but we'll come back and talk. I'll now turn
19 to the Commissioner to give his report.

20
21 HOWARD ZUCKER: Thank you very much, good morning. I will
22 add one thing and there's many to add with Dan but calm and with
23 a smile, because believe me many a time I go in and he just
24 smiles and nods. Many a conversation. From a public health
25 standpoint, 2019 is truly unfolded as the year of the unexpected

1 in New York. Some threats you can anticipate and others have
2 placed us in uncharted territories. We're determining how best
3 to remove the dangers and protect the public's health. With
4 these new challenges, the Department has often had a request
5 over and above input from our partners, and I do want to thank
6 the entire committee and the council for all that you did. We
7 had two emergency meetings within a matter of a few weeks. You
8 all came forward and helped us out and your time, your advice,
9 your council really served the department extremely well, served
10 New York State very well from the government perspective. But
11 also served all of those that are New Yorkers very well given
12 the challenges that we face which brings me to the whole issue
13 of vaping. As New York State and the nation do continue to
14 grapple with the sever pulmonary illness associated with e-
15 cigarettes and vaping. We hear about it on the news on a regular
16 basis. New York State physicians are seeing this illness in
17 patients ranging from about 14 years of age to 69 years of age
18 and who have used at least one vape product prior to becoming
19 ill. We learned on Tuesday just a few days ago of the first
20 vaping related death in New York State and that tragically was a
21 17 years old male in New York City who died on October 4 and he
22 had been hospitalized in early September with a vaping
23 associated respiratory illness and he was readmitted later in
24 the month. The CDC last update data on this illness on October 1
25 and at that time it reported 1080 cases and 18 confirmed deaths

1 in 15 states but since that time the recent update will show
2 that Massachusetts has unfortunately a death as do we so the
3 toll continues to rise. Vaping remains a priority for the
4 Department. Also public health emergency. It does demand
5 immediate attention. The Department has worked extremely hard on
6 this issue, and as you can imagine this is one of those things
7 that we are tackling from all different fronts. The State's
8 decision to ban the sale of flavored e-cigarettes was a direct
9 response to the growing threat that no defend of public health
10 could afford to ignore and the vaping industry is using the
11 flavored e-cigarettes to get young people hooked on potentially
12 dangerous and deadly products. And we need to help ensure the
13 well-being of our children. We are confident that once the
14 courts hear our argument they will agree as well. And while the
15 courts' ruling temporarily delays our schedule of enforcement of
16 this ban, it will not deter us. Using every tool that we have at
17 our disposal to address this crisis. And concurrently the
18 Department remains the leader in nationwide research into vaping
19 products. Our Wadsworth center, our lab has determined that the
20 thickening agent used in the black market vaping products are
21 nearly pure vitamin E acetate oil. We will continue to
22 investigate the high levels of vitamin E acetate in the samples
23 of taint, and that is one possibility we recognize. There could
24 be others. Hopefully we'll have some more conclusive evidence in
25 the coming weeks, and as we always know, public health moves at

1 a clip, but sometimes that news and others are moving at a
2 different, want us to move at a different pace, but we will get
3 the most accurate information and to everybody.

4 This brings us to another issue which is measles. So this
5 month the Department marked the passage of more than 42 days and
6 that's the equivalent of two incubation periods without any new
7 cases of measles reported. Sullivan County, Orange County, since
8 the outbreak began in October 2018, and Rockland County passed
9 that threshold in September as well. So although this is welcome
10 news, the threat of vaccine-preventable diseases remains and the
11 Department is not letting down it's guard. With our Rockland
12 partners, the Department is currently investigating a case who
13 has contracted measles internationally and then travelled to
14 Rockland County. We also have some active public health
15 responses underway in Nassau County, two cases, one in Monroe
16 County, one in Putnam County that are related to measles
17 exposures, again from international travel, but they're not
18 affiliated with the 2018 outbreak. So between October 1, 2018
19 and October 3, 2019, 406 people were infected with measles in
20 Rockland, Orange, and Sullivan, and Westchester Counties, as a
21 result of initial exposures from international travel. And so
22 with our partners we administered 85,000 MMR vaccines in those
23 counties during that timeframe. And amazing amount. New York
24 State is taking strong measures in 2019 to ensure school
25 eligible students are vaccinated and will remain vigilant in

1 protecting New Yorkers from measles and other dangerous vaccine-
2 preventable illnesses.

3 Brings us to flu season. So, flu season begins this month.
4 The Department is aligning it's extensive outreach and awareness
5 efforts with the CDC's recommendations that people get the
6 2019/2020 influenza vaccine by the end of October. In September,
7 unfortunately a four-year-old in California died after testing
8 positive for influenza. So we've already seen the tragic
9 potential even before the season typically gets underway. This
10 is why we aggressively push to make sure everyone gets back
11 saying I will get my flu shot on Tuesday and encourage all New
12 Yorkers to get their shots this month to protect them and their
13 families. My kids had their shot the other day. So keep pushing.
14 As did my wife.

15 Today is the fifth annual organ donation enrollment day in
16 New York state. This is the day in which the registry goes all
17 out to enroll as many new donors as possible during the 24-hour
18 window. The Department and registry had been working to increase
19 the state's organ donation rate of 35 percent. Every 18 hours
20 another New Yorkers tragically dies waiting for a donated organ.
21 And we know that 92 percent of New Yorkers support organ and
22 tissue donation, so the willingness is obviously there. The
23 state and the registry have done a lot in the past few years to
24 harness that willingness. We changed the driver's license
25 applications and renewal process. We've lowered the age of organ

1 donor consent to 16 and 17 year olds who apply for learners
2 permits and drivers licenses, and we've pursued enrollment
3 avenues outside the DMV such as the New York State of Health,
4 the marketplace. And since this new route to donation began
5 April 2017, 200,000 New Yorkers had elected to enroll in organ
6 donation through the marketplace. Which brings me to some good
7 news. Over this, out this month about our health insurance
8 coverage in New York State, so the new United States Census
9 Bureau data revealed that the rate of uninsured New Yorkers
10 declined in more than half of New York's counties in 2018. So
11 last year New York was one of only three states in the nation to
12 see a decrease in it's uninsured population reducing the number
13 of uninsured individuals by 1.2 million since 2010 and one
14 million of those New Yorkers acquired their insurance since the
15 New York State of Health marketplace opened in 2013. New York's
16 annual open enrolment period for enrollment is, begins on
17 November 1 and will run through January 31 of 2019. October,
18 this month is also breast cancer awareness month and New York
19 State continues to promote vigilant breast cancer screening to
20 save lives. Each year almost 16,000 New York women are diagnosed
21 with breast cancer and over 2500 unfortunately die from the
22 disease. Breast Cancer became New York State's most frequently
23 diagnosed cancer in 2013 and the Department and Governor Cuomo
24 have responded to that threat with legislation and programs
25 focused on early detection which is obviously the best possible

1 treatment. This spring the Governor signed legislation
2 requiring large group insurance to cover medically necessary
3 mammograms for women ages 35-39. The department has made 3D
4 mammography available to more New Yorkers by mobile mammography
5 vans and 3D mammography makes it easier for doctors to catch
6 more types of cancer, which is especially helpful for women with
7 dense breast tissue. Nearly half of all women 40 and older have
8 dense breasts. We're seeing positive results from the statewide
9 measures, dating from the behavioral risk factors surveillance
10 system shows that the number one screen for breast cancer in New
11 York state increased from 80.3 percent in 2017 up to 82.1
12 percent in 2018 in just a year. Being that approximately 50,000
13 more women were screened in 2018 compared to the year before. I
14 want to end today on an encouraging note. New data showed that
15 2018 had the largest decrease in new HIV diagnoses in New York
16 State since the launch of the ending the epidemic initiative
17 began in 2014. And we are on track to end the AIDS epidemic by
18 the end of 2020. A new diagnoses for last year reached an all
19 time low of 2481, an 11 percent drop from 2017 and 28 percent
20 drop since 2014. So these advances place the state in an idea
21 position to contribute to the national goal of ending the AIDS
22 epidemic by 2030. Governor Cuomo has designated October 20-26 as
23 a week to raise awareness about preexposure prophylaxis of HIV
24 known as PREP as we know, and this medication is a way for those
25 who do not have HIV but who are at substantial risk of getting

1 it to prevent HIV infection by taking the pill every day. And as
2 we're aware, PREP reduces the risk of getting HIV from sex by 99
3 percent. New York leads the nation with the largest percentage
4 of individuals on PREP medication and new data shows that almost
5 32,000 New Yorkers took PREP in 2018 and again, that's an
6 increase from 2017 by 32 percent. So as you can see, the
7 Department has been incredibly busy focused throughout this
8 eventful year. We keep moving forward. There are many other
9 areas that we tackle every single day. I thank our entire team
10 who work unbelievably hard and 24-hours a day, 7-days a week and
11 they get calls on the weekends and evenings and it's just
12 amazing how hard they work. And I thank the entire council for
13 all that you do to help us move the initiatives forward that the
14 department feel are best for the state of New York and the
15 people who live here. Thanks.

16

17 JEFF KRAUT: Commissioner, thank you and I could attest,
18 this has been a busy 60 days since we last met, and I have an
19 understanding of how hard everybody in the Department's been
20 working on weekends, evenings, and the like so we do appreciate
21 it. Questions for the Commissioner? Howard. Dr. Berliner.

22

23 HOWARD BERLINER: Commissioner, first of all, thank you
24 for appearing here and also congratulations on that excellent
25 article about you in the New Yorker a few weeks ago. That was

1 really great. Question; do you have any sense of when the
2 courts will rule on the vaping?

3

4 HOWARD ZUCKER: I will turn this to our legal counsel.

5

6 RICHARD ZAHNLEUTER: This is easy. This is Richard
7 Zahnleuter, general counsel, and we'll cover that in an
8 executive session later on.

9

10 GLENN MARTIN: Hello. First off congratulations on the
11 measles situation. That was really remarkable response from the
12 state. Very effective. And as I understand, managed to maintain
13 our county's status as measles-free or whatever the designation
14 is. Two questions if I may; what about vaping? It's been real
15 difficult following the CDC numbers have come out because last
16 time there were 500 new or whatever, but half of them had
17 occurred weeks ago and we're just catching up. Do you have any
18 idea just how hospitalizations are going since that would seem
19 to me the track the most acute aspects of it. Do we know what
20 that's doing?

21

22 HOWARD ZUCKER: So I think you bring up a good point here
23 that what has happened, and I have spoken with the CDC director
24 several times, including the other day and our team has been in
25 frequent contact with the CDC pretty much regularly, as you said

1 there are a lot of cases where people have, who are health
2 professionals who have sort of said, I wonder what happened to
3 that person, and then retrospect realize that that's probably
4 what was the cause and is part of the reason why these numbers
5 started at a certain amount and then they jumped up when they
6 started to realize that. The hospital information comes in, but
7 we don't necessarily get some of this information, but we don't
8 necessarily have all the data as fast as we may want this,
9 because it's, and Brad could chime in as to whether we are
10 getting this at a realtime information or after the patient has
11 been discharged or not. Brad, do you know?

12

13 BRAD HUTTON: Dr. Zucker, thanks. We definitely received
14 from healthcare providers (inaudible)
15 And often times they're for hospitalizations that occurred in
16 the past.
17 Complete an investigation which includes (inaudible)
18 That does take some time. And in the midst of all the outbreaks,
19 CDC and the (inaudible)
20 So I think what you're seeing nationally is really just the
21 implementation of that case definition, a reconciliation of the
22 numbers over time. I'll say retrospect the hospitalizations,
23 the overwhelming majority of our case patients in New York have
24 been hospitalized, many of them for long periods of time.

25

1 GLENN MARTIN: And you don't have a sense if the trend is
2 picking up, dropping off...

3

4 BRAD HUTTON: It is not slowing. It has been a pretty
5 steady increase in cases. I don't know that we have an
6 increasing number over time, but it's continuing at a pretty
7 steady pace.

8

9 GLENN MARTIN: Can I ask another question. ...

10 The organ donor; so we're an opt-in state. Are there any
11 opt-out states? And is that something that is - obviously it
12 would take legislation and the like, is there some push in that
13 general direction?

14

15 HOWARD ZUCKER: I'd have to check and see if there are opt-
16 out states. Do you know - I can't think of any.

17

18 [Not yet]

19

20 GLENN MARTIN: There are opt-out countries... and there's
21 still something to consider here obviously.

22

23 LAWRENCE BROWN: I also Commissioner, would like to
24 congratulate you and the state with respect to progress with
25 HIV. As someone who is among the house staff at Harlem Hospital

1 when we were trying to figure out what were the ideologies and
2 things, how we would treat patients. It's been a long time but
3 it is been gratifying that we're getting closer and closer to
4 that destination. I also would like to recognize and appreciate
5 the collaboration that you've had with other sister agencies as
6 we clearly have to understand all the behaviors that are
7 associated with the transmission and acquisition. And some of
8 those populations are clearly more challenging than others to be
9 able to even offer PREP for example. So again, I think this is a
10 wonderful achievement and I would agree that this should get as
11 much attention as the state can muster about this
12 accomplishment.

13

14 HOWARD ZUCKER: I concur 100 percent. I always say, this is
15 one of the greatest public health achievements that we have made
16 because it really is a collaborative effort between everyone,
17 not just state and county, but all providers, communities; this
18 is really health across all policies and health across and we're
19 working together to get us where we are. And this is the
20 advantage of having little history of knowing where we once were
21 and how challenging this was, and now it's sort of like, yeah,
22 it's one of those things we do, but 20 years ago 30 years ago
23 this was forefront. Right in the forefront.

24

1 LAWRENCE BROWN: ... keep it quiet about how long ago it
2 was, but.

3

4 ANGEL GUTIERREZ: Also proof that research and science
5 works.

6

7 JEFF KRAUT: Any other Questions? We have another
8 presentation... Yes.

9

10 ANN MONROE: Hello Commissioner. Ann Monroe. I know that
11 the school districts were a big partner with the state in
12 requiring compliance with the measles issue, and I'm wondering
13 if you felt that that cooperation has been there? Are there
14 children - do you know if there are children still out of school
15 because of family decisions? How effective has that approach
16 been?

17

18 HOWARD ZUCKER: So we've been working very closely with the
19 schools and to address this, and there has been a significant
20 amount of cooperation on this. There are those who have still
21 sort of said, well maybe they'll homeschool their child and
22 we're addressing that as well. But this is one of those issues
23 where we recognize the bigger, the public good of making sure
24 everyone's back... something we need to move forward and will
25 address any of the issues that comes up. And it is a

1 partnership. It's a partnership between the schools as well as
2 the primary health. And I have to tell you that one of the
3 things I've noticed in the period of time in this role is how
4 much education and health really work together on so many areas.
5 The vaping issue is another example. You speak to some of the
6 principles, they will tell you that this is way more involved
7 than you may recognize and what you will hear from even parents
8 because, in the schools and in the classrooms you really
9 understand what is truly happening. And so I think that the
10 partnership is really important. Whether it's for vaccines or
11 whether it's for vaping, or any of the other issues that we deal
12 with.

13

14 PETER ROBINSON: I know we want to quickly move along.
15 Just a quick final question on vaping that relates to the
16 provisions to allow research to continue as we move forward with
17 further and further restrictions on the types and the ages and
18 other kinds of things relating to vaping, so, to see that
19 there's a research exemption in the possession rules of other
20 kinds of things like that are going to be critically important
21 if we're going to understand the science.

22

23 JEFF KRAUT: Thank you Commissioner, and if anybody wants
24 to read that article that Howard referenced, and than you Dr.
25 Hyde for sending it to me because I only read the cartoons

1 first, it was I think the September 2 or the August 26 issue of
2 The New Yorker, we'll get it around and it has a nice shout out
3 to Dr. Zucker's dad and his influence as well. So I think it's
4 something, maybe we'll get a copy of it, assuming the copyright
5 is OK and circulate it around for everybody

6 I'm going to take a little out of order. I had originally
7 said that Greg Allen was going to be unable to join us.
8 Thankfully he was able to rearrange his schedule and he is in
9 Albany able to join us and is going to give us a presentation or
10 discussion or report, an update on DSRIP 2.0 as you requested.

11

12 MR. ALLEN: Thank you very much. I appreciate you being
13 flexible with the schedule here today. I apologize for the
14 confusion this morning. (inaudible)

15 I'll start with just a reminder for those of you who either
16 don't remember or forgot the first DSRIP round. So the state
17 six-year waiver to do healthcare transformation using Medicaid
18 resources and that waiver expires in April 2020. The centerpiece
19 of that was 25 performing providers

20 (inaudible)

21 Trying to reduce hospitalization by 25 percent over the
22 five-year run that was the demonstration period. I am happy to
23 report that we're true

1 We reduced potentially preventable admissions statewide by
2 21 percent toward that 25 percent goal. We have reduced
3 potential readmissions (inaudible)

4 And when we look at the accumulated reduced costs in those
5 potentially preventable readmissions and admissions, we dropped
6 (inaudible)

7 We could still replicate the most promising practices
8 because 11 of the 25 PPSs have already exceeded 25 percent
9 reduction in either potential preventable admissions or
10 readmissions. Four of them have decreased preventable costs by
11 25 percent -- and three PPSs have actually reduced their
12 potential for readmissions by 40 percent during the first four
13 years of demonstration. So some considerable progress. Inside
14 that progress is a trying working with partners (inaudible)

15 Partners across the state to sort of synthesize the most
16 promising practices and the goal of our (inaudible)

17 Is to scale and replicate that most promising work during
18 what was out for a four year extension period to keep
19 (inaudible)

20 This demonstration, the goal was to utilize value-based
21 payment structures to support some of this sort of secret sauce
22 which we'll talk about in a minute, and it has taken more time
23 than originally thought to these value-based payment
24 contracts to basically by the carrying vessel for some of this
25 promising work. So our message to our fellow partners is we've

1 done great work. We've got other great work to do. But we really
2 don't have the replicable systemic reimbursement structure in
3 place to carry the most promising practices which are often
4 careful orchestrations of primary care, of
5 specialty, behavioral and social care all wrapped in packages.
6 Healthcare is a team sport. Multidisciplinary, interdisciplinary
7 teams interfacing our cost and high need patients (inaudible)

8 Almost everything that we look at is some combination of
9 tackling the population health issue as a team sport with
10 multiple providers and multiple

11 (inaudible)

12 Remapped charity structures, remapped pathways, and it is
13 this exact change that takes both time and needs a more flexible
14 reimbursement structure that just doesn't pay for what's
15 involved; one that actually rewards value (inaudible)

16 So very specifically our request is for a four year renewal
17 that will begin April 1, 2020. It's an \$8 (billion) ask, \$5
18 billion of that \$8 billion is squarely focused on continuing the
19 DSRIP performance program. (inaudible)

20 These are broad teams with broad networks representing
21 (inaudible)

22 We asked for another billion on top of that five for
23 workforce development. Much more to go. We did have some
24 (inaudible)

25 We have further distance to travel as all of you know.

1 (inaudible)

2 ... to drive the better integration of social care with
3 healthcare which we all know is so critical

4 Some of the most complex challenges for our most complex
5 patients. And another \$500 million insurance fund
6 that we had in the first demonstration for hospitals that are
7 struggling. Again, the good news story is we've been reducing
8 preventable hospitalizations. The difficult story for some
9 essentially community providers is those and we have
10 to carefully and be mindful that there is time
11 needed to pivot to the ambulatory structures, to the community
12 support structures as we begin to reduce (inaudible)

13 It's a readable document on the weekend with your friends
14 and family in front of the fire, maybe out apple picking. But it
15 goes into detail on what was again, the secret sauce in driving
16 some of this change. Examples include expansion of Medicaid
17 assisted treatment in primary care ED settings from our
18 substance use disorder and opiate disorder. Better part of
19 (inaudible)

20 A lot of focus on special populations including serious
21 Tons of work with social providers on

22 And then trying to support better primary preventive care
23 through alternative payment methods. The goal here over this
24 next period would be to bring the health plans, the Medicaid
25 health plans, particularly the collaboration with these

1 performing provider networks continue the DSRIP DNA of having a
2 broadly represented provider network working on population
3 health, but better healthplans (inaudible)

4 The PPSs are well positioned to becoming value-driving
5 entity, but these value-driving entities will be working on
6 building value-based payment constructs during the four-year
7 demonstration. We have a couple of in the first
8 demonstration based on our hyperfocus on local hospitalizations.
9 We hope to close those gaps in this demonstration period. With a
10 laser-like focus on reducing maternal mortality. Medicaid covers
11 50 percent of the state's births. (inaudible)

12 Children, other than children are not really
13 a central focus of DSRIP because of many (inaudible)

14 47 percent of our state's kids are covered by Medicaid
15 right now, so we have to expand this. (inaudible)

16 Additional focus areas include long term care. (inaudible)

17 Pivot back to long term care. We've got aging population.
18 So we have to think more creatively about how to augment our
19 existing long term care structures (inaudible)

20 As I mentioned before, workforce (inaudible)

21 We want to scale and replicate that and make that work
22 statewide, and we really just also want to begin to broaden the
23 conversation to other

24 There's been a lot of work done in Medicaid populations,
25 but as we know, healthcare is

1 (inaudible)

2 We are actively in the public comment period. One thing we
3 want to hear about is our approach to social determinants of
4 health and social determinant infusion and in the overall
5 structure. We think we have miles to go before we -

6 So very interested in public comment. Very interested in
7 your thoughts on the structure we're trying to build to better

8 Lastly, DSRIP is a performance-based program and we
9 continue that focus on performance measurement, but

10 Those that will be used for value-based payment and payment
11 contracts. We know healthcare providers are (inaudible)

12 We continue the state's effort to help essential community
13 providers transition their operations to improve
14 themselves to be viable and continue to support the communities.

15 So, DSRIP's working. Our measures prove it. We need a
16 little bit more time to make it into the payment structure to
17 make it sustainable. (inaudible)

18

19 JEFF KRAUT: Thanks very much Greg, and do we have
20 questions from the council? You can see it's a very early
21 process. Dr. Boufford.

22

23 JO BOUFFORD: Thanks very much for your sort of outline of
24 the renewal proposal and I appreciate your flagging the issue of
25 broader determinants of health and the issue of primary care. I

1 think the big gap in spite of the efforts that many health
2 systems have made was really conceptual. I think people are
3 moving in that direction, but those that have moved in that
4 direction to create the integrated systems you're talking about
5 and develop primary care have not had the financial incentives
6 to sustain it. And the numbers that you quoted in the different
7 buckets may or may not make that kind of transformational
8 difference in the incentives. So I think that that, I'd like to
9 hear you expand a little bit more on that thinking, because I
10 think most people would indicate that for lots of good reasons
11 the initial rounds of DSRIP have been largely hospital driven
12 and hospital focused and as hospitals have tried to engage more
13 with community-based organizations I think there's not enough
14 funding there, frankly, or reimbursement mechanism there, and
15 similarly as primary care has tried to develop primary care,
16 some of the financial incentives have been missing. I think we
17 may be at crisis point in both of those issues as you move into
18 this potential for the next four years. So I'd just like to hear
19 a little bit more about that and happy you flagged it, but I
20 think the level of concern among folks in those areas is very
21 very high that we won't meet the overall goals unless there is a
22 significant financial shift in the direction of supporting CPOs,
23 developing their partnerships with hospitals and primary care
24 links.

25

1 MR. ALLEN: I think there's a fair amount of
2 conversation around the timing of these reforms and sustaining
3 them. I think it's been the belief of most people participating,
4 in order for it to be long term successful you have to create
5 (inaudible)

6 We have to create a new set of incentives that actually
7 Rather than just rewarding healthcare. And in that, if we
8 have to build incentives to (inaudible)

9 The value-based payment, particularly when we are capable
10 of doing upside and downside risk in the service delivery
11 system, we have seen dramatic changes with regard to behavior on
12 admission avoidance. I will say it has been the scenario of
13 DSRIP being hospital-centric. I think that is a little unfair to
14 the best workgroups has been collaborative, has been integrated
15 and has seen many providers working together to try to drive
16 change, particularly as we look at some of the work, admission
17 avoidance for (inaudible)

18 To create community stabilization structure post-discharge.
19 We set some really examples of exactly what we need which is
20 (inaudible)

21 Those things have to scale. Right now they are promising
22 pilots and in order for them to scale, we have to change the
23 payment structure, and that is why in our narrative for the
24 waiver application we specifically mention that you have to
25 bring the value-based payment train to the reform train in order

1 to sustain and drive these incentives. And in order for
2 providers actually to work together to primary preventive and
3 community. And so that is very specifically our goal. I will say
4 that an impact on this is that the public comment period is open
5 until November 4. If you get out to the Medicaid website we've
6 got some, we link to some public comments (inaudible)

7

8 Our application to the centers for Medicaid and medicare
9 services, our federal partners is due on November 27. So public
10 comment closes on November 4. Our application has to get wrapped
11 up by November 27. Just wanted to also mention that.

12

13 JEFF KRAUT: Mr. Lawrence. And then Dr. Kalkut.

14

15 HARVEY LAWRENCE: I would like to concur with Dr.
16 Boufford, I guess assessment that at least our experience has
17 been that DSRIP however it's been almost entirely hospital-
18 centric, there have been other team members on the team, but I
19 believe all of the dollars have been controlled and most of
20 them, most of the dollars have been accrued to the hospitals.
21 And that's not to say that other members especially effecting
22 the social determinants of health, primary care and social
23 service providers and community-based providers have not
24 participated, but in terms of their value, I don't think it had
25 been reflected in the monetary support that they've received and

1 in terms of value-based payments, how do you factor that in and
2 how do you measure that? The value of a community-based
3 organization who's helping to avoid hospitalization, helping to
4 avoid unnecessary ER visits? These are areas where I think
5 there's a lot of work that has to take place, and I think you're
6 right; it's not necessarily just a focus on healthcare. It is a
7 focus on wellness. And when you focus on wellness, then you're
8 looking at all of those elements that are included in the social
9 determinant of health. And most of that happens outside of the
10 healthcare setting. And so if we're really going to have a team
11 approach and an integrated approach, then we need to find a way
12 to bring all of those players, valuable players in and
13 incentivize them and reward their activity in a balanced way. So
14 I think there has been some success with regard to team play,
15 but in terms of the rewards and the incentives, a lot -- they
16 have been skewed in one direction. And not necessarily based on
17 the value that was brought to the table.

18

19 JEFF KRAUT: Let's take Dr. Kalkut, Dr. Strange, then
20 maybe you can respond collectively.

21

22 GARY KALKUT: Greg, thank you for the update. Really
23 appreciate the opportunity to talk about what has happened thus
24 far and the plans going forward. And I think we all should
25 acknowledge notwithstanding all of the issues that remain, that

1 in now four-and-a-half years there's been a significant decrease
2 in hospital utilization, certainly for readmissions and
3 emergency department use. And I think planning ahead and
4 bringing in the issues centrally to, that you mentioned, preps
5 us for more success, and as you said, teamwork moving forward.
6 The managed care organization is and including them and the
7 value driving entities, I think it's key to move down, to get to
8 value-based payments. And wanted to ask, have you thought about
9 or I'm sure you have, but what incentives for those managed care
10 organizations to participate in a more substantial way,
11 particularly related to data, coordination of interventions,
12 understanding of risk scoring, going forward in these new
13 entities.

14

15 JEFF KRAUT: So, Greg, before you respond, just maybe
16 respond to Mr. Lawrence's issues first, and then Dr. Kalkuts,
17 and then I'm going to... I think its too many people we're going
18 to lose the questions.

19

20 (inaudible)

21

22 I do believe in order to solve the issues that have been
23 mentioned by all three, we clearly have to begin to drive
24 payment upstream. That is a goal, remains a goal, and something

1 that we're watching and we have to make sure there's adequate
2 to fuel

3

4 It has to be primarily a set of ambulatory hands that are
5 working in the communities with patients, in home with patients.
6 That's what's worked the best. That's what we're getting after.

7 (inaudible)

8

9 I think the initial setup was sub-optimal relative to
10 optimizing partnerships between the PPSs and the (MCOs) bringing
11 them into the bigger ship, the management, the governance, the
12 steerage and the national process here

13 Help to bring it better to the table with data, with items
14 like you mention on risk. Again, we are wide open for all those
15 standards to kind of govern that relationship going forward.

16

17 JEFF KRAUT: Dr. Strange, and Mr. LaRue. Guys, Greg has a
18 time issue. He has to get to Saratoga, so, just if we can get to
19 the point of the question so he can be responsive. And we can
20 get him on the road when I promised him.

21

22 THEODORE STRANGE: So again, thank you for the wonderful
23 update and we're so pleased that this is moving forward. I'm
24 from Staten Island I work with Joe Conte very well and we manage
25 primary care group on Staten Island. We're a little unique

1 because we're an island so that kind of keeps the attribution in
2 house, so to speak, without leakage. But I want to report that
3 we have seen some of the downstream revenue and we've done some
4 good projects where we've embedded behavioral health providers,
5 social workers in our primary care practices, not just in
6 person, but also by using new technology like telemedicine. And
7 where we can have real time psychiatry or real time social
8 workers deal with whatever is needed because there is a
9 workforce shortage in those areas. And we need to come up with
10 new innovative ideas to support the primary care practices. To
11 that end, we still need to divert out attention away from acute
12 care into the ambulatory field, and that's still tough because
13 the fuel, And that's still tough because the fuel that runs the
14 engine is still the payment factor of the hospitals. So there's
15 still work to be done there. But the PPS on Staten Island with
16 all it's partners has been a success story, I think as you
17 mentioned, and you know, we're just proud that we can move this
18 forward, although we didn't achieve the goals, we came rather
19 close with the numbers you mentioned. The other big area as I am
20 also involved with, the Medicare piece of this on a different
21 level with ACOs, the problem with this DSRIP, with the
22 population that we deal with is these are people who think they
23 are healthy, although they may not be healthy. So they tend not
24 to go to the doctors at 25 and 30 and 35 years old other than if
25 they're having, women who are having their babies and

1 childbearing years, which again, we have to take care of those
2 women very well also. So, there is an issue in that 20-30 group,
3 and of course, as you mentioned in the adolescent group that
4 we're going to have to figure out a way again with the new
5 millennials or GenXs or whatever we call them now of how to get
6 them to understand that they need to be part of the healthcare
7 system to remain healthy and not wait until the acute care
8 issues arise when it becomes too late. Whether that's with HIV
9 disease as we just mentioned or asthma as we always talk about.
10 Or just childhood obesity. Just the early forms of
11 atherosclerotic heart disease. Osteoporosis at an early age.
12 Diabetes. We can mention all of these things which really happen
13 at the earliest stages at those ages. So I'm happy to report
14 Staten Island is doing OK. We have work to do. And I thank you
15 for the kind comments.

16

17 JEFF KRAUT: Thank you Ted. Dr. Brown.

18

19 LAWRENCE BROWN: I too want to add my congratulations
20 for the great work that has occurred under DSRIP. I too want to
21 share that I have had conversations with my colleagues in
22 community-based organizations that have the same sense that Mr.
23 Lawrence raised. So it may mean the need to do greater marketing
24 so that to provide the information to all the appropriate
25 stakeholders. I don't have a question, but I do have a

1 recommendation. One of the things that we have in substance use
2 disorder is the concept of recovery. And admittedly with that
3 concept it has challenges that are different from what we would
4 see in other causes of excess morbidity and mortality. There's
5 not always a objectively measured thing like hemoglobin A1C. So
6 I think it really will take some greater effort and
7 collaboration with those in the field to be able to clearly
8 identify what are the performance indicators that make sense for
9 populations for which this phonometer is still an important
10 aspect of achieving health and recovery is part of that. But
11 again, I want to thank you for your work, and you have motivated
12 me to read that report more intently so that I can add some
13 comments during this process.

14

15 JEFF KRAUT: Thank you Dr. Brown. Mr. LaRue.

16

17 SCOTT LARUE: Again, thank you for the report. And the
18 great work. Kind of representing the long term care industry
19 which I think has a very important role in achieving those
20 goals. I have to agree with Mr. Lawrence that certainly the
21 industry doesn't feel that that was represented in the financial
22 rewards of the first DSRIP and I'm certainly glad to hear that
23 you brought it up and it's going to be a part of round two of
24 the DSRIP. Secondly, a question, how do you see the nature of
25 the relationship between the PPS and the managed care companies?

1 Do you see that in a different way than it currently is going
2 forward? Is it going to be a contractual strictly value-based
3 payment type arrangement?
4

5 GREG ALLEN: So I think some of that remains to be seen.
6 Many options exist. But what we reference in the concept paper
7 that's out for public comment is that the MCOs would be part of
8 the partnership very specifically included in sort of the
9 management and the oversight structure. So if you can envision a
10 scenario where a (inaudible)

11
12 A concept we're proposing. We'll work with the plan to get
13 that governance structure to do broad population health, maybe
14 two, three, four in the plans that work with the providers
15 working together to try to develop some standardized but
16 customized approaches to managing population health. Very
17 specifically we're asking those teams to locate our (inaudible)

18
19 And figure out ways to build the structures to help stream,
20 to drive more of that change, and then connect those structures
21 to the contract. So the driving entity with a health plan it
22 does not have to be, and we did imagine it would always be, the
23 risk bearing and contracted party. It can be an assistor to
24 subcontracted entities - by subcontracted I mean entities that
25 are separate from the value driving entity that would do the

1 services contracting. They could be closely monitoring, they
2 could be parallel, they could be but they may right now, PPS
3 stands as sort of neutral space between plan and provider in
4 driving population health. That relationship could be preserved
5 more, sort of connection to the managed care plans to design
6 some I'll just say blueprints for contracting that would allow
7 us to build these promising practices into sustainable payment
8 structures.

9

10 JEFF KRAUT: Thank you Mr. Allen. And again, you echo the
11 concerns of the other speakers. Thanking you, and we hope that
12 as you hit certain milestones in the application process you'll
13 come back periodically to give us an update. So thank you again
14 for the time this morning. Thank you.

15

16 I'm now going to turn to Brad Hutton to give a report of
17 the office of public health.

18

19 BRAD HUTTON: Thank you very much. I first want to
20 acknowledge two items that Dr. Zucker covered which really have
21 been requiring a tremendous amount of work on the part of the
22 office of public health and that is response to vaping and
23 response to measles. Both activities continue. I want to really
24 feature in my comments other updates. One related to
25 implementation of the lowered blood lead level. We have been

1 before this body for rulemaking. Just alert you that October 1
2 the lowered blood lead level went into effect. The Center for
3 Environmental Health has been working feverishly for the last
4 several months to implement that new legislation, working
5 closely with local health departments. We have issued guidance
6 to healthcare providers on the lower level providing training
7 We've modified our which is a software system that we have and
8 used for tracking children who have elevated blood lead levels
9 and the activities they receive to lower them. This has really
10 been a tremendous effort and we're not at implementation and
11 look forward to identifying increasing numbers of children and
12 dealing with those situations so that we're able to identify the
13 contributing causes and remove them and protect them from the
14 ongoing effects of lead poisoning.

15

16 Second item I wanted to just share an update on is our
17 activities in the area of drinking water. We have recently
18 completed a public comment period for the contaminant levels for
19 PFOA and PFOS and 1-4 dioxane. Public comment period ended on
20 September 24. We received thousands of public comments. Staff
21 are going through them and in the early stages of completing our
22 assessment of public comment and we look forward to coming to
23 you and featuring potentially as early as to give you an update
24 and a recommendation on the next steps with that rulemaking.

1 We also recently received two very prestigious federal
2 grants that I think demonstrated the role that the Department
3 played nationally with respect to response PFOS. First the
4 Department in collaboration with the University of Albany School
5 of Public Health is one of seven grantees that have been awarded
6 it's prestigious multistate health study. This is along term
7 health study during which we'll be learning more about the
8 health effects of exposure to PFOS contamination. Members of the
9 communities of Hoosick Falls and region and Newburgh will
10 eventually be enlisted to potentially participate in that study
11 which we'll look at a broad array of non-cancer health effects
12 including, immune, kidney, liver, cognitive and other
13 developmental effects. Blood pressure. So we really continue to
14 the knowledge of the impact of this (inaudible)

15
16 And hundreds of communities around the nation that are
17 certainly impacted and we're proud to be part of it—
18 The second grant is by way of the environmental protection
19 agency, EPA. We're one of eight grantees who have been awarded a
20 special grant. In this instance we'll be studying landfills
21 across New York state and constructing a database of the PFOS
22 contamination that arises from landfill contamination and better
23 understanding the sources and potential strategies to respond to
24 that type of contamination. So again, really just very
25 prestigious and fortunate that we're able to have funding from

1 the federal government to support our ongoing work and response
2 to PFAS.

3 Finally I want to mention a we are going to have an
4 exciting day. There will be a presentation on violence
5 prevention for the public health committee. So we're looking
6 forward to that committee and its movement now that the work for
7 maternal mortality has reached a closing point, I'm sure they'll
8 continue to stay connected to all the activities we have on
9 maternal mortality, but I think we're now at a launching point
10 of doing a broad presentation to the community on violence
11 prevention and look forward to continuing that discussion.

12

13 JEFF KRAUT: Thanks Brad. Before I open it up for
14 questions, I'm going to give it to Dr. Boufford.

15

16 JO BOUFFORD: Just to elaborate on Brad's last comment,
17 the public health committee will meet on the 18th of October and
18 they have identified originally maternal mortality five years
19 ago as an area of focus and now we're going to take up the issue
20 of violence prevention in the context of the prevention agenda,
21 and I just want to also say, the committee when we met last also
22 indicated a desire to continue to track, as Brad said, progress
23 on maternal mortality activities in this state, understanding
24 that the commission as a set of activities and there may be
25 others that are needed to be supported and tracked, if you will,

1 to achieve real reduction in maternal mortality. And we area
2 also shooting for getting, hopefully getting a meeting of the
3 ad-hoc committee to oversee the prevention agenda before the end
4 of the year. It may be tight but we're going to try. Thank you.

5

6 JEFF KRAUT: Any questions for Mr. Hutton? Ms. Soto and
7 then Ms. Monroe after. And then Dr. Martin.

8

9 NILDA SOTO: Nilda Soto, Council member. In regards to
10 the implementation of lowering the blood lead level, is there
11 any partnerships with other organizations and agencies and what
12 I'm thinking of, a lot of this is coming from dwellings, houses,
13 and all of that, so is there any support or whatever to address
14 the source or sending these children back into those kinds of
15 communities.

16

17 BRAD HUTTON: Thanks for the question. The Department has
18 a long standing set of contracts with local health departments
19 for our lead poisoning primary prevention and through that we
20 definitely work with local health departments, local housing
21 agencies, to make sure that when we identify children found to
22 have elevated blood lead levels that we do a comprehensive
23 assessment of what the potential contributing sources are and
24 when we have neighborhoods that are commonly have housing that
25 is aged and that has chipping, peeling paint that we're working

1 with our housing partners, local agencies to make sure that
2 we're prevent those exposures from occurring and get into those
3 homes and conduct inspections before a child is poisoned and has
4 an elevated blood lead level.

5

6 ANN MONROE: Thank you. You've got two big federal grants
7 for PFOS and I don't know what that is. So I'm wondering if I
8 need to be aware of that in my own community. Could you explain
9 what that is that it's generating such significant federal
10 dollars?

11

12 BRAD HUTTON: PFAS is the acronym for a pretty large
13 family of chemical compounds known as per, and polyflouroalco.
14 PFOA and PFOS are the two primary contaminants and members of
15 that family that have been found to have contamination in New
16 York State. PFOA is association with contamination from plastics
17 industry around Hoosick Falls and it's a contaminant that was
18 used very widely in manufacturing because of it's chemical
19 properties. Scotch Guard on carpets, that non-stick pans, inside
20 of popcorn bags and pizza boxes. So it's really unfortunately
21 ubiquitous and it persists in the environment for long periods
22 of time. PFOS, another compound is something that was very
23 commonly used in firefighting foams and so many of the sites
24 across the country including the New York that have been found
25 to have been impacted by PFOS are in and around airports where

1 there have been fires, fire training centers and so again, the
2 family of compounds is a large one. The compound that we're most
3 concerning with are PFOA and PFOS in New York State, but there
4 are others in the class of compounds that we're watching very
5 closely.

6

7 GLENN MARTIN: Thank you. Could you speak for a moment
8 about EEE, the Eastern Equine Encephalitis? And is this outbreak
9 or whatever is going on right now in our area and New England,
10 is this unusual? Is it just one of the usual cyclic things that
11 occurs that we don't talk about for a decade and then we do? Or
12 is there something going on? And can you give us some general
13 idea of what's happening in New York State? I know that at least
14 on Long Island mosquitos have been found with the virus. I'm not
15 sure what the UN situation. If you could explain, it'd be
16 helpful. Thank you.

17

18 BRAD HUTTON: Yes. Thanks. Eastern Equine Encephalitis
19 virus is an unfortunate virus that we see especially in four
20 counties in central New York because of the ecology there is
21 very much supportive of the species of mosquito that is a common
22 factor for that virus. That ecology is also very similar in
23 other parts of the Northeast especially Massachusetts. It's
24 something that we watch very closely for every year and we have

1 a pretty robust system of mosquito surveillance in counties
2 across New York State. We have not had a case of EEE in
3 Have had some cases in and we've had quite a few positive
4 mosquito pools. So when we find those mosquito pools especially
5 ones that are they typically result in counties doing some
6 collective spraying with an insecticide to knock down the
7 mosquito population. The rest of the Northeast has really had an
8 incredibly bad year with respect to the number of human cases.
9 We have not seen it here in New York. I don't think we fully
10 understand why it is at this point, but we have typically seen
11 between one and two or three cases each year over the last
12 decade of cases that are unfortunately very serious, often fatal
13 because they involve encephalitis. So our response here In New
14 York is primarily to have a pretty robust system of mosquito
15 surveillance so we can identify through testing at the Wadsworth
16 Center the viruses present in mosquito pools, we go out and the
17 counties take initiatives to spray and educate the public about
18 ways that they can reduce their risk by taking some protective
19 measures.

20

21 JEFF KRAUT: Any other questions? Mr. Hutton, thank you
22 so much for your report as well. And now I'm going to turn it
23 over to Mr. Robinson to give a report on the Establishment and
24 Project Review Committee.

25

1 PETER ROBINSON: It's still morning. Good morning. WE
2 will as Mr. Kraut indicated in his introduction batch the
3 applications that we're bringing forward from the committee
4 meeting two weeks ago, and we'll get right into it. The first
5 category actually is an individual one so we won't batch that
6 one. Application 191203C, which is St. Anne's Community in
7 Monroe County. This is to renovate space to reconfigure floors
8 three through eight and decertify 96 residential healthcare
9 facility beds resulting in a total new bed capacity of 374. The
10 Department recommends approval with conditions and contingencies
11 as does the committee, and I so move.

12

13 JEFF KRAUT: I have a second, motion and a second. Any
14 questions? Hearing none I'll call for a vote. All those in
15 favor, aye.

16

17 [Aye]

18 Opposed? Abstention? The motion carries.

19

20 PETER ROBINSON: Because of specific recusals here we'll
21 have to take the next few individually as well. Application for
22 acute care services. 191344C, North Central Bronx Hospital in
23 the Bronx. Noting a conflict and recusal by Dr. Yang. And also
24 an interest and abstaining by Ms. Soto. Dr. Yang left the room.

1 This is to certify North Central Bronx Hospital NCB as a
2 division of Jacoby Medical Center. Again, the Department
3 recommends approval with a condition and contingency as does the
4 committee, and I so move.

5

6 JEFF KRAUT: I have a motion. I have a second by Dr.
7 Gutierrez. Any questions? Hearing none, I'll call the vote. All
8 those in favor, aye.

9

10 [Aye]

11 Opposed? The motion carries. Please ask Dr. Yang to return.

12

13 PETER ROBINSON: And may I ask Dr. Kalkut to leave the
14 room. Calling application 182232C, This is NYU Winthrop Hospital
15 in Nassau County. To construct an addition to the New Life
16 Center Building and convert a variety of beds into 27 neonatal
17 intensive care beds. With no change in total beds. The
18 Department is recommending approval with conditions and
19 contingencies. As does the committee and I so move.

20

21 JEFF KRAUT: I have a motion, I have a second, Dr.
22 Gutierrez. Does anyone have any questions? All those in favor,
23 aye.

24

25 [Aye]

1 Opposed? Abstention? The motion carries.

2 Now, ask Dr. Kalkut to return. Mr. Robinson to leave. I'm
3 going to call application 192002C, Highland Hospital in Monroe
4 County. A conflict has been declared by Mr. Robinson who has
5 left the room. An interest has been declared by Mr. Thompson.
6 Thomas. Sorry. The application - somebody fact-checking me, it's
7 great - the application is to construct a five-story addition on
8 top of a three-story southeast wing to add additional private
9 medical surgical beds with no change to the total certified
10 beds. DOH recommends approval with conditions and contingencies,
11 and the establishment committee recommended the same; approval
12 with conditions and contingencies. I have a motion Dr.
13 Gutierrez. A second by Dr. Kalkut. I know the air conditioning
14 just came on. Bear with us. Any questions about these
15 applications? Hearing none I'll call for a vote all those in
16 favor, aye.

17

18 [aye]

19 Opposed? The motion carries. Could we ask Mr. Robinson to
20 return to the room. And I will depart.

21

22 PETER ROBINSON: Loud, it will be. I just wanted to
23 point out, we're going through this agenda pretty quickly - like
24 this. We're going through this agenda very quickly here because
25 we had a fairly thorough conversation and discussion about all

1 these applications at the committee meeting. However, should any
2 of you want to ask questions or ask the Department to provide
3 additional detail before you take action, please wave your hands
4 and sign up.

5 This is application 191—actually I'm going to batch these
6 three because they all relate - has Mr. Lawrence left the room?
7 Application 191280C, Maimonides Medical Center in Kings County.
8 Certifying a new division to be an off-campus emergency
9 department located at 9036 7th Avenue in Brooklyn at the former
10 Victor Memorial Hospital Site. And to perform associated
11 renovations. The department and the committee recommend approval
12 with conditions and contingencies, and I so move.

13

14 JO BOUFFORD: Motion and a second. Questions? Comments?
15 All in favor?

16

17 [Aye]

18 Opposed? Abstentions? Motion passes.

19

20 PETER ROBINSON: Thank you. Have Mr. Lawrence return.
21 Batching the next two applications. 192019C, Southside Hospital
22 in Suffolk County. Perform renovations to the first floor of the
23 obstetrics unit and convert five neonatal continuing care beds
24 into five neonatal intermediate care beds. The Department here
25 recommends approval with conditions and contingencies as does

1 the committee. And then 192020C, Southside Hospital in Suffolk
2 County. Modernize and expand the maternity nursing unit on the
3 current second floor east building into the adjacent center and
4 north buildings and certify 10 additional maternity beds. Again,
5 the department is recommending approval with conditions and a
6 contingency. As a committee I move both these applications.

7

8 JO BOUFFORD: I have a motion and a second. Any questions?

9 All in favor?

10 [Aye]

11 Opposed? Any abstentions? Motion passes. Get Mr. Kraut back
12 in.

13

14 PETER ROBINSON: Mr. LaRue I think it's your turn to
15 depart. Welcome back. Application 182117E, TCPRNC LLC d/b/a New
16 Riverdale Nursing Home. This is in Bronx County. To establish
17 TCPRNC LLC as the new operator of the Riverdale Nursing Home, an
18 existing 146 bed residential healthcare facility currently
19 operated by Riverdale Nursing Home Inc., and located at 641 West
20 230th Street in the Bronx. There is a companion CON 182120 which
21 will come up later. The Department is recommending approval with
22 a condition and contingencies. The Committee recommended
23 approval with a condition and contingencies but with one member
24 in opposition. I make a motion to approve the application.

25

1 JEFF KRAUT: I have a motion. I have a second by Dr.
2 Gutierrez. Is there any conversation about this or any questions
3 that want to be raised? Hearing none, I'll call for a vote. All
4 those in favor, aye.

5

6 [Aye]

7 Opposed? One opposition. Dr. Berliner. The motion carries.

8

9 PETER ROBINSON: Thank you. The following are going to
10 be batched. 191263E, Schollkopf Health Center in Niagara County.
11 To establish Niagara Falls Memorial Medical Center as the co-
12 operator of Schollkopf Health Center at 120 bed residential
13 healthcare facility. In this case the Department is recommending
14 approval with a condition and contingencies as did the
15 committee. Application 191270E, Troy Diamond Operations LLC
16 d/b/a the Diamond Hill Nursing and Rehabilitation Center. This
17 is in Rensselaer County and this is to establish Troy Diamond
18 Operations LLC as the new operator of the 120 bed residential
19 healthcare facility located at 100 New Turnpike Road in Troy.
20 Currently operated as Diamond Hill Nursing and Rehabilitation
21 Center. The Department is recommending approval with a condition
22 and contingency, as did the committee. Application 191341E,
23 Marquis Certified Homecare, LLC in Albany County. Establish
24 Marquis Certified Homecare, LLC as the new operator of the
25 certified home health agency located at 300 Washington Ave.,

1 extension in Albany currently operated by Living Resources
2 Certified Health Agency Inc. Here the Department is recommending
3 approval with a contingency as did the committee. Application
4 191137B, Binghamton ASC, LLC d/b/a Greater Binghamton Eye
5 Surgery Center in Broome County. This is to establish and
6 construct a single specialty ambulatory surgery center for
7 ophthalmology to be located at 1016 Vestal Parkway East in
8 Vestal. The Department is recommending approval with conditions
9 and contingencies, and an expiration of the operating
10 certificate five (days) [sic] from the date of issuance. The
11 committee makes a similar recommendation. Application - five
12 years. Five days?

13

14 JEFF KRAUT: It's an experiment we're not willing to
15 entertain right now.

16

17 PETER ROBINSON: Many thanks for that correction. So,
18 modified to be five years of course. 191314B, Staten Island ASC,
19 LLC d/a/b specialty surgery center of Staten Island in Richmond
20 County. To establish and construct a multispecialty ambulatory
21 surgery center located at 3869 Victory Blvd. in Staten Island.
22 Approval of this is recommended by the Department and the
23 committee. The committee also noted a contingency that includes
24 an expiration of the operating certificate five years from the
25 date of the issuance. Application 191170B, AIDS Healthcare

1 Foundation Bronx County. Establish and construct a diagnostic
2 and Treatment center to be located at 655 Morris Avenue in the
3 Bronx. Department and committee recommend approval with
4 conditions and contingencies. 191326B, Sunrise MedPlus LLC in
5 Suffolk County. To establish and construct a new diagnostic and
6 treatment center to be located at 456 Suffolk Ave., in
7 Brentwood. Again, Department recommends approval and with
8 conditions and contingencies as does the committee. 192007B.
9 Cayuga Community Service in Tompkins County. Establish and
10 construct a diagnostic and treatment center to be located at 201
11 Dates Drive in Ithaca, Division of Primary and Specialty Medical
12 Services. Department and committee recommend approval with
13 conditions and contingencies. 191012B, Hollis AK, LLC, d/b/a
14 Hollis Diagnostic and Treatment... 192012. Thank you. I appreciate
15 that Dr. Gutierrez. B. This is Hollis AK LLC, d/b/a Hollis
16 Diagnostic and Treatment Center in Queens County. To establish
17 and construct a new diagnostic and treatment center to be
18 located at 190-02 Jamaica Ave., in Hollis. Here the Department
19 is recommending approval with conditions and contingencies as
20 does the committee. I move all these applications.

21

22 JEFF KRAUT: I have a motion for this batch. I have a
23 second by Dr. Gutierrez. Any member of the council have a
24 question on any one of the items in this batch?

1 We have an abstention for the Staten Island Ophthalmologic
2 Surgi Center. Dr. Strange. All those in favor, aye.

3

4 [Aye]

5 Opposed? Abstention? One abstaining on the am-surg center.
6 Next.

7

8 PETER ROBINSON: Mr. LaRue, I have to ask you to leave
9 the room again, I skipped an application that you are also
10 recused for. This is application 182120C, the Plaza Rehab and
11 Nursing Center in Bronx County. Construct a six story addition
12 and transfer 146 residential healthcare facility beds from New
13 Riverdale Rehab and Nursing for a total of 890 beds. This is the
14 companion CON to 192117 that we just approved earlier. The
15 Department is recommending approval with conditions and
16 contingencies. The committee similarly recommended approval with
17 contingencies with one member in opposition, and I so move.

18

19 JEFF KRAUT: I have a motion and a second Dr. Gutierrez.
20 Any questions? All those in favor, aye.

21

22 [Aye]

23 Opposed? One opposition, Dr. Berliner. And the abstention,
24 motion carries. Please ask Mr. LaRue to return.

25

1 PETER ROBINSON: Thank you. These are applications for
2 dialysis services being batched. 191284E, Citadel Renal Center
3 LLC in Bronx County. Establish Citadel Renal Center LLC as the
4 new operator of the 15 station renal dialysis center located at
5 100 West Kingbridge Road in the Bronx. Currently operated by
6 Bronx River Nephro Care. The Department is recommending approval
7 with conditions and contingencies as does the committee.
8 Application 191264E, Freedom Center of Troy, LLC, d/b/a
9 Fresenius Kidney Care of Troy in Rensselaer County. This is to
10 certify Freedom Center of Troy LLC as the new operator of the 12
11 station chronic renal dialysis center located at 106 North
12 Greenbush Rd., Troy. Currently operated as an extension clinic
13 of FMS Southern Manhattan Dialysis Center. Department here
14 recommends approval with conditions and contingencies, as did
15 the committee. Application 191288E, Freedom Center of Rockland
16 County, LLC, d/b/a Fresenius Kidney Care Valley Cottage in
17 Rockland County. This establishes Freedom Center of Rockland
18 County LLC as the new operator of Renal Care of Rockland which
19 is an 18 station dialysis center located at 131 Rt. 303 in
20 Valley Cottage and it's 31 station extension clinic, located at
21 30, rt. 59 in Suffern. The Department recommends approval with
22 conditions and contingencies as does the committee. I move these
23 three applications.

24

1 JEFF KRAUT: I have a motion. I have a second, Dr.
2 Gutierrez. Any questions on these applications? All those in
3 favor, aye.

4
5 [Aye]

6 Opposed? Abstention? The motion carries.

7
8 PETER ROBINSON: The following are a variety of
9 certificates for approval. The Hemophilia Center of Western New
10 York Inc., for a corporate name change. WMC Health Network in
11 Ulster County inc., amending the purpose of the entity. Health
12 Alliance Inc., an amendment that repurposes the organization.
13 Northwest Buffalo Community Health Care Center inc., for a
14 corporate name change. And then three certificates of amendment
15 of the restated certificate of incorporation; one for Catskill
16 Regional Medical Center for a corporate name change, Greater
17 Hudson Valley Health System Inc., for a name change, and Orange
18 Regional Medical Center also for a name change. The Department
19 is recommending approval as does the committee. And I so move.

20
21 JEFF KRAUT: I have a motion. I have a second Dr.
22 Gutierrez. Question, Dr. Boufford.

23
24 JO BOUFFORD: Sorry. Because of the titles of WMC Health
25 Network and Health Alliance I'm not sure what they are when it

1 says amendment to purposes. Could you just get to that very
2 briefly?

3

4 PETER ROBINSON: Ms. Raleigh could you help us with
5 that.

6

7 JO BOUFFORD: what the amendment to purposes is.

8

9 TRACY RALEIGH: Previously the council had approved a
10 restructuring of the corporate structure of Westchester Medical
11 Center Health Network to bring, to basically eliminate a layer
12 of corporate entity to make Westchester Health Corporation the
13 active parent, establish it as the active parent of Health
14 Alliance. And so this is an a last legal to confirm this. This
15 is the action to amend the corporate purpose for that change.

16

17 (inaudible)

18

19 JEFF KRAUT: Any other questions? All those in favor,
20 aye.

21

22 [Aye]

23 Opposed? Abstention? The motion carries. Call application
24 192001E, St. Joseph's Hospital Skilled Nursing Facility in
25 Chemung County. A conflict declared by Mr. Robinson who has left

1 the room. This application is to certify Arnet Ogden Medical
2 Center as the new operator of the 85 bed residential healthcare
3 facility located at 555 St. Joseph's Blvd., in Elmira. DOH
4 recommends approval with conditions and contingencies, as did
5 the committee. And I so move the motion. I have a second by Dr.
6 Gutierrez. Is there any questions? Hearing none, I'll call for a
7 vote. All those in favor, aye.

8

9 [Aye]

10 Opposed? Abstentions? The motion carries. Where's Mr.
11 Robinson to return. And Mr. Thomas, get ready to leave.

12

13 PETER ROBINSON: Application 192030E, Unity Hospital of
14 Rochester and Monroe County. I've declared an interest.
15 Establish Regional Health Reach Inc,. as co-operator for Unity
16 Hospital of Rochester's two HRSA funded section 330H FQHC
17 clinics only. The Department here is recommending approval with
18 a condition and contingencies as does the committee. I so move.

19

20 JEFF KRAUT: I have a motion. I have a second, Dr.
21 Gutierrez. Any questions? All those in favor, aye.

22

23 [aye]

24 Opposed? Abstentions? Motion carries. Please ask Mr. Thomas
25 to return. Ms. Baumgartner you can begin to leave.

1

2 PETER ROBINSON: Thank you. This is application 191164B,
3 Harlem Road Ambulatory Surgery Center. This is in Erie County.
4 To establish and construct a new single specialty ambulatory
5 surgical center specializing in urology procedures to be located
6 at 3085 Harlem Rd. in Cheektowaga. The Department is
7 recommending approval with conditions and contingencies with a
8 five-year expiration, five-year expiration from the date of
9 issuance and the committee makes a similar recommendation, and I
10 so move.

11

12 JEFF KRAUT: I have a motion, I have a second by Dr.
13 Gutierrez. Any questions? All those in favor, aye
14 [Aye]

15 Opposed? Abstention. The motion carries. Please ask Ms.
16 Baumgartner to return.

17

18 JO BOUFFORD: Mr. Kraut has left the room. Recusing
19 himself from this discussion.

20

21 PETER ROBINSON: this is for a certificate. This is a
22 certificate of amendment of the certificate of incorporation for
23 Southside Hospital. Dr. Strange is also recusing himself and
24 leaving the room. My apologies for not noticing. This is a
25 corporate name change for Southside Hospital with a conflict and

1 recusal by Mr. Kraut and Dr. Strange. Simply enough the
2 Department and the committee both recommend approval and I so
3 move.

4

5 JO BOUFFORD: Motion and second by Dr. Gutierrez. Any
6 discussion? All in favor?

7

8 [aye]

9 Opposed? Any abstentions? Motion passes.

10 Invite the two gentlemen back in.

11

12 PETER ROBINSON: And finally we have home health
13 licensure, home health agency licensure. There's two. One is a
14 change of ownership with consolidation. This is application
15 191340E, Marquis Homecare LLC in Albany County. The Department
16 is recommending approval with conditions, with contingencies.
17 And then there's a serious concern access program. There's two
18 of them actually 182282E, BAYADA Home Health Care Inc., in
19 Queens County and 191104E, Intrathecal Care Solutions LLC d/b/a
20 Advanced Nursing Solutions in Sullivan County. The Department
21 here is recommending approval with contingencies as does the
22 committee. I move all three of these applications.

23

1 JEFF KRAUT: I have a motion I have a second. Any
2 questions? Hearing none I'll call for a vote. All those in
3 favor, aye.

4
5 [aye]

6 Opposed? Abstentions? Motion carries.

7

8 PETER ROBINSON: That is the end of the report of the
9 Establishment and Project Review Committee. Thank you.

10

11 JEFF KRAUT: thank you very much. The meeting of the
12 Public Health and Health Council is going to be adjourned. We're
13 going to note that the next agenda cycle of meetings will be
14 held in New York City and not as Albany as previously noted. The
15 next committee day is November 21 in New York City and the Full
16 Council meeting is going to convene on December 12 in New York
17 City. We're going to ask the members of the public to exit the
18 meeting room where we may go next door. Not sure yet. We'll
19 figure that out. The Council is going to enter into executive
20 session to consider a case arising under public health law
21 section 2801-B, which we'll receive the report of the committee
22 on health personnel and interprofessional relations. Should I
23 adjourn? I'm going to adjourn the public portion of the meeting.
24 I have a motion to do so. Motion made. All those in favor aye.

25

1 [Aye]

2 Thank you. Could you please, the public exit the room

3 immediately.

4

5 [end of audio.]

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, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Subpart 9-2, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows.

The title of Part 9 is amended to read as follows:

Part 9 [Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited] Prohibited Substances

A new Subpart 9-1, titled “Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited” is added and section 9.1 through 9.6 are renumbered 9-1.1 through 9-1.6.

A new Subpart 9-2, titled “Required Signage”, is added to read as follows:

Section 9-2.1 Definitions.

As used in this Subpart, the following terms shall have the following meanings:

- (a) The terms “electronic cigarette” and “e-cigarette” mean an electronic device that delivers vapor which is inhaled by an individual user, and shall include any refill, cartridge and any other component of such a device; provided, however, that “electronic cigarette” and “e-cigarette” shall not mean any product approved by the United States food and drug administration as a drug or medical device, or manufactured and dispensed pursuant to title five-A of article thirty-three of the public health law.

(b) The terms “electronic liquid” and “e-liquid” means the solution, substance or material used in an e-cigarette and heated to produce an aerosol or emission to be inhaled by the user, whether the liquid contains nicotine or not.

9-2.2 Required Signage Warning Against the Dangers of Illegal Products.

Any person operating a place of business wherein e-cigarettes or e-liquids are sold or offered for sale shall post in a conspicuous place a sign, to be published by the Department, that warns against the dangers of using illegal e-cigarette and e-liquid products.

Section 9-2.3 Penalties.

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that a place of business fails to post signage required by this Subpart shall constitute a separate violation under this Subpart.

Section 9-2.4 Severability.

If any provisions of this Subpart or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Subpart or the application thereof to other persons, entities, and circumstances.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) 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. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

Legislative Objectives:

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. This regulation furthers the legislative objective by requiring sellers of e-liquids and e-cigarettes to post signage that warns against consumption of illegal products.

Needs and Benefits:

Regulations are necessary to address the alarming number of people that have suffered injury or died from consuming illegal e-liquids and e-cigarette products, which can be adulterated with chemicals that are dangerous or deadly when inhaled. Currently, there is an outbreak of severe lung disease among persons who use illegal e-liquids and e-cigarettes, and the Department is engaged in an educational campaign to warn people against the use of these products. By requiring sellers of legitimate products to warn consumers against the dangers of illegitimate ones, the Department expects that consumers will become more educated and that consumption of illegal products will decrease.

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

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available.

Paperwork:

This regulation does not require any additional paperwork.

Duplication:

These regulations would not duplicate any State or federal regulations regarding e-cigarettes or e-liquids.

Alternatives:

The alternative to the regulation is to not exercise the Department's authority to require these notices to the public. That alternative was rejected.

Federal Standards:

There are no federal standards regarding signage for dangerous and illegal e-liquid and e-cigarette products.

Compliance Schedule:

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

Contact Person:

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect the small businesses that are engaged in selling e-liquids or e-cigarettes. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 “vape shops” employing 2700 persons across the state.

Local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Compliance Requirements:

Small businesses must comply with the proposed regulation by posting signage published by the Department. Local governments must comply by enforcing the proposed regulations as they are part of the State Sanitary Code.

Professional Services:

Small businesses will need no additional professional services to comply.

Compliance Costs:

Costs to Private Regulated Parties:

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding. In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

Economic and Technological Feasibility:

The rule does not impose any economic or technological compliance burdens.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website. The Department will assist small businesses by providing the required sign electronically.

Small Business and Local Government Participation:

Small business and local governments were not consulted during the creation of this proposed rule; however, small businesses and local governments will be able to submit public comments during the public comment period.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. Given the public health emergency caused by the consumption of illegal e-liquids and e-cigarettes, no cure period was included.

Rural Area Flexibility Analysis

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

No job impact statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

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, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Subpart 9-3, to be effective upon filing with the Department of State.

A new Subpart 9-3, titled “Prohibition on the Sale of Electronic Liquids with Characterizing Flavors”, is added to read as follows:

Section 9-3.1 Definitions.

As used in this Subpart, the following terms shall have the following meanings:

- (a) The terms “electronic cigarette,” “e-cigarette”, “electronic liquid,” and “e-liquid” shall have the same meanings as established in Subpart 9-2.
- (b) The term “flavored e-liquid” means any e-liquid with a distinguishable taste or aroma, other than the taste or aroma of tobacco or menthol, imparted either prior to or during consumption of an e-cigarette or a component part thereof, including but not limited to tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, mint, wintergreen, herb or spice, or any “concept flavor” that imparts a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor. An e-liquid shall be presumed to be a flavored e-liquid if a tobacco retailer, manufacturer, or a manufacturer’s agent or employee has made a statement or claim directed to consumers or the public, whether expressed or implied, that the product or device has a distinguishable taste or aroma other than the taste or aroma of tobacco or menthol.

(c)The term “possession” means having physical possession or otherwise exercising dominion or control over flavored e-liquids or a product containing the same. For purposes of this definition, among other circumstances not limited to these examples, the following individuals and/or entities shall be deemed to possess flavored e-liquids, or a product containing the same: (1) any individual or entity that has an ownership interest in a retail, distribution or manufacturing establishment that possesses, distributes, sells or offers for sale flavored e-liquids, or a product containing the same; and (2) any clerk, cashier or other employee or staff of a retail establishment, where the establishment possesses, distributes, sells or offers for sale a flavored e-liquids or a product containing the same, and who interacts with customers or other members of the public.

Section 9-3.2 Possession, Manufacture, Distribution, Sale or Offer of Sale of Flavored E-Liquid Prohibited.

It shall be unlawful for any individual or entity to possess, manufacture, distribute, sell or offer for sale any flavored e-liquid or product containing the same.

Section 9-3.3 Penalties.

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each individual container or other separate unit of flavored e-liquid, product containing the same, or any component part that imparts flavor to an e-cigarette, that is possessed, manufactured, distributed, sold, or offered for sale, shall constitute a separate violation under this Subpart.

Section 9-3.4 Severability.

If any provisions of this Subpart or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Subpart or the application thereof to other persons, entities, and circumstances.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) 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. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

Legislative Objectives:

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. This proposed regulation furthers this legislative objective by prohibiting the possession, manufacture, distribution, sale or offer for sale of flavored electronic liquids (e-liquids) to discourage youth electronic cigarette (e-cigarette) use.

Needs and Benefits:

Emergency regulations are necessary to address the alarming increase of e-cigarette use among New York's youth. New York State-specific surveillance data shows that youth e-cigarette use has risen at a dramatic rate over just the last four years, driven primarily by the abundance of e-liquid flavors. Swift interventions are needed to protect our youth from a lifetime addiction to nicotine. Therefore, restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use.

According to the U.S. Food and Drug Administration (FDA), the use of e-cigarettes by youth has reached epidemic proportions nationally. Since the New York State Department of Health (Department) began tracking e-cigarette use in New York State (NYS) in 2014, use by youth in high school has increased 160 percent, from 10.5 percent in 2014, to 20.6 percent in 2016, to an astounding 27.4 percent in 2018. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. The rate for 2018 is equivalent to youth use of combustible cigarettes in 2000 prior to the dramatic decline in the use of combustible cigarettes among NYS youth. Currently, just 4.8 percent of NYS youth smoke a combustible cigarette, one of the lowest rates in the nation. However, the rate of smoking by youth is increasing, as the rate in 2016 was 4.3 percent. Schools across New York State are finding it especially challenging to address the alarming increase in e-cigarette use by adolescents. Enforcement of minimum age statute and prohibitions on school grounds are especially difficult given that most products are sleek and easy to conceal by youth users.

The recently published National Academy of Science, Engineering, and Medicine (NASEM) report on the *Public Health Consequences of E-Cigarettes* concluded that there is:

- 1) “...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,” and
- 2) “...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking” among youth and young adults.

Given the recent rise in combustible cigarette use by youth and the fact that e-cigarettes are now the most commonly used tobacco product by youth in NYS, evidence exists that use of

e-cigarettes could reverse the long-standing decline in combustible cigarette use and reverse the public health benefits that NYS has achieved. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

The flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion only; however, these chemicals have not been approved for inhalation. Because inhalation and ingestion are very different processes, nothing about the approval for ingestion should be interpreted to suggest that these products are safe for inhalation. Food products, chemicals and flavorings that are ingested are detoxified through the liver before entering the circulatory system. Aerosols that are inhaled have a direct impact on lung tissue and directly enter the circulatory system, and are not detoxified through the liver.

Some of the over 15,000 flavors now available include fruit flavors (apple, cherry, peach, melon, strawberry), dessert flavors (vanilla custard, peanut butter cup, cream cookie, milk ‘n honey), candy flavors (cinnablaze, bubblerazz, mango burst, caramel), and menthol flavor, including mint and wintergreen. More recently, manufacturers have developed “concept flavors” that may be difficult to perceive as a single distinctive flavor and the product names reflect that (e.g., Jazz, First Flight, and Unicorn Milk) and simple color names (such as Blue and Yellow) that substitute for the names of flavors (Vanilla and Banana respectively). The list of flavors continues to grow. The commonality of all these flavors is that they are distinct from plain tobacco flavor or unflavored tobacco.

The dramatic increase in use of e-cigarettes by youth is driven in large part by flavored

e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. In a 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 percent of adolescent e-cigarette users, flavors were the primary reason for first use. Some flavors also confer misperceptions about the relative safety of e-cigarettes. The survey also found that adolescents are more likely to believe that sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

There is also concern regarding human exposure to nicotine. Users are often unaware of how much nicotine they are consuming. The newest and most popular e-cigarettes deliver high levels of nicotine, the addictive component in all tobacco products.

Nicotine is not a benign chemical. Nicotine has deleterious effects on the developing human brain – a process that continues through the mid-twenties. According to the US Surgeon General, these deleterious effects from nicotine can lead to lower impulse control and mood disorders; disrupt attention and learning among youth and young adults; and prime the developing brain for addiction to alcohol and other drugs.

Adult use of e-cigarettes differs by age category. Adults over age 24 use e-cigarettes at very low rates; just 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) use combustible cigarettes. Almost 40 percent of the young adult smokers are concurrently using e-cigarettes, known as dual use. The same health concerns described above apply to the use of e-cigarettes by adults aged 18 to 24.

The Department will continue to monitor the impact of new legislation that takes effect on November 13, 2019 that raises the legal age for purchase of e-cigarettes and related products to 21 years to determine the impact that has on youth use rates. In addition, the Department routinely conducts surveys that ask youth, among other things, their preference and current use of flavored products and will monitor the trends with respect to use of menthol, mint and other broad flavoring categories.

In addition, although it is too soon to understand the long-term health effects of a lifetime of e-cigarette use, research is beginning to accumulate about certain health effects related to cardiovascular conditions and respiratory conditions. Some e-cigarette flavors contain diacetyl, the buttery-flavored chemical that is used in foods like popcorn and caramel. When inhaled, diacetyl can cause bronchiolitis obliterans, a scarring of the tiny air sacs in the lungs, which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

In a study performed at the Stanford University School of Medicine, scientists found that menthol and cinnamon flavored e-liquids, specifically, caused the most damage to endothelial cells (the cells that line the interior of blood vessels). Some of the effects of the e-liquid flavors were independent of the nicotine concentration. Researchers concluded that flavoring liquid used in e-cigarettes may increase the risk of heart disease. In a study at the Duke University School of Medicine, high levels of a carcinogenic oil banned in the U.S. as a food additive were found in samples of menthol-flavored e-cigarette liquids and smokeless tobacco products. Concentrations of the additive pulegone were 100 to more than 1,000 times higher than the concentrations considered safe for ingested food products by the FDA.

The Department will continue to closely monitor the research literature for health impact related to e-cigarettes. Adult smokers who want to continue to use e-cigarettes will have the option of unflavored or tobacco flavored e-cigarettes.

Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available.

Paperwork:

The regulation imposes an increase of administrative paperwork for program implementation in regard to developing adequate enforcement mechanisms, record-keeping of enforcement activities and compliance history, and complaint-driven enforcement actions.

Duplication:

There are currently no State or federal regulations regarding the possession, manufacture, distribution, sale or offer for sale of e-cigarettes with characterizing flavors.

Alternatives:

The alternative to the proposed regulation is to wait for the FDA to regulate in this area; however, due to the health concerns associated with increase e-cigarette use among youths, this alternative was rejected.

Federal Standards:

The FDA has not proposed any standards for e-cigarette devices or for the constituents used in the devices to create the aerosol, including characterizing flavors. FDA only requires that those purchasing e-cigarette products be at least 18 years old, that e-liquids carry a warning statement about the addictiveness of nicotine, and that e-liquids be in child-proof containers.

Compliance Schedule:

The regulation will be effective upon filing with the Department of State.

Contact Person:

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect the small businesses that are engaged in selling flavored e-liquids or e-cigarettes. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists.

Compliance Requirements:

Small businesses must comply with the proposed regulation by not engaging in any possession, manufacturing, distribution, sale, or offer of sale of flavored e-liquids. Local governments must comply by enforcing the proposed regulations as they are part of the State Sanitary Code.

Professional Services:

Small businesses will need no additional professional services to comply.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Economic and Technological Feasibility:

The rule does not impose any economic or technological compliance burdens.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website.

Small Business and Local Government Participation:

Small business and local governments were not consulted during the creation of this proposed rule; however, small businesses and local governments will be able to submit public comments during the public comment period.

Cure Period:

Violations of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by flavored e-liquids, the risk that some small businesses will not comply with the regulations and continue to possess, manufacture, distribute,

sell or offer for sale any flavored e-liquid or product containing the same justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas. The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

E-cigarettes and e-liquids are sold in many types of retail outlets. The impact on businesses where e-cigarette sales is not the focus of the business (e.g., convenience store) will have no job impact from this regulation as e-cigarettes make up only a small percentage of their sales. Some e-cigarette retailers focus the bulk of their business on e-cigarettes and e-liquids and these outlets will be affected by this regulation. Although they will still be able to sell e-cigarette devices and unflavored, menthol or tobacco flavored e-liquid, the prohibition on flavored e-liquids is likely to affect these businesses. The Department does not have an accurate estimate of the number of stores affected since the registration requirement for e-cigarette retailers will not be effective until December 1, 2019.

Categories and Numbers Affected:

The main category affected by this regulation is the store that focuses its primary business on the sale of e-cigarette devices and e-liquids. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 of such “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists. Because of the lack of data about the number of these stores, it is not possible to accurately estimate the number of jobs affected.

Regions of Adverse Impact:

The Department anticipates any jobs or employment impacts will occur equally throughout the regions of the state.

Minimizing Adverse Impact:

The Department will consider different types/levels of enforcement while retailers adapt to the new regulation.

Emergency Justification

Emergency regulations are necessary to address the alarming increase of e-cigarette use among New York's youth. New York State-specific surveillance data shows that youth e-cigarette use has risen at a dramatic rate over just the last four years, driven primarily by the abundance of e-liquid flavors. Swift interventions are needed to protect our youth from a lifetime addiction to nicotine. Therefore, restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use.

According to the U.S. Food and Drug Administration (FDA), the use of e-cigarettes by youth has reached epidemic proportions nationally. Since the New York State Department of Health (Department) began tracking e-cigarette use in New York State (NYS) in 2014, use by youth in high school has increased 160 percent, from 10.5 percent in 2014, to 20.6 percent in 2016, to an astounding 27.4 percent in 2018. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. The rate for 2018 is equivalent to youth use of combustible cigarettes in 2000 prior to the dramatic decline in the use of combustible cigarettes among NYS youth. Currently, just 4.8 percent of NYS youth smoke a combustible cigarette, one of the lowest rates in the nation. However, the rate of smoking by youth is increasing, as the rate in 2016 was 4.3 percent. Schools across New York State are finding it especially challenging to address the alarming increase in e-cigarette use by adolescents. Enforcement of minimum age statute and prohibitions on school grounds are especially difficult given that most products are sleek and easy to conceal by youth users.

The recently published National Academy of Science, Engineering, and Medicine (NASEM) report on the *Public Health Consequences of E-Cigarettes* concluded that there is:

- 3) "...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults," and
- 4) "...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking" among youth and young adults.

Given the recent rise in combustible cigarette use by youth and the fact that e-cigarettes are now the most commonly used tobacco product by youth in NYS, evidence exists that use of e-cigarettes could reverse the long-standing decline in combustible cigarette use and reverse the public health benefits that NYS has achieved. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

The flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion only; however, these chemicals have not been approved for inhalation. Because inhalation and ingestion are very different processes, nothing about the approval for ingestion should be interpreted to suggest that these products are safe for inhalation. Food products, chemicals and flavorings that are ingested are detoxified through the liver before entering the circulatory system. Aerosols that are inhaled have a direct impact on lung tissue and directly enter the circulatory system, and are not detoxified through the liver.

Some of the over 15,000 flavors now available include fruit flavors (apple, cherry, peach, melon, strawberry), dessert flavors (vanilla custard, peanut butter cup, cream cookie, milk 'n

honey), candy flavors (cinnablaze, bubblerazz, mango burst, caramel), and menthol flavor, including mint and wintergreen. More recently, manufacturers have developed “concept flavors” that may be difficult to perceive as a single distinctive flavor and the product names reflect that (e.g., Jazz, First Flight, and Unicorn Milk) and simple color names (such as Blue and Yellow) that substitute for the names of flavors (Vanilla and Banana respectively). The list of flavors continues to grow. The commonality of all these flavors is that they are distinct from plain tobacco flavor or unflavored tobacco.

The dramatic increase in use of e-cigarettes by youth is driven in large part by flavored e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. In a 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 percent of adolescent e-cigarette users, flavors were the primary reason for first use. Some flavors also confer misperceptions about the relative safety of e-cigarettes. The survey also found that adolescents are more likely to believe that sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

There is also concern regarding human exposure to nicotine. Users are often unaware of how much nicotine they are consuming. The newest and most popular e-cigarettes deliver high levels of nicotine, the addictive component in all tobacco products.

Nicotine is not a benign chemical. Nicotine has deleterious effects on the developing human brain – a process that continues through the mid-twenties. According to the US Surgeon General, these deleterious effects from nicotine can lead to lower impulse control and mood

disorders; disrupt attention and learning among youth and young adults; and prime the developing brain for addiction to alcohol and other drugs.

Adult use of e-cigarettes differs by age category. Adults over age 24 use e-cigarettes at very low rates; just 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) use combustible cigarettes. Almost 40 percent of the young adult smokers are concurrently using e-cigarettes, known as dual use. The same health concerns described above apply to the use of e-cigarettes by adults aged 18 to 24.

The Department will continue to monitor the impact of new legislation that took effect on November 13, 2019 that raises the legal age for purchase of e-cigarettes and related products to 21 years to determine the impact that has on youth use rates. In addition, the Department routinely conducts surveys that ask youth, among other things, their preference and current use of flavored products and will monitor the trends with respect to use of menthol, mint and other broad flavoring categories.

In addition, although it is too soon to understand the long-term health effects of a lifetime of e-cigarette use, research is beginning to accumulate about certain health effects related to cardiovascular conditions and respiratory conditions. Some e-cigarette flavors contain diacetyl, the buttery-flavored chemical that is used in foods like popcorn and caramel. When inhaled, diacetyl can cause bronchiolitis obliterans, a scarring of the tiny air sacs in the lungs, which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

The Department will continue to closely monitor the research literature for health impact related to e-cigarettes. Adult smokers who want to continue to use e-cigarettes will have the option of unflavored, menthol or tobacco flavored e-cigarettes.

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, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Subpart 9-3, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 9-3, titled “Prohibition on the Sale of Electronic Liquids with Characterizing Flavors”, is added to read as follows:

Section 9-3.1 Definitions.

As used in this Subpart, the following terms shall have the following meanings:

- (a) The terms “electronic cigarette,” “e-cigarette”, “electronic liquid,” and “e-liquid” shall have the same meanings as established in Subpart 9-2.
- (b) The term “flavored e-liquid” means any e-liquid with a distinguishable taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of an e-cigarette or a component part thereof, including but not limited to tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, mint, wintergreen, menthol, herb or spice, or any “concept flavor” that imparts a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor. An e-liquid shall be presumed to be a flavored e-liquid if a tobacco retailer, manufacturer, or a manufacturer’s agent or employee has made a statement or claim directed to consumers or the public, whether expressed or implied, that the product or device has a distinguishable taste or aroma other than the taste or aroma of tobacco.

(c)The term “possession” means having physical possession or otherwise exercising dominion or control over flavored e-liquids or a product containing the same. For purposes of this definition, among other circumstances not limited to these examples, the following individuals and/or entities shall be deemed to possess flavored e-liquids, or a product containing the same: (1) any individual or entity that has an ownership interest in a retail, distribution or manufacturing establishment that possesses, distributes, sells or offers for sale flavored e-liquids, or a product containing the same, for purposes of retail sale in New York State; and (2) any clerk, cashier or other employee or staff of a retail establishment, where the establishment possesses, distributes, sells or offers for sale a flavored e-liquids or a product containing the same, and who interacts with customers or other members of the public.

Section 9-3.2 Possession, Manufacture, Distribution, Sale or Offer of Sale of Flavored E-Liquid Prohibited.

It shall be unlawful for any individual or entity to possess, manufacture, distribute, sell or offer for sale any flavored e-liquid or product containing the same, for purposes of retail sale in New York State.

Section 9-3.3 Exemptions. The provisions of this Subpart prohibiting the possession of any flavored e-liquid or product containing the same shall not apply to:

(a) individuals who are in possession of flavored e-liquids or products containing the same for personal use;

(b) public officers or their employees in the lawful performance of their official duties requiring possession of flavored e-liquids or products containing the same;

(c) temporary or incidental possession of flavored e-liquids or products containing the same by employees or agents of persons lawfully entitled to possession, or persons whose possession is for the purpose of aiding public officers in performing their official duties;

(d) a person in the employ of the United States government or of any state, territory, district, county, municipal or insular government, obtaining or possessing flavored e-liquids or products containing the same, by reason of his or her official duties;

(e) common carriers or warehouse worker, while engaged in lawfully transporting or storing of flavored e-liquids or products containing the same, or to any employee of the same within the scope of his or her employment; and

(f) an accredited college or university, laboratory, hospital, medical center or other institution that is possessing flavored e-liquids or products containing the same for health, scientific or other research or experimental purposes.

Section 9-3.4 Penalties.

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each individual container or other separate unit of flavored e-liquid, product containing the same, or any component part that imparts flavor

to an e-cigarette, that is possessed, manufactured, distributed, sold, or offered for sale, shall constitute a separate violation under this Subpart.

Section 9-3.5 Severability.

If any provisions of this Subpart or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Subpart or the application thereof to other persons, entities, and circumstances.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) 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. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

Legislative Objectives:

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. This proposed regulation furthers this legislative objective by prohibiting the possession, manufacture, distribution, sale or offer for sale of flavored electronic liquids (e-liquids) to discourage youth electronic cigarette (e-cigarette) use.

Needs and Benefits:

These regulations are necessary to address the alarming increase of e-cigarette use among New York's youth. New York State-specific surveillance data shows that youth e-cigarette use has risen at a dramatic rate over just the last four years, driven primarily by the abundance of e-liquid flavors. Swift interventions are needed to protect our youth from a lifetime addiction to nicotine. Therefore, restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use.

According to the U.S. Food and Drug Administration (FDA), the use of e-cigarettes by youth has reached epidemic proportions nationally. Since the New York State Department of Health (Department) began tracking e-cigarette use in New York State (NYS) in 2014, use by youth in high school has increased 160 percent, from 10.5 percent in 2014, to 20.6 percent in 2016, to an astounding 27.4 percent in 2018. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. The rate for 2018 is equivalent to youth use of combustible cigarettes in 2000 prior to the dramatic decline in the use of combustible cigarettes among NYS youth. Currently, just 4.8 percent of NYS youth smoke a combustible cigarette, one of the lowest rates in the nation. However, the rate of smoking by youth is increasing, as the rate in 2016 was 4.3 percent. Schools across New York State are finding it especially challenging to address the alarming increase in e-cigarette use by adolescents. Enforcement of minimum age statute and prohibitions on school grounds are especially difficult given that most products are sleek and easy to conceal by youth users.

The recently published National Academy of Science, Engineering, and Medicine (NASEM) report on the *Public Health Consequences of E-Cigarettes* concluded that there is:

- 1) “...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,” and
- 2) “...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking” among youth and young adults.

Given the recent rise in combustible cigarette use by youth and the fact that e-cigarettes are now the most commonly used tobacco product by youth in NYS, evidence exists that use of

e-cigarettes could reverse the long-standing decline in combustible cigarette use and reverse the public health benefits that NYS has achieved. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

The flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion only; however, these chemicals have not been approved for inhalation. Because inhalation and ingestion are very different processes, nothing about the approval for ingestion should be interpreted to suggest that these products are safe for inhalation. Food products, chemicals and flavorings that are ingested are detoxified through the liver before entering the circulatory system. Aerosols that are inhaled have a direct impact on lung tissue and directly enter the circulatory system, and are not detoxified through the liver.

Some of the over 15,000 flavors now available include fruit flavors (apple, cherry, peach, melon, strawberry), dessert flavors (vanilla custard, peanut butter cup, cream cookie, milk ‘n honey), candy flavors (cinnablaze, bubblerazz, mango burst, caramel), and menthol flavor, including mint and wintergreen. More recently, manufacturers have developed “concept flavors” that may be difficult to perceive as a single distinctive flavor and the product names reflect that (e.g., Jazz, First Flight, and Unicorn Milk) and simple color names (such as Blue and Yellow) that substitute for the names of flavors (Vanilla and Banana respectively). The list of flavors continues to grow. The commonality of all these flavors is that they are distinct from plain tobacco flavor or unflavored tobacco.

The dramatic increase in use of e-cigarettes by youth is driven in large part by flavored

e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. In a 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 percent of adolescent e-cigarette users, flavors were the primary reason for first use. Some flavors also confer misperceptions about the relative safety of e-cigarettes. The survey also found that adolescents are more likely to believe that sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

There is also concern regarding human exposure to nicotine. Users are often unaware of how much nicotine they are consuming. The newest and most popular e-cigarettes deliver high levels of nicotine, the addictive component in all tobacco products.

Nicotine is not a benign chemical. Nicotine has deleterious effects on the developing human brain – a process that continues through the mid-twenties. According to the US Surgeon General, these deleterious effects from nicotine can lead to lower impulse control and mood disorders; disrupt attention and learning among youth and young adults; and prime the developing brain for addiction to alcohol and other drugs.

Adult use of e-cigarettes differs by age category. Adults over age 24 use e-cigarettes at very low rates; just 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) use combustible cigarettes. Almost 40 percent of the young adult smokers are concurrently using e-cigarettes, known as dual use. The same health concerns described above apply to the use of e-cigarettes by adults aged 18 to 24.

The Department will continue to monitor the impact of new legislation that takes effect on November 13, 2019 that raises the legal age for purchase of e-cigarettes and related products to 21 years to determine the impact that has on youth use rates. In addition, the Department routinely conducts surveys that ask youth, among other things, their preference and current use of flavored products and will monitor the trends with respect to use of menthol, mint and other broad flavoring categories.

In addition, although it is too soon to understand the long-term health effects of a lifetime of e-cigarette use, research is beginning to accumulate about certain health effects related to cardiovascular conditions and respiratory conditions. Some e-cigarette flavors contain diacetyl, the buttery-flavored chemical that is used in foods like popcorn and caramel. When inhaled, diacetyl can cause bronchiolitis obliterans, a scarring of the tiny air sacs in the lungs, which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

In a study performed at the Stanford University School of Medicine, scientists found that menthol and cinnamon flavored e-liquids, specifically, caused the most damage to endothelial cells (the cells that line the interior of blood vessels). Some of the effects of the e-liquid flavors were independent of the nicotine concentration. Researchers concluded that flavoring liquid used in e-cigarettes may increase the risk of heart disease. In a study at the Duke University School of Medicine, high levels of a carcinogenic oil banned in the U.S. as a food additive were found in samples of menthol-flavored e-cigarette liquids and smokeless tobacco products. Concentrations of the additive pulegone were 100 to more than 1,000 times higher than the concentrations considered safe for ingested food products by the FDA.

The Department will continue to closely monitor the research literature for health impact related to e-cigarettes. Adult smokers who want to continue to use e-cigarettes will have the option of unflavored or tobacco flavored e-cigarettes.

Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available.

Paperwork:

The regulation imposes an increase of administrative paperwork for program implementation in regard to developing adequate enforcement mechanisms, record-keeping of enforcement activities and compliance history, and complaint-driven enforcement actions.

Duplication:

There are currently no State or federal regulations regarding the possession, manufacture, distribution, sale or offer for sale of e-cigarettes with characterizing flavors.

Alternatives:

The alternative to the proposed regulation is to wait for the FDA to regulate in this area; however, due to the health concerns associated with increase e-cigarette use among youths, this alternative was rejected.

Federal Standards:

The FDA has not proposed any standards for e-cigarette devices or for the constituents used in the devices to create the aerosol, including characterizing flavors. FDA only requires that those purchasing e-cigarette products be at least 18 years old, that e-liquids carry a warning statement about the addictiveness of nicotine, and that e-liquids be in child-proof containers.

Compliance Schedule:

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

Contact Person:

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect the small businesses that are engaged in selling flavored e-liquids or e-cigarettes. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists.

Compliance Requirements:

Small businesses must comply with the proposed regulation by not engaging in any possession, manufacturing, distribution, sale, or offer of sale of flavored e-liquids. Local governments must comply by enforcing the proposed regulations as they are part of the State Sanitary Code.

Professional Services:

Small businesses will need no additional professional services to comply.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Economic and Technological Feasibility:

The rule does not impose any economic or technological compliance burdens.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website.

Small Business and Local Government Participation:

Small business and local governments were not consulted during the creation of this proposed rule; however, small businesses and local governments will be able to submit public comments during the public comment period.

Cure Period:

Violations of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by flavored e-liquids, the risk that some small businesses will not comply with the regulations and continue to possess, manufacture, distribute,

sell or offer for sale any flavored e-liquid or product containing the same justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas. The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

E-cigarettes and e-liquids are sold in many types of retail outlets. The impact on businesses where e-cigarette sales is not the focus of the business (e.g., convenience store) will have no job impact from this regulation as e-cigarettes make up only a small percentage of their sales. Some e-cigarette retailers focus the bulk of their business on e-cigarettes and e-liquids and these outlets will be affected by this regulation. Although they will still be able to sell e-cigarette devices and unflavored or tobacco flavored e-liquid, the prohibition on flavored e-liquids is likely to affect these businesses. The Department does not have an accurate estimate of the number of stores affected since the registration requirement for e-cigarette retailers will not be effective until December 1, 2019.

Categories and Numbers Affected:

The main category affected by this regulation is the store that focuses its primary business on the sale of e-cigarette devices and e-liquids. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 of such “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists. Because of the lack of data about the number of these stores, it is not possible to accurately estimate the number of jobs affected.

Regions of Adverse Impact:

The Department anticipates any jobs or employment impacts will occur equally throughout the regions of the state.

Minimizing Adverse Impact:

The Department will consider different types/levels of enforcement while retailers adapt to the new regulation.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, section 405.4 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (2) of subdivision (g) of Section 405.4 is amended to read as follows:

(2) physicians who possess limited permits to practice medicine issued by the New York State Education Department pursuant to section 6525 of the State Education Law if such physicians are under the supervision of a physician licensed and currently registered to practice medicine in the State of New York, [and if the physicians possessing limited permits are:

(i) graduates of medical school offering a medical program accredited by the Liaison Committee on Medical Education or the American Osteopathic Association, or registered with the State Education Department or accredited by an accrediting organization acceptable to the State Education Department, and have satisfactorily completed one year of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department;

(ii) graduates of a foreign medical school and have satisfactorily completed three years of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department; or

(iii) graduates of a foreign medical school who have satisfactorily completed three years in a postgraduate training program and who are receiving advanced training as part of an official exchange visitor program approved by the United States Information Agency and the Educational Commission for Foreign Medical Graduates (ECFMG);]

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

10 NYCRR §405.4(g)(2) allows an unlicensed physician to provide medical services in a hospital under a limited permit to practice medicine under Education Law §6525 when the State Education Department (SED) determines that the applicant meets SED criteria for issuance of a limited permit and appropriate levels of supervision and oversight are in place. Section 405.4(g)(2) requires additional years of training, beyond what is required for a limited permit under Education Law §6525. This proposed regulation would eliminate the extra years of training required for limited permittees to work in hospitals.

New York State is experiencing a shortage of licensed physicians in all areas of the state. Limited permit holders are fully trained physicians, often graduates of international medical

schools, that are working in various health care settings until full licensure requirements can be met. It is typically the U.S. citizenship requirement that prevents many limited permit holders from initially obtaining full licensure.

Currently, section 405.4(g)(2) imposes additional years of training for limited permit holders, specifically one year for domestic medical graduates and three years for international (foreign) medical graduates, as a condition of working in a New York State hospital. This requirement was originally intended to ensure that international students' educations were equivalent to those of physicians educated in the United States. SED has confirmed the understanding of the New York State Department of Health that any educational disparities are minimal today due to medical school accreditation standards. Nevertheless, under the current regulations, hospitals must require the limited permit holders to have the additional years of training. As a result, hospitals hiring doctors to meet patient needs often must turn away otherwise qualified applicants to maintain compliance with the regulation. These candidates, if unable to work in New York State hospitals, may seek employment in other states or in other types of health care settings where the extra years of experience are not required.

SED already considers training and experience before approving and issuing limited permits; however, SED does not screen candidates for their eligibility to work in hospitals. In addition, limited permit holders working in other settings in New York State, such as nursing homes and psychiatric hospitals, are not required to have these additional years of training. As such, there is inconsistency in the standards required of limited permit holders with equivalent background and training, making limited permit holders less likely to be to be utilized in hospitals. Given the shortage of licensed physicians to cover vital hospital services, this proposed amendment will eliminate a barrier to limited permit holders practicing in hospitals.

Finally, since all limited permit holders are subject to supervision and oversight by a licensed physician, their practice within the hospital will be monitored and safe.

COSTS:

Costs to Private Regulated Parties:

This proposal will not result in increased costs to regulated parties.

Costs to Local Government:

This regulation amendment will not impact local governments unless they operate a general hospital. In any event, this proposal will not increase costs for local governments.

Costs to the Department of Health:

The proposed regulatory changes will not result in any additional operational costs to the Department of Health.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other state agencies.

Local Government Mandate:

The proposed regulatory changes will not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposed regulatory changes will not create any additional paperwork.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulatory changes.

Alternatives:

The alternative would be to take no action and have hospitals continue to screen limited permit holders for additional years of training as a condition of employment.

Federal Standards:

The proposed regulatory changes do not duplicate or conflict with any federal regulations.

Compliance Schedule:

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

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because the proposed amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

Summary of Express Terms

The proposal would amend various provisions of Part 765 of Title 10 NYCRR to implement recently enacted legislation.

Section 765-1.2. Applications for licensure. This section will be amended to require applications for licensure as a Licensed Home Care Service Agency (LHCSA) to include information on the public need for additional LHCSAs and the financial resources of the proposed agency as required by law, in addition to the existing requirement of a character and competence review. Amendments would specify that applications for licensure based on change of ownership for LHCSAs actively serving at least 25 patients shall only be evaluated based on financial feasibility and the character and competence of the proposed operator.

Section 765-1.3. Requirements for approval. This section will be amended to require applicants for licensure as a LHCSA to satisfactorily demonstrate to the Public Health and Health Planning Council (PHHPC) the public need for the agency and the financial resources of the agency in order to be approved for licensure, in addition to the existing requirement of a character and competence review.

Section 765-1.4. Amendments to applications. This section will be amended to add to the list of actions that constitute an amendment to a pending application for licensure for a home care services agency, requiring review and approval by PHHPC. The proposal will require that any significant change to the proposed patient capacity, any change in the agency's proposed service area, and any significant change to the agency's proposed annual operating budget will constitute an amendment and require approval by PHHPC, in addition to the existing language stating that changes to services and changes in the principles of the applicant as considered by PHHPC are

amendments. A new section will be added specifying that failure to disclose this information prior to the issuance of a license shall be grounds for revocation, limitation, or annulment of the approval for licensure. This is consistent with the approval processes for other types of home care agencies including certified home health agencies and hospices.

This proposal would also add a new section 765-1.16, Determinations of public need, to detail the public need methodology to be used to implement recent statutory changes. Subdivisions of this new section will include planning area designations, determination of public need, public need exemption criteria and additional requirements for applications seeking PHHPC approval, and priority considerations for the Department.

The regulations will affect all agencies applying for licensure as a home care services agency or for changes of ownership on or after April 1, 2020.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 3612 of the Public Health Law, Subpart 765-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective on April 1, 2020.

Section 765-1.2 is amended to read as follows:

765-1.2 Applications for licensure. (a) An application to the Public Health and Health Planning Council for its approval, as required by law, shall be in writing on application forms provided by the department and subscribed by the chief executive officer duly authorized by the board of a corporate applicant, a general partner or proprietor of the proposed licensed home care service agency, or, where an application is to be submitted by a governmental subdivision as the applicant, the president or chairman of the board of the proposed agency or the chief executive officer if there is no board; and accompanied by a certified copy of a resolution of the board of a corporate applicant authorizing the undertaking which is the subject of the application, and the subscribing and submission thereof by an appropriate designated individual. In the event that an application is to be submitted by an entity which necessarily remains to be legally incorporated, it shall be subscribed and submitted by one of the proposed principal stockholders or directors. If a local government applicant submitting an application has not designated a president, chairman or chief executive officer for the proposed agency, the application shall be subscribed by the chairman or president of the local legislature or board of supervisors having jurisdiction, or another appropriate executive officer. If available, the application must be electronically submitted to the Department of Health in a form designated by the commissioner. In the absence of an electronic system, an original application and five copies thereof shall be prepared and filed

with the Public Health and Health Planning Council through the project management unit in the department's central office in Albany [, which shall transmit one copy to the health systems agency having jurisdiction].

(b) Applications to the council shall contain information and data as applicable with reference to:

(1) the public need for the existence of the licensed home care service agency or proposed agency at the time and place and under the circumstances proposed as outlined in Section 765-1.16 of this Title;

(2) the character, experience, competence and standing in the community of the proposed persons, incorporators, directors, controlling persons, officers, principal stockholders, sponsors, governmental subdivisions, individual operators or partners of the applicant or of any parent or health-related subsidiary corporation as applicable. The application shall include copies of personal qualifying and disclosure information, as appropriate, as may be required by the council with regard to any such individual or organization[.];

[(1)] (i) Disclosure information shall include, but not be limited to, a list of health care, adult care or mental health facilities, programs or agencies controlled or operated in the United States by an individual or organization specified in this subdivision; the name and address of each such facility, program or agency; and the dates of control or operation of each such facility, program or agency.

[(2)] (ii) In the event that any such health care, adult care or mental health facility, program or agency, while under the control or operation of an individual or organization specified in this subdivision, has been subjected to financial penalties, or suspension or revocation of its operating certificate, license or certification because of a failure to comply with provisions governing the conduct and operation of the facility, program or agency, then information must be

provided which describes the nature of the violation, the agency or body enforcing the violation (including its name and mailing address), the steps taken by the facility, program or agency to remedy the violation or violations, and an indication of whether the suspension, revocation or accreditation has since been restored.

(3) the financial resources of the proposed licensed home care service agency and its projections of revenues and expenses. The standards of this review will require, at a minimum:

(i) an examination of the sources of available working capital that the proposed licensed home care services agency operators have, with a minimum requirement equal to at least two months of estimated operating expenses of the agency;

(ii) that the application passes a reasonableness test with respect to the financial capability of the agency or sources for start-up funding; and

(iii) an examination of the financial feasibility of the agency or projections indicating that the agency's operating revenues will be equal to or greater than projected expenditures over time.

(4) any other information that the commissioner shall deem pertinent for inclusion in the application.

(c) The following documents shall be filed as attachments to the application: (1) where the applicant will be operating the licensed home care service agency under an assumed name, a photocopy of the applicant's existing or executed proposed certificate of doing business;

(2) where the applicant is a partnership, full and true copies of all partnership agreements, which shall include the following language:

"By signing this agreement, each member of the partnership created by the terms of this agreement acknowledges that the partnership and each member thereof has a duty to report to the New York State Department of Health any proposed changes in the membership of the

partnership. The partners also acknowledge that the prior written approval of the Public Health and Health Planning Council is necessary for such change before such change is made, except that a change resulting from an emergency caused by the severe illness, incompetency or death of a member of the partnership shall require immediate notification to the New York State Department of Health of such fact, and application shall be made for the approval by the Public Health and Health Planning Council of such change within 30 days of the commencement of such emergency. The partners also acknowledge that they shall be individually and severally liable for failure to make the aforementioned reports and/or applications."

(3) where the applicant or licensed operator has or proposes to have a controlling person or a parent corporation, or is affiliated with a health-related subsidiary corporation, full and true copies of any such corporation's bylaws, certificate of incorporation and any existing or proposed amendments thereto, all agreements between the applicant and any such controlling person or parent corporation relating to the manner and mechanisms by which any such controlling person or parent corporation controls or will control the applicant and/or all agreements by which the applicant is affiliated with any health-related subsidiary corporation, and a detailed description of such control or affiliation relationship;

(4) where an applicant corporation is formed pursuant to the requirements of section 3611 of the Public Health Law, documentation demonstrating the designation of an agent for service of process pursuant to section 305 of the Business Corporation Law or section 305 of the Not-for-Profit Corporation Law, as applicable; and

(5) such additional pertinent information or documents necessary for the council's consideration, as requested.

Section 765-1.3 is amended to read as follows:

765-1.3 Requirements for approval. (a) The application must be complete and in proper form. It shall provide all the information essential for the Public Health and Health Planning Council's consideration.

(b) The applicant must satisfactorily demonstrate to the council:

(1) that there is a public need for the licensed home health care service agency pursuant to the methodology outlined in Section 765-1.16 of this Title;

(2) that there are adequate finances and sources of future revenue to properly establish and operate the licensed home care service agency pursuant to the minimum requirements outlined in Section 765-1.2 of this Title;

[(1)] (3)(i) if a not-for-profit corporation, that the controlling persons and sponsors, if any, the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(2)] (ii) if a proprietary business, that the owner, or all the partners of a partnership, are persons of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the business in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(3)] (iii) if a business corporation, that the controlling persons and sponsors, if any, the members of the board of directors, the officers and the principal stockholders of the corporation or, in the case of an application solely for a change in the principal stockholder(s), that the proposed new

principal stockholder(s) of the corporation, are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(4)] (iv) with respect to any parent corporation or health-related subsidiary corporation, that the directors, sponsors, controlling persons and principal stockholders of any such corporation, insofar as applicable, are of such character, competence and standing in the community as to give reasonable assurance that, to the extent they have or will have the ability, through control or influence, to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care service agency;

[(5)] (v) with respect to any application solely for the acquisition of control of an operator of a licensed home care service agency by a controlling person or a change of a controlling person, that such new controlling person, insofar as applicable, is of such character, competence and standing in the community as to give reasonable assurance that, to the extent it has or will have the ability to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care service agency; or

[(6)] (vi) if a public or government agency, that the governing authority of the governmental subdivision applying to operate the agency has provided reasonable assurance of its ability to

conduct the affairs of the agency in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency.

[(c)] (4) that the proposed operator has demonstrated satisfactory character and competence. In conducting a character and competence review, the Public Health and Health Planning Council shall, as applicable, evaluate any parent or health-related subsidiary corporation, the controlling persons, sponsors, members of the board of directors, the officers and principal stockholders, if any, of a corporate applicant, any sole proprietor, all partners in a partnership or, in the case of a governmental subdivision as the applicant, the governmental subdivision and the governing body thereof as a whole rather than the individual elected or appointed members thereof, by:

[(1)] (i) reviewing the findings of inspection reports, patient care reviews, complaint investigations and any other pertinent information relating to the operation of any health care, adult care or mental health facility, program or agency located in New York approved to operate by the Department of Health, [Department of Social Services] or the Department of Mental Hygiene or, if located outside New York, would require the approval to operate by any one of such agencies if located in New York, with which an individual, corporation, other organization or governmental subdivision has been affiliated as a director, sponsor, controlling person, principal stockholder, sole proprietor, partner or governmental operator;

[(2)] (ii) reviewing whether such individual, corporation, other organization or governmental subdivision exercised supervisory responsibility of the facility/agency operation to assure a consistent pattern of compliance with applicable standards and to prevent conditions which could result in harm to the health, safety or welfare of patients/residents; and

[(3)] (iii) determining that, if a violation of applicable standards did occur, the applicant investigated the circumstances surrounding the violation and took steps appropriate to the gravity

of the violation which a reasonably prudent operator would take to promptly correct and to prevent the reoccurrence of the violation. [; and]

[(4) considering such other pertinent matters relating to the character, competence and standing in the community of the applicant(s).]

(5) any other pertinent matters that the commissioner shall deem appropriate for inclusion in the application.

(d) The applicant must supply:

(1) any additional information requested by the department within 30 days of such request, or must obtain from the department an extension of the time in which to provide such information.

Any request for such extension of time shall set forth the reasons why such information could not be obtained within the prescribed time. The granting of such extension of time shall be at the discretion of the commissioner, provided such extensions are not for more than 30 days and the commissioner is satisfied as to the reasons why such information could not be obtained within the prescribed time. The commissioner is authorized to deny a request for an extension of time. Failure to provide such information within the time prescribed shall constitute an abandonment and withdrawal of the application by the applicant.

(2) any authorization the department requests in order to verify any information contained in the application or to obtain additional information which the department finds is pertinent to the application. Failure to provide such authorization shall constitute an abandonment and withdrawal of the application.

Section 765-1.4 is amended to read as follows:

765-1.4 Amendments to applications. (a) An application made to the Public Health and Health Planning Council pursuant to this Subpart may be amended while the matter is pending before the council. Such amendments shall be made on appropriate forms supplied by the department.

(b) Any amendment to an application which constitutes a substantial change in the information contained in the original application, or any prior amendments thereto, must be accompanied by a satisfactory written explanation as to the reason such information was not contained in the original application.

(c) Prior to the issuance of a license, any change as set forth in this subdivision shall constitute an amendment to the application and the applicant shall submit appropriate documentation as may be required in support of such amendment. The amended application shall be referred to the [health systems agency having geographic jurisdiction and the State Hospital Review and] Public Health and Health Planning Council for [their] its comments. The approval of the Public Health and Health Planning Council must be obtained for any amended application. Each of the following shall constitute an amendment:

(1) any change in the types of licensed services to be provided; [and/or]

(2) any significant change in the principals of the applicant as considered by the council[.];

(3) any significant change in the proposed patient capacity;

(4) any change in the agency's proposed service area; and/or

(5) any significant change to the agency's proposed annual operating budget.

(d) Failure to disclose an amendment prior to the issuance of a license shall constitute sufficient grounds for the revocation, limitation or annulment of the approval.

A new Section 765-1.16 is added to Subpart 765-1 of Part 765 of 10 NYCRR to read as follows:

765-1.16. Determinations of public need. (a) The process of determining need in this section will be used in the evaluation of certificate of need applications requiring a review of the public need by the Public Health and Health Planning Council.

(b) Planning areas. (1) The commissioner shall designate each county as a separate planning area.

(c) Determination of need.

(1) There shall be a presumption of no need for additional licensed home care service agencies in a planning area if there are 5 or more Licensed Home Care Service Agencies (LHCSA) actively serving patients within the planning area as of April 1, 2020. Beginning in 2021, the commissioner shall have the authority to adjust the target date for determining need for additional LHCSAs in a planning area, in subsequent years.

(2) Applications for licensure based on change of ownership for Licensed Home Care Service Agencies actively serving at least 25 patients will not be subject to public need review and shall be evaluated only on financial feasibility and the character and competence of the proposed operator unless the proposed operator seeks to serve patients outside of the approved planning area.

(3) The determination of need for licensed home care service agencies in accordance with this subdivision does not include Assisted Living Program (ALP) or Program of All-Inclusive Care for the Elderly (PACE) affiliated licensed home care services agencies. ALP or PACE -affiliated agencies are not subject to the public need review unless the agency seeks to serve patients outside the ALP program or who are not PACE members. For the purpose of this regulation affiliated shall mean common ownership.

(4) The department shall review the adequacy of the need methodology set forth under paragraph (1) of this subdivision and issue a report to the commissioner and the Public Health and Planning Council no later than 6 years from adoption.

(d) Notwithstanding any other provision of this section, factors to be considered when determining need for licensed home care service agencies shall include, but are not limited to:

(1) the demographics and/or health status of the residents in the planning area or the state, as applicable;

(2) documented evidence of the unduplicated number of patients on waiting lists who are appropriate for and desire admission to a licensed home care service agency but who experience a long waiting time for placement and who cannot be served adequately in other settings;

(3) the number and capacity of currently operating licensed home care services agencies;

(4) the quality of services provided by existing agencies;

(5) the availability and accessibility of the workforce;

(6) personnel and resources dedicated to adding and training additional members of the workforce including committed resources in an organized training program;

(7) cultural competency of existing agencies; and

(8) subpopulations requiring specialty services.

When making recommendations to the Public Health and Health Planning Council concerning the impact of the factors set forth above, the department shall, to the extent practicable, indicate the relative priority of such factors.

(e) In addition to meeting the other applicable provisions of this section, an applicant for initial certification shall be approved as meeting public need only if the applicant agrees to serve population groups in the planning area that have difficulty gaining access to appropriate licensed

home care service agency care due to minority status, age, medical history, case complexity, or payment source.

(f) Any application wherein a determination of public need is made pursuant to this section shall be subject to the following: (1) The Public Health and Health Planning Council and/or the commissioner, as appropriate, may, during the processing of an application, propose to disapprove the application solely on the basis of a determination of public need in advance of the consideration of the other review criteria required by article 36 of the Public Health Law without, however, waiving the right to consider such other criteria at a later date.

(2) In the event the Public Health and Health Planning Council and/or the commissioner proposes to disapprove an application on the basis of a lack of public need and the applicant requests a hearing according to the provisions provided in Section 765-1.9 of this Title, the Public Health and Health Planning Council and/or the commissioner, as appropriate, may direct the completion of the other reviews required by Article 36 of the Public Health Law. The application shall then be returned to the Public Health and Health Planning Council and/or the commissioner as appropriate, to consider such reviews, the results of which may then be included as grounds for the proposed disapproval to be considered at the hearing. If the Public Health and Health Planning Council and/or the commissioner, as appropriate, directs the completion of such reviews, a copy of the report containing the results of the reviews shall be mailed to the applicant at least 60 days prior to the date set for hearing.

(3) In the processing of an establishment application, the commissioner may recommend disapproval based on a review limited to a determination of public need. In the event the Public Health and Health Planning Council does not concur with the commissioner's recommendation of disapproval, it shall return the application to the department at which time all other required

reviews shall be completed. When all other reviews are completed, the application shall be returned to the Public Health and Health Planning Council for action.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 3612 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations to effectuate the provisions and purposes of PHL Article 36 with respect to licensed home care service agencies (LHCSAs). Additionally, Section 9-b, Part B of Chapter 57 of the Laws of 2018 (codified at Public Health Law § 3605[4]) requires PHHPC to consider the public need for new LHCSAs as well as the financial resources and revenues of the proposed LHCSA when PHHPC reviews initial licensure and change of ownership applications.

Legislative Objectives:

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

Needs and Benefits:

The proposed regulation is necessary to implement statutory changes required under Section 9-b, Part B of Chapter 57 of the Laws of 2018. The proposal will revise Part 765 of Title 10 NYCRR to include the relevant statutory requirements related to the new public need determination for licensed home care services agencies, the review of the proposed agency's financial feasibility, and the process for reviewing applications for licensure.

Part 765 of Title 10 of the NYCRR regulates the approval and licensure of home care services agencies. Sections 765-1.2 and 765-1.3 outline what is required to be included in applications for licensure as a home care services agency and the information that an applicant for licensure must supply to PHHPC for approval. Section 765-1.4 includes what types of changes to a pending application for licensure constitute an amendment and what an applicant must submit to PHHPC for the amendment to be considered.

These current regulations were developed to govern the approval of licensure applications for home care services agencies when PHHPC was only required to conduct a character and competence review of applicants and was prohibited from considering the public need for these agencies under Public Health Law. To comply with changes made to the Public Health Law under Section 9-b, Part B of Chapter 57 of the Laws of 2018, the regulations must be updated to include the new requirement of public need review and financial feasibility review.

With the existing regulatory prohibition on public need consideration for new agencies, the Department of Health (Department) and PHHPC have been unable to limit the growth of unnecessary agencies. Currently, there are approximately 1,100 approved licensed home care operators with over 1,300 licensed, registered sites statewide. An average of 40 new LHCSA sites have been approved on an annual basis over the past ten years. There is no consideration of the need for additional services based on the public demand. Applications for licensure are submitted to the Department and are subject to approval by PHHPC. As part of the application process, applications are reviewed to ensure the character, competence, and standing in the community of the applicant's incorporators, directors, sponsors, stockholders, or operators.

Applications must be submitted for initial licensure, purchase or mergers, change of stock ownership, or other acquisition or control change.

Given the new statutory mandate, new regulations are required to define the public need methodology and the process that will be used to apply the methodology to new licensure applications. The public need methodology will also assist the Department in planning for the appropriate number of licensed agencies and may also inform policy and practice around the types of services needed, underserved populations that require additional focus, and other factors that contribute to the long term care landscape, such as workforce issues or transportation infrastructure.

Costs:

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

The rule does not impose any new implementation or compliance costs on regulated parties.

Costs to the State and Local Governments:

The proposed changes are not expected to impose any costs upon New York State or local governments.

Costs to the Department of Health:

Additional work by Department staff to determine public need and to process applications with the new requirements will be managed with existing resources.

Local Government Mandates:

The proposed regulations do not impose any new mandates on local governments.

Paperwork:

Consistent with the statutory provisions, the proposed regulations will require a new application form to be completed by home care services agencies seeking initial licensure or change of ownership on or after April 1, 2020. New documentation will be required as part of the application process that was not included in the application for licensure prior to April 1, 2020.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There are no viable alternatives to this proposal. The regulatory changes are necessary to implement a statutory mandate, which directs PHHPC to include public need and financial feasibility in the review process for initial applications for licensure of home care services agencies.

One alternative considered including the development of a county normative use rate using the number of cases and visits/hours for LHCSA services for each agency in a planning area as reported on the LHCSA Statistical Report. This alternative may account for variation in the amount of services used per patient, however, and it is a more complex methodology that may

lead to greater error in ongoing need methodology calculations. As such, this option was rejected as unviable.

A second alternative considered establishing estimates of need based on demographics. Under this proposal, the Department would undertake a review of the total number of residents in each planning area with a reported disability resulting in a limitation in completing activities of daily living. The information could be broken down by age group and projected to accommodate the expected growth in the older adult population. This method to determine use rates may better reflect the number of residents in need of care, rather than using the patient count. However, reporting on disease and disability status and limitations in functional abilities has proven difficult, as various definitions of disability exist with multiple reporting methods. Therefore, this alternative was also rejected.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The amendments will take effect on April 1, 2020.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

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



**Project # 162148-C
Nyack Hospital**

**Program: Hospital
Purpose: Construction**

**County: Rockland
Acknowledged: September 8, 2016**

Executive Summary

Description

Montefiore Nyack Hospital (Nyack), a 391-bed, voluntary not-for-profit, Article 28 acute care hospital located at 160 North Midland Avenue, Nyack (Rockland County), requests approval to certify Cardiac Catheterization – Percutaneous Coronary Intervention (PCI) and Cardiac Catheterization – Electrophysiology (EP) services, with requisite renovations. The applicant will renovate 5,484 square feet in the existing radiology department and adjacent shell space to create a Cardiac Catheterization Suite. The project will include one dedicated adult PCI-capable Cardiac Catheterization lab, one multipurpose interventional radiology suite, bays for preparation, recovery and continuity of care, and other support areas.

Nyack will undertake the project with Montefiore Health System, Inc. (MHS), its active parent and co-operator, and with the direct clinical and quality oversight of Montefiore Medical Center (MMC), a New York State cardiac surgery center located at 111 East 210 Street, Bronx (Bronx County). MHS became Nyack’s passive parent and sole member in 2014 and its active parent and co-operator in 2018.

The applicant states that they currently transfer over 100 patients annually for emergency PCIs who present to their Emergency Department (ED) and/or are admitted with acute myocardial infarction or chest pain. Establishing these cardiac catheterization services at Nyack will alleviate the need to transfer patients whose outcome is time-sensitive. The goals of this project include the following: improve patient access to diagnostic cardiac catheterization and PCI procedures for the residents of Rockland

County; improve cardiac health outcomes for the residents of the local service area; provide oversight of procedures performed in the new laboratory; improve continuity of care within one health system and region to achieve better outcomes; facilitate transformation of the healthcare delivery system allowing Nyack and MHS to achieve value-based goals; and support Nyack’s Delivery System Reform Incentive Payment (DSRIP) goals in association with the Montefiore Hudson Valley Collaborative (MHVC) Performing Provider System.

**OPCHSM Recommendation
Contingent Approval**

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018, Rockland County residents received 125 treatments outside of the Hudson Valley region. Nyack Hospital projects 100 emergency PCI procedures in Year One and beyond.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility’s current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

Total project costs of \$6,408,657 will be funded via \$674,205 in equity from the Montefiore Nyack Hospital Foundation and a \$5,734,452 capital lease for a five or seven-year term (option) at 2.73% interest (as of October 11, 2019). Bank of American Leasing & Capital, LLC has provided a letter of interest for the capital lease. Montefiore Nyack Hospital Foundation has provided a commitment letter to provide the project's equity.

<u>Incremental</u>	<u>First Year</u>	<u>Third Year</u>
Revenues	\$7,805,568	\$9,726,646
Expenses	<u>\$6,008,985</u>	<u>\$7,024,564</u>
Gain/(Loss)	\$1,796,583	\$2,702,082

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 Cardiac Catheterization Services Agreement, acceptable to the Department of Health. (BFA)
3. Submission of an executed capital lease agreement, acceptable to the Department of Health. (BFA)
4. Submission of a fully executed clinical sponsorship agreement, acceptable to the Department. [HSP]
5. Submission of a pre-procedure risk stratification policy to ensure that high risk and/or complex patients are treated at a Cardiac Surgery Center, acceptable to the Department. [HSP]
6. Submission of documentation that a data manager has been hired, acceptable to the Department. [HSP]
7. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-03. [AER]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Policies and Procedures adopted from the Cardiac Surgical Affiliate need to be incorporated as applicant's policies and procedures. [HSP]
3. Construction must start on or before February 1, 2020 and construction must be completed by October 30, 2020, 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 start date this shall constitute abandonment of the approval. [PMU]
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]

Council Action Date

December 12, 2019

Need Analysis

Background

New York Title 10, Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in year one of service. Emergency PCI includes any procedure not scheduled and not elective. In the Hudson Valley Health Services Area, seven facilities currently provide PCI services. In 2018, 1,221 Hudson Valley Residents were treated outside of the HSA for currently-defined emergency PCI procedures. The six Hudson Valley applicants on the Public Health and Health Planning Council-PHHPC December Agenda that seek certification of Cardiac Catheterization-Percutaneous Coronary Intervention services all project, at minimum, 36 emergency PCI procedures in year-one.

In 2018, Rockland County residents received 125 treatments outside of the Hudson Valley region. Nyack Hospital projects 100 emergency PCI procedures in year one and beyond. Accompanying patient selection criteria for Electrophysiology procedures has been submitted.

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

Table 1: 2018 Emergency (709.14: 09/25/19) PCI's Performed on Hudson Valley Residents: By: County, By Operational Hudson Valley Facilities, By: Location of Treatment.											
Patient County of Residence	Operational Facilities in the Hudson Valley Region							Resident Outmigration			
	Good Samaritan Suff. (Rockland)	Orange Regional (Orange)	St Luke's Cornwall Newburgh (Orange)	Vassar Brothers (Dutchess)	New York Presbyterian Lawrence (Westchester)	Westchester Med (Westchester)	White Plains (Westchester)	Total	County Residents Treated: All Locations	County Residents Receiving Emergency PCI Treatment in Hudson Valley	County Residents Leaving Hudson Valley for Emergency PCI Treatment
Delaware				4			0	4	131	4	127
Dutchess		3	21	461	4	37	1	527	575	527	48
Orange	90	358	190	24	3	9	0	674	777	674	103
Putnam			2	30	10	55	7	104	137	104	33
Rockland	268	2	2	1	1	11	2	287	412	287	125
Sullivan		141		5		4	0	150	163	150	13
Ulster	3	19	26	263		9	0	320	359	320	39
Westchester		2		6	173	253	331	765	1,498	765	733
Total H. V. Residents receiving Emergency PCIs in Region	361	525	241	794	191	378	341	2,831	4,052	2,831	1,221

Table 2: Applicant Facilities Projected Emergency PCI's

Project	Facility	County	Projected Emergency PCIs	
			Year One	Year Three
152243	Northern Westchester Hospital	Westchester	115	115
162211	New York-Presbyterian Hudson Valley Hospital	Westchester	50	64
162148	Nyack Hospital	Rockland	100	100
171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region. Nyack Hospital projects 100 Emergency PCI procedures by Year One of opening. By providing PCI-capable Cardiac Cath and EP services, Nyack Hospital proposes to achieve the following goals:

- Improve patient access to high-quality, coordinated diagnostic cardiac catheterization and PCI procedures for residents.
- Improve cardiac health outcomes for the residents of the local service area who currently experience health disparities and poor cardiac health outcomes.
- Provide high quality oversight of procedures performed in the new laboratory as a result of a clinical service agreement with Montefiore Medical Center (MMC).
- Improve continuity of care within one health system and region to achieve better outcomes, by decreasing outmigration of interventional cardiology cases from the local service area to facilities in Orange, Westchester, Bronx and Manhattan counties in New York and Bergen County in New Jersey.
- Facilitate the Transformation and DSRIP goals of Nyack and MHS to achieve value-based goals in the Hudson Valley region.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Program Description

The proposed program will operate with clinical oversight from Montefiore Medical Center-Henry & Lucy Moses Division (MMC-Moses) in accordance with the terms of an executed clinical sponsorship agreement. MMC-Moses, an 816-bed hospital located at 111 East 210th Street, Bronx (Kings County), is a full-service cardiac surgery provider.

Nyack plans to renovate existing space on the first floor. Staffing is expected to increase by 14.7 FTEs in the first year after completion and remain at this level by the third year of operation.

The project will result in Nyack's operating certificate changing to add the following certified services:

- Cardiac Catheterization - Percutaneous Coronary Intervention (PCI)
- Cardiac Catheterization - Electrophysiology (EP)

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and Cardiac Electrophysiology (EP) and they have assured the Department that their program will meet all of the requirements of 405.29(e)(1-3) and 405.29(e)(5).

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

The hospital did not specify how the documented barriers these residents face (e.g., economic, cultural or linguistic) would be addressed. Almost 40% of all visits are from Medicaid, uninsured or dual-eligible patients. Population-based statistics are included.

Nyack Hospital served on a Steering Committee to develop the 2016-2018 CHIP. While the identified needs pertained to all five Prevention Agenda priority areas, the county selected Preventing Chronic Diseases and Promoting Healthy Women, Infants and Children to focus on. Because of the observed risk factor and mortality patterns in Rockland County, Nyack believes that a Cardiac Cath Lab would aid in diagnosing patients with the associated risk factors and conditions, and then recommending a personalized treatment plan. The need for a Cardiac Rehabilitation Center is also addressed.

Nyack Hospital collaborated with 19 organization to develop the county's Prevention Agenda plan. The proposed project will advance the county's goal to prevent chronic diseases by implementing Diabetes Prevention Programs (DPP) in Ramapo and the hospital is being considered by CDC to be a recognized DPP provider. The same list of activities to address diabetes was included in response to information about advancing Prevention Agenda priorities (7b) and supporting local Prevention Agenda goals (8). A description of the Bariatric Center was included as the vehicle to support a Prevention Agenda goal (which was not specified). Finally, information was included from the Dashboard about obesity and diabetes to support the proposed objectives and interventions.

The majority of interventions described in the application involve health education services to raise awareness and improve treatment outcomes, particularly for diabetes and obesity. In 2017 the applicant spent \$259,765 on community health improvement services, representing less than one percent of total operating expenses.

Conclusion

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

Cardiac Catheterization Clinical Sponsorship Agreement

The applicant has submitted a draft Cardiac Catheterization Clinical Sponsorship Agreement regarding the operation and oversight of an adult cardiac catheterization suite on-site at Nyack. The terms are summarized below:

Client:	Montefiore Nyack Hospital f/k/a The Nyack Hospital
Provider:	Montefiore Medical Center (MMC)
Services:	<p>MMC will serve as clinical sponsor of the Cath Lab at Nyack and assign a NY licensed/registered physician to serve as Cath Lab Program Director. MMC representative(s) shall participate in and be deemed members of Nyack's quality assurance committee and shall provide reviews of the quality of cardiac care and recommendations for quality improvement of cardiac services. MMC's representative(s) will review data for quality improvement purposes, Nyack's policies and procedures, care provided by health care practitioners, the appropriateness /timeliness of patient referrals and patients retained at Nyack who met criteria for transfer to MMC or another cardiac surgery center, and examine adverse events or occurrences including death and major complications. Host a joint cardiology/cardiac surgery conference at least quarterly to review all cardiac laboratory related morbidity and mortality, review uncomplicated routine cases, patient selection criteria, rates of normal out comes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, the quality of the studies conducted, rates of patients referred for and receiving intervention procedures subsequent to the diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failure. A telemedicine link between Nyack and MMC will be developed for off-site review of digital studies and timely treatment consultation by physicians. MMC will participate in developing privileging criteria for physicians, provide consultation on equipment, staffing, ancillary services and policies and procedures, develop and implement a pre-procedure risk stratification tool which ensures high risk and or complex cases are treated at MMC. In conjunction with Nyack, develop and implement procedures to provide for appropriate patient transfer. Assume responsibility on behalf Nyack for the cardiac reporting system provided all data is delineated at facility level.</p> <p>Joint Activities of MMC and Nyack – Notify NYS Department of Health (DOH) of any proposed changes to this agreement. Jointly sponsor and conduct annual studies of the impact that Cath Lab has on costs and access to cardiac service in Nyack's service area. Develop a plan for how the proficiency of physicians, nurses and other staff at Nyack will maintained through rotational or other training opportunities at MMC. Develop a plan for how the Cath Lab will maintain the capacity to provide PCI services on a 24 hour a day, 365 days a year basis and be capable of assembling a team within 30 minutes of the activation call to provide coronary intervention.</p>
Term	Automatically one-year renewals. Termination upon mutual written agreement of the parties, upon at least ninety (90) days 'written notice. The termination or expiration of the agreement shall result in the closure of the Cardiac Catheterization Laboratory.
Fee	\$250,000 per year

Total Project Cost and Financing

Total project costs for renovation and moveable equipment are estimated at \$6,408,657, as follows:

Renovation & Demolition	\$2,869,429
Design Contingency	\$286,943
Construction Contingency	\$286,943
Architect/Engineering Fees	\$196,479
Construction Manager Fees	\$157,819
Other Fees	\$35,000
Movable Equipment	\$2,539,000
Application Fee	\$2,000
Additional Fee for Projects	<u>\$35,044</u>
Total Project Cost with Fees	\$6,408,657

Project costs are based on a nine-month construction starting February 2020.

The applicant's financing plan is as follows:

Equity - Montefiore Nyack Hospital Foundation	\$674,205
Capital Lease (option of 60 or 84 months, 2.73% as 10/11/19)	<u>5,734,452</u>
Total	\$6,408,657

The applicant has provided a letter of interest from Banc of America Leasing & Capital, LLC for a capital lease at the above stated terms. Montefiore Nyack Hospital Foundation has provided a commitment letter to fund the \$674,205 in project's equity. BFA Attachment C is Montefiore Nyack Hospital and Subsidiaries' 2018 financial statement (broken out by subsidiary), which shows the Foundation has sufficient resources to provide the equity.

Operating Budget

The applicant has submitted an incremental operating budget, in 2019 dollars, for Years One and Three:

	First Year		Third Year	
	Per Disch.	Total	Per Disch.	Total
Revenues-Inpatient:				
Medicaid FFS	\$18,435	\$331,829	\$18,980	\$379,597
Medicaid MC	\$17,918	447,956	\$18,330	513,242
Medicare FFS	\$19,634	3,259,312	\$20,212	3,779,564
Medicare MC	\$18,715	655,012	\$19,035	761,389
Commercial FFS	\$22,982	689,460	\$24,528	833,957
Commercial MC	\$22,536	653,550	\$24,704	790,522
Private Pay	\$4,351	21,754	\$4,945	29,671
All Other	\$17,407	69,628	\$17,759	106,554
Bad Debt		<u>-264,541</u>		<u>-298,167</u>
Subtotal Inpatient		\$5,863,960		\$6,896,329
Revenues-Outpatient:				
Medicaid FFS	Per Visit \$5,685	First Year \$85,280	Per Visit \$5,411	Third Year \$129,853
Medicaid MC	\$5,373	118,195	\$5,293	179,972
Medicare FFS	\$7,618	1,097,009	\$7,378	1,652,717
Medicare MC	\$7,249	224,722	\$7,058	338,807
Commercial FFS	\$8,543	222,110	\$8,136	333,573
Commercial MC	\$8,422	210,541	\$8,321	316,199
Private Pay	\$5,227	20,906	\$2,814	19,698
All Other	\$5,985	23,938	\$5,207	36,450
Bad Debt		<u>-61,093</u>		<u>-176,952</u>
Subtotal Outpatient		\$1,941,608		\$2,830,317
Total Revenue		\$7,805,568		\$9,726,646
Expense-Inpatient				
Operating	\$11,260	\$3,512,986	\$10,492	\$3,703,647
Capital	<u>\$1,108</u>	<u>345,908</u>	<u>\$839</u>	<u>296,175</u>

Subtotal Expenses	\$12,368	\$3,858,894	\$11,331	\$3,999,822
Expense-Outpatient				
Operating	\$7,002	\$1,897,563	\$6,580	\$2,783,311
Capital	<u>\$932</u>	<u>252,528</u>	<u>\$571</u>	<u>241,431</u>
Subtotal Expenses	\$7,934	\$2,150,091	\$7,151	\$3,024,742
Total Expenses		\$6,008,985		\$7,024,564
Net Income		\$1,796,583		\$2,702,082
Inpatient discharges		312		353
Outpatient visits		<u>271</u>		<u>423</u>
Total		583		776
Avg Cost/Procedure		\$10,307		\$9,052

The following is noted with respect to the operating budget:

- Revenues reflect the applicable diagnosis-related groups (DRG), outpatient rates for various interventional cardiology procedures and current contract rates.
- The projected expenses are based on staffing guidelines and input provided by MMC using Nyack's pay rates. The budget reflects the additional clinical services agreement expenses.
- Utilization is based on analysis of Rockland County outmigration and transfers from Nyack's ED to the closest PCI facility. The applicant notes that these estimations assume that Nyack would capture 20% of the outmigration of both diagnostic catheterization and PCI. In terms of EP cases, it is anticipated that Nyack will retain 20 cases they currently handle and will add cases that currently leave the state, for a total of 88 EP cases in year one and 165 cases in year three. These cases include the following: EP Studies, ICD implants, Biventricular pacemakers, and Cardiac resynchronization therapy devices (CRT-D).
- Utilization by payor source is as follows:

Inpatient Payor	<u>Year One</u>		<u>Year Three</u>	
	<u>Disch.</u>	<u>%</u>	<u>Disch.</u>	<u>%</u>
Medicaid FFS	18	5.77%	20	5.67%
Medicaid MC	25	8.01%	28	7.93%
Medicare FFS	166	53.22%	187	52.97%
Medicare MC	35	11.22%	40	11.33%
Commercial FFS	30	9.62%	34	9.63%
Commercial MC	29	9.28%	32	9.07%
Private Pay	5	1.60%	6	1.70%
All Other	4	<u>1.28%</u>	6	<u>1.70%</u>
Total	312	100%	353	100%

Outpatient Payor	<u>Year One</u>		<u>Year Three</u>	
	<u>Visits</u>	<u>%</u>	<u>Visits</u>	<u>%</u>
Medicaid FFS	15	5.54%	24	5.67%
Medicaid MC	22	8.12%	34	8.04%
Medicare FFS	144	53.14%	224	52.96%
Medicare MC	31	11.44%	48	11.35%
Commercial FFS	26	9.57%	41	9.69%
Commercial MC	25	9.23%	38	8.99%
Private Pay	4	1.48%	7	1.65%
All Other	4	<u>1.48%</u>	7	<u>1.65%</u>
Total	271	100%	423	100%

Capability and Feasibility

Total project costs of \$6,408,657 will be funded via \$674,205 in equity from Montefiore Nyack Hospital Foundation and a \$5,734,452 capital lease for a five or seven-year term at 2.73% interest (as of October 11, 2019). Banc of America Leasing & Capital, LLC has provided a letter of interest for the capital lease. Montefiore Nyack Hospital Foundation has provided a letter committing to fund the project's equity.

Total working capital is estimated at \$1,170,761 based on two months of third year expenses. Funding comes from the program's positive margin, ongoing operations, and existing cash resources.

The submitted budget demonstrates net income of \$1,796,583 and \$2,702,082 in Year One and Year Three, respectively. Revenues reflect the applicable diagnosis-related groups (DRG), outpatient rates for various interventional cardiology procedures and current contract rates. The budget appears reasonable.

BFA Attachment A and B are Montefiore Nyack Hospital 2017 and 2018 certified financial statements and internal financial statements as of September 30, 2019, which shows negative working capital, positive net assets, and a net loss. Management is pursuing a financial stabilization plan aimed at increasing revenue, reducing costs and evaluating opportunities for efficiencies. This includes working closely with MHS to maximize the clinical and financial opportunities. The stabilization plan includes pursuing replacement financing arrangements with a creditor, additional financial support from State and Federal sources, such as funding under the DSRIP, Value Based Payment-Quality Improvement Program (VBP-QIP) and Capital Restructuring Financing Program (CRFP). For the year ended December 31, 2018, approximately \$907,000 and \$17,719,419 was recognized related to DSRIP and VBP-QIP, respectively. Additionally, \$4,936,748 was recognized under CRFP. It is expected that successful culmination of certain of the above-mentioned initiatives will result in improved liquidity and operating results in the near term.

Conclusion

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

Attachments

RNR Attachment A	Map
BFA Attachment A	Financial Statement certified, Montefiore Nyack Hospital 2017 and 2018
BFA Attachment B	Financial Statement internal, Montefiore Nyack Hospital, Sept. 30, 2019
BFA Attachment C	Financial Statement subsidiaries, Montefiore Nyack Hospital Foundation 2018



**Project # 172251-C
Putnam Hospital Center**

Program: Hospital
Purpose: Construction

County: Putnam
Acknowledged: October 23, 2017

Executive Summary

Description

Putnam Hospital Center (PHC), a 164-bed, Article 28 acute care hospital located at 670 Stoneleigh Avenue, Carmel (Putnam County), requests approval to certify Cardiac Catheterization - Percutaneous Coronary Intervention (PCI) services, with requisite construction. The catheterization laboratory will be operated as part of an integrated delivery model between PHC and Vassar Brothers Medical Center (VBMC), a 365-bed, Article 28 acute care hospital located at 45 Reade Place in Poughkeepsie. Both hospitals are part of Nuvance Health, an integrated healthcare delivery system formally known as HQ-WCHN Health Systems, Inc. Effective June 18, 2019, Nuvance became the sole member and active parent of Health Quest Systems, Inc. (Health Quest). In addition to PHC, Health Quest's New York licensed entities include Vassar Brothers Hospital and Northern Dutchess Hospital.

By integrating the resources of VBMC's cardiac capabilities into PHC's catheterization laboratory and coordinating the care from an integrated system perspective, PHC will be able to expand VBMC's cardiac program across the Nuvance/Health Quest System, enhancing clinical quality and outcomes by adopting common protocols, quality measures, and safety standards. Per the applicant, the system wide approach to cardiac care will offer the following benefits to patients in the region:

- Oversight & Management – PHC's cardiac catheterization laboratory will be staffed and overseen by physicians, directors, and administrators at Nuvance Health's employed cardiology group (The Heart Center). The cardiology group operates in

an integrated manner across all sites of care, and its physicians collaborate to deliver patient care through interdisciplinary committees and a centralized physician-led governance.

- Consistent Staffing Closer to Home - Patients in PHC's planning region are already being treated by cardiologists employed at The Heart Center. Bringing these physicians into PHC to perform cardiac catheterizations will promote continuity of care for both patient and cardiologist, enabling consistent and trusted care closer to home.
- Standardized EMS Protocols - EMS providers in the region are already familiar with VBMC's cardiac triage and cardiac catheterization protocols. Extending these same protocols into the PHC planning region will be seamless and ensure consistent EMS-to-hospital transfers and enhance integration in the event of a hospital-to-hospital transfer.
- Seamless & Safe Intra-System Transfers - PHC is only 37 miles from VBMC and the entire distance is covered by major thoroughfares (I-84 and Route 9), so any patient who needs advanced cardiac surgical care could be transferred from PHC's catheterization laboratory to VBMC's operating room in less than forty (40) minutes by ambulance. The hospitals are also on the same electronic medical record platform and other clinical systems (including PACS).

- Improved Quality & Safety - By leveraging the expertise of the VBMC staff and experience in operating the heart center, PHC can bring proven expertise and established protocols and measurement tools to monitor and improve care.
- Lower Costs & Faster Ramp-Up - By leveraging existing expertise, protocols, and staff, PHC can establish its catheterization laboratory faster and more efficiently than another hospital that is building a new catheterization program.

OPCHSM Recommendation
Contingent Approval

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.

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018 Putnam County residents received 33 treatments outside of the Hudson Valley region. Putnam Hospital projects 36 emergency PCI procedures in Year One and beyond.

Financial Summary

Project costs of \$3,192,063 will be met with accumulated funds.

<u>Incremental</u>	<u>First Year</u>	<u>Third Year</u>
Revenues	\$2,915,365	\$6,415,111
Expenses	<u>\$2,647,458</u>	<u>\$3,687,130</u>
Gain	\$267,907	\$2,727,981

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 State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-02. [AER]
3. Submission of (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before April 1, 2020 and construction must be completed by November 30, 2020, 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 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.

Council Action Date

December 12, 2019

Need Analysis

Background

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In 2018 Putnam County residents received 33 treatments outside of the Hudson Valley region. Putnam Hospital projects 36 emergency PCI procedures in Year One and beyond.

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

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171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region.

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments as classified under New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region. Putnam Hospital projects 36 Emergency PCI procedures by Year One of operation.

By providing PCI-capable Cardiac Catheterization services, Putnam Hospital proposes to achieve the following goals:

- Improve regional access to advanced cardiac services including diagnostic cardiac catheterization and PCI services for the communities served by Putnam Hospital;
- Enhance clinical quality by adopting common protocols with Vassar Brothers Hospital.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Project Proposal

The proposed program will operate with clinical oversight from Vassar Brothers Medical Center (VBMC) in accordance with the terms of an executed clinical sponsorship agreement. VBMC and PHC are members of Nuvance Health, an integrated delivery system. Vassar Brothers Medical Center is a 365-bed hospital located at 45 Reade Place in Poughkeepsie (Dutchess County) which is a full-service cardiac surgery provider.

Upon completion of the project Putnam Hospital Center will have the following service added to their operating certificate:

- Cardiac Catheterization - Percutaneous Coronary Intervention (PCI)

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and they have assured the Department that their program will meet all of the requirements of 405.29.

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

The applicant identified the Prevention Agenda priorities selected for action in the most recent Community Service Plan submitted on behalf of the member hospitals. They are in alignment with the jointly developed Community Health Improvement Plan. These priorities include:

- Reducing obesity in children and adults, and preventing chronic disease prevention, through education and workshops
- Promoting mental health and preventing substance abuse, by participating in Drug Take-Back Days and suicide prevention strategies such as Safe Talk, Assist and Postvention Program.
- Promote Healthy and Safe Environment, specifically focusing on preventing falls in older adults through Tai Chi classes.

The applicant specified the evidence-based interventions selected to address these priorities. The hospital has engaged with diverse local organizational partners in Prevention Agenda efforts to plan and/or implement appropriate interventions and will continue to do in the merged structure. The Prevention Agenda Dashboard is being used to measure progress toward the appropriate Prevention Agenda objectives

In the most recent Schedule H for 2016, Putnam Hospital reported Community Benefit Spending in the Community Health Improvement Services and Community Benefit operations category. In 2016, St Putnam Hospital spent \$275,063 on community health improvement services, representing 0.169% of total operating expenses.

Conclusion

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

Total Project Cost and Financing

Total project cost for renovations and the acquisition of moveable equipment is estimated at \$3,192,063, broken down as follows:

Renovation & Demolition	\$ 924,415
Asbestos Abatement or Removal	77,250
Design Contingency	92,441
Construction Contingency	92,441
Fixed Equipment	66,950
Architect/Engineering Fees	73,954
Other Fees (Consultant)	154,409
Movable Equipment	1,665,004
Telecommunications	25,750
CON Application Fees	2,000
Additional Processing Fee	<u>17,449</u>
Total Project Cost	<u>\$3,192,063</u>

Project costs are based on an eight-month construction starting April 2020. The applicant will finance the project via accumulated funds. BFA Attachment C shows sufficient accumulated funds for this project.

Incremental Operating Budget

The applicant has submitted an incremental operating budget, in 2019 dollars, for the first and third years:

	<u>Year One</u>		<u>Year Three</u>	
<u>Inpatient Revenues</u>	<u>Per Discharge</u>	<u>Total</u>	<u>Per Discharge</u>	<u>Total</u>
Commercial MC	\$24,855	\$372,825	\$24,855	\$1,093,620
Medicare FFS	\$18,140	390,080	\$18,140	1,251,660
Medicare MC	\$18,140	72,560	\$18,140	235,820
Medicaid FFS	\$15,406	30,812	\$15,406	77,030
Medicaid MC	\$15,406	61,624	\$15,406	231,090
Private Pay/Other	\$3,126	6,252	\$3,126	18,756
Less: Bad Debt		<u>(15,991)</u>		<u>(58,153)</u>
Total Inpt Revenue		\$927,162		\$2,849,823
<u>Outpatient Revenues</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Commercial MC	\$12,340	\$1,394,420	\$12,340	\$2,505,020
Medicare FFS	\$5,584	374,128	\$5,584	675,664
Medicare MC	\$5,584	83,760	\$5,584	150,768
Medicaid FFS	\$3,018	21,126	\$3,018	39,234
Medicaid MC	\$3,018	111,666	\$3,018	199,188
Private Pay/Other	\$1,569	37,656	\$1,569	67,467
Less: Bad Debt		<u>(34,553)</u>		<u>(72,053)</u>
Total Outpt Revenue		\$1,988,203		\$3,565,288
Total Revenues		\$2,915,365		\$6,415,111
<u>Inpatient Expenses</u>	<u>Per Discharge</u>	<u>Total</u>	<u>Per Discharge</u>	<u>Total</u>
Operating	\$15,364.61	\$752,866	\$7,511.77	\$1,141,789
Capital	<u>\$2,052.24</u>	<u>100,560</u>	<u>\$661.58</u>	<u>100,560</u>
Total Inpt Expenses	\$17,416.86	\$853,426	\$8,173.35	\$1,242,349
<u>Outpatient Expenses</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Operating	\$6,247.88	\$1,643,192	\$4,849.77	\$2,293,941
Capital	\$573.54	<u>150,840</u>	\$318.90	<u>150,840</u>
Total Outpt Expenses	\$6,821.41	\$1,794,032	\$5,168.67	\$2,444,781
Total Expenses		\$2,647,458		\$3,687,130
Excess Rev. over Exp.		<u>\$267,907</u>		<u>\$2,727,981</u>
<u>Utilization (procedures)</u>				
Inpatient		49		152
Outpatient		263		473
Total		312		625
Avg Cost Per Procedure		\$8,485.44		\$5,899.41

The following was noted with respect to the first- and third-year incremental budgets:

- The rates by payor were based on historical analysis, third party market data and certain ICD 9 billing codes utilized for billing Cardiac Catheterization patients. Revenue was then calculated based on a blended CMI applied to the observed payor mix of patients within the relevant diagnosis and inpatient/outpatient classifications.

- Utilization by payor source for inpatient and outpatient services for years one and three, is as follows:

<u>Inpatient</u>	<u>Year One</u>	<u>Year Three</u>
Commercial MC	30.6%	28.9%
Medicare FFS	44.9%	45.4%
Medicare MC	8.2%	8.6%
Medicaid FFS	4.1%	3.3%
Medicaid MC	8.2%	9.9%
Self-Pay/Other	4.0%	3.9%

<u>Outpatient</u>	<u>Year One</u>	<u>Year Three</u>
Commercial MC	43.0%	42.9%
Medicare FFS	25.5%	25.6%
Medicare MC	5.7%	5.7%
Medicaid FFS	2.7%	2.7%
Medicaid MC	14.1%	14.0%
Self-Pay/Other	9.0%	9.1%

- Utilization and expense projections are based on the experience of hospitals provided cardiac catheterization services and the expected market share of cardiac catheterization services within the PHC service area.

Capability and Feasibility

The project cost of \$3,192,063 will be met through hospital resources. BFA Attachment C is a financial summary for PHC, which indicates the availability of sufficient funds.

The submitted budget indicates an excess of revenues over expenses of \$267,907 and \$2,727,981 during the first and third years of operation, respectively. Revenues reflect current reimbursement methodologies for Cardiac Cath services. The budget appears reasonable.

BFA Attachment A is the 2017 and 2018 certified financial statements of Health Quest Systems, Inc. and Subsidiaries, which show the entity maintained positive working capital and net asset positions and generated net operating income of \$68,261,000 and \$79,554,000 in 2017 and 2018, respectively.

PHC is part of the Health Quest Systems, Inc. Obligated Group. BFA Attachment B is the Obligated Group's 2018 Balance Sheet and Statement of Operations, which shows that PHC maintained positive working capital and net asset positions and had net operating income of \$3,484,000.

BFA Attachment C is PHC's internal financial statements as of June 30, 2019, which indicates PHC maintained positive working capital and net asset positions and had excess revenue over expenses of \$1,436,579.

Conclusion

Based on the preceding, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

RNR Attachment A	Map
BFA Attachment A	Health Quest Systems, Inc and Subsidiaries - 2017 and 2018 certified financials
BFA Attachment B	2018 Health Quest Systems, Inc. and Subsidiaries Obligated Group
BFA Attachment C	Financial Summary, Putnam Hospital Center - internal as of June 30, 2019
BFA Attachment D	Nuvance Health Organizational Chart



Project # 171415-C Northern Dutchess Hospital

Program: Hospital Purpose: Construction

County: Dutchess Acknowledged: July 14, 2017

Executive Summary

Description

Northern Dutchess Hospital (NDH), an 84-bed, voluntary not-for-profit, Article 28 acute care hospital located at 6511 Springbrook Avenue, Rhinebeck (Dutchess County), request approval to certify Cardiac Catheterization - Percutaneous Coronary Intervention (PCI) services, with requisite construction. The service will be provided within the main hospital operating room space that was recently renovated to enhance Interventional Radiology services (CON 172054-L). The catheterization laboratory will be operated as part of an integrated delivery model between NDH and Vassar Brothers Medical Center (VBMC), a 365-bed, Article 28 acute care hospital located at 45 Reade Place in Poughkeepsie. Both hospitals are part of Nuvance Health, an integrated healthcare delivery system formally known as HQ-WCHN Health Systems, Inc. Effective June 18, 2019, Nuvance became the sole member and active parent of Health Quest Systems, Inc. (Health Quest). In addition to NDH, Health Quest's New York licensed entities include Vassar Brothers Hospital and Putnam Hospital Center.

By integrating the resources of VBMC's cardiac capabilities into NDH's catheterization laboratory and coordinating the care from an integrated system perspective, NDH will be able to expand VBMC's cardiac program across the Nuvance/Health Quest System, enhancing clinical quality and outcomes by adopting common protocols, quality measures, and safety standards.

Per the applicant, the system-wide approach to cardiac care will offer the following benefits to patients in the region:

- Oversight & Management – NDH's cardiac catheterization laboratory will be staffed and overseen by physicians, directors, and administrators at Nuvance Health's employed cardiology group (The Heart Center). The cardiology group operates in an integrated manner across all sites of care, and its physicians collaborate to deliver patient care through interdisciplinary committees and a centralized physician-led governance.
• Consistent Staffing Closer to Home - Patients in NDH's planning region are already being treated by cardiologists employed at The Heart Center. Bringing these physicians into NDH to perform cardiac catheterizations will promote continuity of care for both patient and cardiologist, enabling consistent and trusted care closer to home.
• Standardized EMS Protocols - EMS providers in the region are already familiar with VBMC's cardiac triage and cardiac catheterization protocols. Extending these same protocols into the NDH planning region will be seamless and ensure consistent EMS-to-hospital transfers and enhance integration in the event of a hospital-to-hospital transfer.
• Seamless & Safe Intra-System Transfers - NDH is only 18 miles, by major state highway, from VBMC so any patient who needs advanced cardiac surgical care could be transferred from NDH's catheterization laboratory to VBMC's operating room in less than thirty (30) minutes by ambulance. The hospitals are also on the same electronic

medical record platform and other clinical systems (including PACS).

- Improved Quality & Safety - By leveraging the expertise of the VBMC staff and experience in operating the heart center, NDH can bring proven expertise and established protocols and measurement tools to monitor and improve care.
- Lower Costs & Faster Ramp-Up - By leveraging existing expertise, protocols, and staff, NDH can establish its catheterization laboratory faster and more efficiently than another hospital that is building a new catheterization program.

OPCHSM Recommendation
Contingent Approval

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.

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018, Dutchess County saw 575 Hudson Valley residents treated for emergency PCI's. Forty-eight residents left the county to receive treatment. Northern Dutchess projects 51 emergency PCI treatments in Year One.

Financial Summary

Total project cost of \$481,360 will be met with accumulated funds.

<u>Incremental</u>	<u>First Year</u>	<u>Third Year</u>
Revenues	\$6,442,357	\$10,939,252
Expenses	<u>\$3,307,301</u>	<u>\$4,995,323</u>
Gain	\$3,135,056	\$5,943,929

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-00 and DSG-01. [AER]
3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-00 and DSG-01. [AER]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before January 15, 2020 and construction must be completed by May 15, 2020, 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 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.

Council Action Date

December 12, 2019

Need Analysis

Background

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in year one of service. Emergency PCI includes any procedure not scheduled and not elective. In the Hudson Valley Health Services Area, seven facilities currently provide PCI services. In 2018, 1,221 Hudson Valley Residents were treated outside of the HSA for currently defined emergency PCI procedures. The six Hudson Valley applicants on the Public Health and Health Planning Council-PHHPC December Agenda that seek certification of Cardiac Catheterization-Percutaneous Coronary Intervention services all project, at minimum, 36 emergency PCI procedures in Year One.

Northern Dutchess and HealthAlliance Hospital Mary's Ave. Campus are close in proximity but separated by the Hudson River. In 2018, Dutchess County saw 575 Hudson Valley residents treated for emergency PCI's. Forty-eight residents left the county to receive treatment. Northern Dutchess projects 51 emergency PCI treatments in Year One. Ulster County saw 359 Hudson Valley Residents treated for emergency PCI's. Thirty-Nine residents left Ulster County to receive treatment. HealthAlliance Hospital Mary's Ave. projects 103 emergency PCI treatments in Year One (based on the transfer of AMI cases transferred with/without complications).

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

Table 1: 2018 Emergency (709.14: 09/25/19) PCI's Performed on Hudson Valley Residents: By: County, By Operational Hudson Valley Facilities, By: Location of Treatment.											
Patient County of Residence	Operational Facilities in the Hudson Valley Region							Resident Outmigration			
	Good Samaritan Suff. (Rockland)	Orange Regional (Orange)	St Luke's Cornwall Newburgh (Orange)	Vassar Brothers (Dutchess)	New York Presbyterian Lawrence (Westchester)	Westchester Med (Westchester)	White Plains (Westchester)	Total	County Residents Treated: All Locations	County Residents Receiving Emergency PCI Treatment in Hudson Valley	County Residents Leaving Hudson Valley for Emergency PCI Treatment
Delaware				4			0	4	131	4	127
Dutchess		3	21	461	4	37	1	527	575	527	48
Orange	90	358	190	24	3	9	0	674	777	674	103
Putnam			2	30	10	55	7	104	137	104	33
Rockland	268	2	2	1	1	11	2	287	412	287	125
Sullivan		141		5		4	0	150	163	150	13
Ulster	3	19	26	263		9	0	320	359	320	39
Westchester		2		6	173	253	331	765	1,498	765	733
Total H. V. Residents receiving Emergency PCIs in Region	361	525	241	794	191	378	341	2,831	4,052	2,831	1,221

Table 2: Applicant Facilities Projected Emergency PCI's

Project	Facility	County	Projected Emergency PCIs	
			Year One	Year Three
152243	Northern Westchester Hospital	Westchester	115	115
162211	New York-Presbyterian Hudson Valley Hospital	Westchester	50	64
162148	Nyack Hospital	Rockland	100	100
171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region.

Northern Dutchess Hospital projects 51 Emergency PCI procedures by Year One of operation.

By providing PCI-capable Cardiac Catheterization services, Northern Dutchess Hospital proposes to achieve the following goals:

- Improve regional access to advanced cardiac services including diagnostic cardiac catheterization and PCI services for the communities served by Northern Dutchess Hospital.
- Enhance clinical quality by adopting common protocols with Vassar Brothers Hospital.
- Utilize the integrated delivery system known as Health Quest Systems, Inc. (Health Quest). Health Quest is the largest system in the mid-Hudson Valley.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Project Proposal

The proposed program will operate with clinical oversight from Vassar Brothers Medical Center (VBMC) in accordance with the terms of an executed clinical sponsorship agreement. VBMC and NDH are members of Nuvance Health, an integrated delivery system. Vassar Brothers Medical Center is a 365-bed hospital located at 45 Reade Place in Poughkeepsie (Dutchess County) which is a full-service cardiac surgery provider.

The new catheterization laboratory will be staffed and overseen by interventional cardiologists employed by Health Quest, and the facilities are on the same electronic medical record (EMR) platform, allowing access to clinical information at both facilities. The applicant believes by leveraging staff and protocols, it can establish its catheterization laboratory faster and at a lower cost. The applicant also believes providing these services will enable patients to have their procedures closer to home, with the ability to rapidly and seamlessly move patients to a higher level of care as needed.

Upon completion of the project Northern Dutchess will have the following service added to their operating certificate:

- Cardiac Catheterization - Percutaneous Coronary Intervention (PCI)

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and they have assured the Department that their program will meet all of the requirements of 405.29.

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

The applicant identified the Prevention Agenda priorities selected for action in the most recent Community Service Plan submitted on behalf of the member hospitals. They are in alignment with the jointly developed Community Health Improvement Plan. These priorities include:

- Reducing obesity in children and adults, and preventing chronic disease prevention, through education and workshops
- Promoting mental health and preventing substance abuse, by participating in Drug Take-Back Days and suicide prevention strategies such as Safe Talk, Assist and Postvention Program.
- Promote Healthy and Safe Environment, specifically focusing on preventing falls in older adults through Tai Chi classes.

The applicant specified the evidence-based interventions selected to address these priorities. The hospital has engaged with diverse local organizational partners in Prevention Agenda efforts to plan and/or implement appropriate interventions and will continue to do in the merged structure. The Prevention Agenda Dashboard is being used to measure progress toward the appropriate Prevention Agenda objectives

In the most recent Schedule H for 2016, Northern Dutchess Hospital reported negligible Community Benefit Spending in the Community Health Improvement Services and Community Benefit operations category. In 2016, Northern Hospital spent \$182 on community health improvement services, representing 0% of total operating expenses.

Conclusion

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

Total Project Cost and Financing

Total project cost for renovations and the acquisition of moveable equipment is estimated at \$481,360, broken down as follows:

Renovation & Demolition	\$31,500
Design Contingency	\$5,150
Construction Contingency	\$5,150
Architect/Engineering Fees	\$8,000
Movable Equipment	\$418,938
Telecommunications	\$8,000
CON Application Fees	\$2,000
Additional Processing Fee	<u>\$2,622</u>
Total Project Cost	<u>\$481,360</u>

Project costs are based on a four-month construction period. The applicant will finance the project via accumulated funds. BFA Attachment C shows sufficient accumulated funds for this project.

Incremental Operating Budget

The applicant submitted an incremental operating budget, in 2019 dollars, for the first and third years:

	Year One		Year Three	
	Per Discharge	Total	Per Discharge	Total
<u>Inpatient Revenues</u>				
Medicare FFS	\$18,140	\$1,433,060	\$18,140	\$2,086,100
Medicare MC	\$18,140	\$399,080	\$18,140	\$598,620
Medicaid FFS	\$15,406	\$61,624	\$15,406	\$92,436
Medicaid MC	\$15,406	\$385,150	\$15,406	\$570,022
Commercial MC	\$24,855	\$1,541,010	\$24,855	\$2,286,660
Private Pay/Other	\$3,126	\$12,504	\$3,126	\$18,756
Less: Bad Debt		<u>(\$61,369)</u>		<u>(\$92,181)</u>
Total Inpt Revenue		\$3,771,059		\$5,560,413
<u>Outpatient Revenues</u>	Per Visit	Total	Per Visit	Total
Medicare FFS	\$5,584	\$474,640	\$5,584	\$960,448
Medicare MC	\$5,584	\$139,600	\$5,584	\$279,200
Medicaid FFS	\$3,018	\$36,216	\$3,018	\$72,432
Medicaid MC	\$3,018	\$153,918	\$3,018	\$307,836
Commercial MC	\$12,340	\$1,863,340	\$12,340	\$3,751,360
Private Pay/Other	\$1,569	\$47,070	\$1,569	\$95,709
Less: Bad Debt		<u>(\$43,486)</u>		<u>(\$87,546)</u>
Total Outpt Revenue		\$2,671,298		\$5,379,439
Total Revenues		\$6,442,357		\$10,939,252
<u>Inpatient Expenses</u>	Per Discharge	Total	Per Discharge	Total
Operating	\$6,487.81	\$1,278,098	\$6,712.40	\$1,953,307
Capital	<u>\$227.52</u>	<u>\$44,822</u>	<u>\$154.03</u>	<u>\$44,822</u>
Total Inpt Expenses	\$6,715.33	\$1,322,920	\$6,866.42	\$1,998,129
<u>Outpatient Expenses</u>	Per Visit	Total	Per Visit	Total
Operating	\$5,385.24	\$1,917,147	\$4,092.12	\$2,929,960
Capital	<u>\$188.86</u>	<u>\$67,234</u>	<u>\$93.90</u>	<u>\$67,234</u>
Total Outpt Expenses	\$5,574.10	\$1,984,381	\$4,186.03	\$2,997,194
Total Expenses		\$3,307,301		\$4,995,323
Excess Rev. Over Exp.		<u>\$3,135,056</u>		<u>\$5,943,929</u>
Utilization (procedures)				
Inpatient		197		291
Outpatient		<u>356</u>		<u>716</u>
Total		553		1,007
Avg Cost Per Procedure		\$5,980.65		\$4,960.60

The following was noted with respect to the first- and third-year incremental budgets:

- The rates by payor were based on historical analysis, third party market data and certain ICD 9 billing codes utilized for billing Cardiac Catheterization patients. Revenue was then calculated based on a blended CMI applied to the observed payor mix of patients within the relevant diagnosis and inpatient/outpatient classifications.

- Utilization by payor source for inpatient and outpatient services for Years One and Three is:

<u>Inpatient</u>	<u>Year One</u>	<u>Year Three</u>
Medicare FFS	40.10%	39.52%
Medicare MC	11.17%	11.34%
Commercial FFS	31.47%	31.62%
Medicaid FFS	2.03%	2.06%
Medicaid MC	12.69%	12.71%
Private Pay/Other	2.03%	2.06%
Charity Care	.51%	.69%

<u>Outpatient</u>	<u>Year One</u>	<u>Year Three</u>
Medicare FFS	23.88%	24.02%
Medicare MC	7.02%	6.98%
Commercial FFS	42.42%	42.46%
Medicaid FFS	3.37%	3.35%
Medicaid MC	14.33%	14.25%
Private Pay/Other	8.43%	8.52%
Charity Care	.55%	.42%

- Utilization and expense projections are based on the experience of hospitals provided cardiac catheterization services and the expected market share of cardiac catheterization services within the NDH service area.

Capability and Feasibility

The project cost of \$481,360 will be met through accumulated funds. BFA Attachment A is a financial summary for NDH, which indicates the availability of sufficient funds.

The submitted incremental budget indicates an excess of revenues over expenses of \$3,135,056 and \$5,943,929 during the first and third years of operation, respectively. Revenues reflect current reimbursement methodologies for Cardiac Cath services. The budget appears reasonable.

BFA Attachment A is the 2017 and 2018 certified financial statements of Health Quest Systems, Inc. and Subsidiaries, which show the entity maintained positive working capital and net asset positions and generated net operating income of \$68,261,000 and \$79,554,000 in 2017 and 2018, respectively.

NDH is part of the Health Quest Systems, Inc. Obligated Group. BFA Attachment B is the Obligated Group's 2018 Balance Sheet and Statement of Operations, which shows that NDH maintained positive working capital and net asset positions and had net operating income of \$20,939,000.

BFA Attachment C is NDH's internal financial statements as of August 31, 2019, which indicates NDH maintained positive working capital and net asset positions and had excess revenue over expenses of \$9,715,000.

Conclusion

Based on the preceding the applicant demonstrated the capability to proceed in a financially feasible manner.

Attachments

RNR Attachment A	Map
BFA Attachment A	Health Quest Systems, Inc. and Subsidiaries - 2017 and 2018 certified financials
BFA Attachment B	2018 Health Quest Systems, Inc. and Subsidiaries Obligated Group
BFA Attachment C	Financial Summary, Northern Dutchess Hospital - internal as of August 31, 2019
BFA Attachment D	Nuvance Health Organizational Chart



**Project # 191260-C
HealthAlliance Hospital Mary's Avenue Campus**

**Program: Hospital
Purpose: Construction**

**County: Ulster
Acknowledged: May 21, 2019**

Executive Summary

Description

HealthAlliance Hospital Mary's Avenue Campus (HA Mary's Ave), a 150-bed, Article 28 acute care hospital located at 105 Mary's Avenue, Kingston (Ulster County), requests approval to certify Cardiac Catheterization – Percutaneous Coronary Intervention (PCI) and Cardiac Catheterization – Electrophysiology (EP) services, with requisite renovations. The proposed PCI lab will be operated under the established, co-operated parent model, whereby Westchester County Health Care Corporation d/b/a Westchester Medical Center (WMC), the active parent of HA Mary's Ave and a cardiac surgery provider, will provide oversight of the proposed PCI program. HA Mary's Ave will implement this project in two phases, as follows:

- Phase 1 - Upgrade the existing lab for PCI and EP services. This will allow the Hospital to immediately perform both PCI and EP services within the existing diagnostic cardiac catheterization laboratory, which is located on the first floor of the Hospital. The upgrade represents a software upgrade only; there will be no construction.
- Phase 2 - Construct a second PCI-capable cardiac catheterization and EP laboratory on the 1st floor of the Hospital within existing shell space. This laboratory is located close to the existing diagnostic cardiac catheterization laboratory and cardiac testing areas and the future Emergency Department being constructed under CON 162234. Once this second lab is constructed, it will become the primary PCI/EP laboratory, and the lab upgraded under Phase 1 will become the backup lab.

Per the applicant, the proposed PCI and EP programs are needed resources for patients attributed to the WMC-led PPS who are living in the mid-Hudson Valley, enabling ready access to regional EP, PCI and other interventional cardiology services, without the need to travel significant distances to other PPS-based facilities certified to perform PCI and EP procedures, primarily located in the lower Hudson Valley region.

OPCHSM Recommendation
Contingent Approval

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018, Ulster County saw 359 Hudson Valley Residents treated for emergency PCI's. Thirty-nine residents left Ulster County to receive treatment. HealthAlliance Hospital Mary's Ave. projects 103 emergency PCI treatments in Year One (based on the transfer of Acute MI cases transferred with/without complications).

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

Project cost of \$6,908,803 will be met with cash equity of \$690,881 and financing through Philips Healthcare of \$6,217,922 at 6% interest for seven years.

<u>Incremental</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$4,085,808	\$7,485,929
Expenses	<u>\$4,012,133</u>	<u>\$5,949,389</u>
Gain	\$73,675	\$1,536,540

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 with Philips Healthcare, acceptable to the Department of Health. (BFA)
3. Submission of Pre-Procedure Risk Stratification tool that ensures high-risk patients are treated at the Cardiac Surgery Center, acceptable to the Department. [HSP]
4. Submission of a fully executed Cardiac Surgery backup agreement., acceptable to the Department. [HSP]
5. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
6. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before January 1, 2020 and construction must be completed by July 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction.

Council Action Date

December 12, 2019

Need Analysis

Background

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in year one of service. Emergency PCI includes any procedure not scheduled and not elective. In the Hudson Valley Health Services Area, seven facilities currently provide PCI services. In 2018, 1,221 Hudson Valley Residents were treated outside of the HSA for currently defined emergency PCI procedures. The six Hudson Valley applicants on the Public Health and Health Planning Council-PHHPD December Agenda that seek certification of Cardiac Catheterization-Percutaneous Coronary Intervention services all project, at minimum, 36 emergency PCI procedures in Year One.

Northern Dutchess and HealthAlliance Hospital Mary's Ave. Campus are close in proximity but separated by the Hudson River. In 2018, Dutchess County saw 575 residents treated for emergency PCI's. Forty-eight residents left the County to receive treatment. Northern Dutchess projects 51 emergency PCI treatments in year one. In 2018, Ulster County saw 359 Hudson Valley Residents treated for emergency PCI's. Thirty-nine residents left Ulster County to receive treatment. HealthAlliance Hospital Mary's Ave. projects 103 emergency PCI treatments in Year One (based on the transfer of Acute MI cases transferred with/without complications). Accompanying patient selection criteria for Electrophysiology procedures has been submitted.

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

Table 1: 2018 Emergency (709.14: 09/25/19) PCI's Performed on Hudson Valley Residents: By: County, By Operational Hudson Valley Facilities, By: Location of Treatment.											
Patient County of Residence	Operational Facilities in the Hudson Valley Region							Resident Outmigration			
	Good Samaritan Suff. (Rockland)	Orange Regional (Orange)	St Luke's Cornwall Newburgh (Orange)	Vassar Brothers (Dutchess)	New York Presbyterian Lawrence (Westchester)	Westchester Med (Westchester)	White Plains (Westchester)	Total	County Residents Treated: All Locations	County Residents Receiving Emergency PCI Treatment in Hudson Valley	County Residents Leaving Hudson Valley for Emergency PCI Treatment
Delaware				4			0	4	131	4	127
Dutchess		3	21	461	4	37	1	527	575	527	48
Orange	90	358	190	24	3	9	0	674	777	674	103
Putnam			2	30	10	55	7	104	137	104	33
Rockland	268	2	2	1	1	11	2	287	412	287	125
Sullivan		141		5		4	0	150	163	150	13
Ulster	3	19	26	263		9	0	320	359	320	39
Westchester		2		6	173	253	331	765	1,498	765	733
Total H. V. Residents receiving Emergency PCIs in Region	361	525	241	794	191	378	341	2,831	4,052	2,831	1,221

Table 2: Applicant Facilities Projected Emergency PCI's

Project	Facility	County	Projected Emergency PCIs	
			Year One	Year Three
152243	Northern Westchester Hospital	Westchester	115	115
162211	New York-Presbyterian Hudson Valley Hospital	Westchester	50	64
162148	Nyack Hospital	Rockland	100	100
171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region.

HealthAlliance Hospital Mary's Ave. Campus projects 103 Emergency PCI procedures by Year One of opening.

By providing PCI-capable Cardiac Cath and EP services, HealthAlliance Hospital Mary's Ave proposes to achieve the following goals:

- Improve regional access to advanced cardiac services including diagnostic cardiac catheterization, PCI, and EP services for the communities in the mid to lower Hudson Valley;
- Reduce travel for patients requiring cardiac services;
- Provide emergency services for patients otherwise forced to travel outside the service area.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Project Proposal

The proposed program will operate with clinical oversight under the established, co-operated parent model whereby Westchester Medical Center and a cardiac surgery provider, will provide strict oversight of the program. Westchester Medical Center will pursue a collaborative effort regarding cardiac services for the HealthAlliance service area with WMC providing oversight for the program. Westchester Medical Center is a 652-bed hospital located at 100 Woods Road in Valhalla (Westchester County) which is a full-service cardiac provider. Because WMC (the co-operator of the proposed PCI capable program) is 71.7 miles and 88 minutes travel time away from HealthAlliance-Mary's Avenue, the proposed cardiac surgery backup facility is Good Samaritan Hospital of Suffern (GSHS). GSHS is located at 255 Lafayette Avenue in Suffern (Rockland County). The applicant acknowledges that GSHS, which is 66.5 miles and 68 minutes travel time away, can and does meet the needs of the community.

Upon completion of the project HealthAlliance Mary's Avenue Campus will have the following service added to their operating certificate:

- Cardiac Catheterization - Percutaneous Coronary Intervention (PCI)
- Cardiac Catheterization – Electrophysiology Services

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and Electrophysiology Services and they have assured the Department that their program will meet all of the requirements of 405.29 and 709.14.

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

Health Alliance Hospital – Mary's Avenue Campus identifies the highly ranked health needs in the community addressed in the *Prevent Chronic Disease* priority are coronary health disease and cardiovascular disease. The services that will be provided with this PCI certification are consistent with both community-identified disease health priorities.

The applicant provides many evidence-based interventions to address the *Prevent Chronic Disease* and *Promoting Mental Health* and *Preventing Substance Abuse* Prevention Agenda goals aligned with the community identified priority areas. Health Alliance Hospital – Mary's Avenue Campus describes active engagement with community partners including the Ulster County Department of Health and Mental Health in the development of the CHA/CHIP.

In addition to tracking the percentage of new mothers exclusively breastfed as inpatients to address the *Prevent Chronic Disease* goal, the applicant provides a variety of metrics tracking the impact on the two community identified goals.

In 2017 the applicant spent \$264,379 on community health improvement services, representing 0.421% of total operating expenses.

Conclusion

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

Total project Cost and Financing

The total project costs for renovations and the acquisition of moveable equipment is estimated at \$6,908,803 broken down as follows:

Renovation & Demolition	2,861,200
Design Contingency	286,120
Construction Contingency	286,120
Architect/Engineering Fees	155,500
Other Fees	51,833
Moveable Equipment	3,017,357
Telecommunications	72,567
Interim Interest Expense	155,448
Application Fee	2,000
Processing Fee	20,658
Total Project Cost	6,908,803

Project costs are based on a seven-month construction starting January 2020. The applicant will finance the project with cash equity of \$690,881 and financing through Philips Healthcare of \$6,217,922 at 6% interest for seven years.

Incremental Operating Budget

The applicant has submitted an incremental operating budget, in 2019 dollars, for the first and third years of operation, summarized below:

	<u>Year One</u>		<u>Year Three</u>	
<u>Inpatient Revenues</u>	<u>Per Discharge</u>	<u>Total</u>	<u>Per Discharge</u>	<u>Total</u>
Medicaid FFS	\$19,433	\$97,167	\$19,433	\$155,466
Medicaid MC	\$19,327	\$347,884	\$19,327	\$483,172
Medicare FFS	\$17,614	\$1,003,982	\$17,614	\$1,356,257
Medicare MC	\$17,614	\$281,820	\$17,614	\$369,888
Commercial FFS & MC	\$34,000	\$612,000	\$34,000	\$850,000
Private/Charity	\$40,000	\$80,000	\$40,000	\$160,000
Other (Bad Debt)		<u>-\$116,075</u>		<u>-\$143,057</u>
Total Inpt Revenue		\$2,306,778		\$3,231,726
<u>Outpatient Revenues</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Medicaid FFS	\$3,420	\$44,460	\$3,322	\$106,317
Medicaid MC	\$3,258	\$140,079	\$3,317	\$334,972
Medicare FFS	\$13,548	\$636,738	\$13,717	\$1,522,635
Medicare MC	\$13,528	\$216,441	\$13,620	\$517,576
Commercial FFS & MC	\$19,118	\$1,032,361	\$19,137	\$2,468,689
Private/Charity	\$36,399	\$400,388	\$33,015	\$957,440
Other (Bad Debt)		<u>(\$691,437)</u>		<u>(\$1,653,426)</u>
Total Outpt Revenue		\$1,779,030		\$4,254,203
Total Revenues		\$4,085,808		\$7,485,929
<u>Expenses (Combined)</u>	<u>Per Procedure</u>	<u>Total</u>	<u>Per Procedure</u>	<u>Total</u>
Operating	\$10,307	\$3,091,955	\$8,538	\$5,122,927
Capital	<u>\$3,067</u>	<u>\$920,178</u>	<u>\$1,377</u>	<u>\$826,462</u>
Total Expenses	\$13,374	\$4,012,133	\$9,916	\$5,949,389
Gain (Loss)		<u>\$73,675</u>		<u>\$1,536,540</u>
<u>Utilization (Procedures)</u>				
Inpatient		116		160
Outpatient		<u>184</u>		<u>440</u>
Total Procedures		300		600
Average Cost Per Procedure		\$13,374		\$9,916

Utilization by payor for inpatient services is as follows:

	<u>Year One</u>		<u>Year Three</u>	
<u>Inpatient</u>	<u>Disch</u>	<u>%</u>	<u>Disch</u>	<u>%</u>
Medicaid FFS	5	4.3%	8	5.0%
Medicaid MC	18	15.5%	25	15.6%
Medicare FFS	57	49.2%	77	48.1%
Medicare MC	16	13.8%	21	13.1%
Commercial FFS & MC	18	15.5%	25	15.6%
Private Pay	1	.8%	2	1.3%
Charity Care	<u>1</u>	<u>.9%</u>	<u>2</u>	<u>1.3%</u>
Total	116	100.0%	160	100.0%

Utilization by payor for outpatient services is as follows:

<u>Outpatient</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Visits</u>	<u>%</u>	<u>Visits</u>	<u>%</u>
Medicaid FFS	13	7.1%	32	7.3%
Medicaid MC	43	23.4%	101	23.0%
Medicare FFS	47	25.5%	111	25.2%
Medicare MC	16	8.7%	38	8.6%
Commercial FFS & MC	54	29.3%	129	29.3%
Private Pay	4	2.2%	11	2.5%
Charity Care	<u>7</u>	<u>3.8%</u>	<u>18</u>	<u>4.1%</u>
Total	184	100.0%	440	100.0%

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

- The projected utilization is based on volume support letters provided by the interventional cardiologists and electrophysiologists who have committed to providing PCI and EP procedures at HA Mary's Ave. This utilization is based on expected market share within HA's service area.
- The number and mix of staff were determined based on the experience of WMC in staffing its existing PCI-capable cardiac catheterization and EP lab on its main campus in Valhalla. The Incremental expenses include labor costs related to new staff (1 FTE Nurse Practitioner, 5.5 FTE RNs and 2.0 to 2.5 FTE Respiratory Therapists) and increased medical supply costs including implants (total \$2.1M Year One, \$3.96M Year Three).
- Revenues are based on the prevailing payment rates by payor for cardiac catheterization procedures per the experience of WMC.

Capability and Feasibility

The total project costs of \$6,908,803 will be funded by cash equity of \$690,881 and financing through Philips Healthcare of \$6,217,922 at 6% interest for seven years.

The submitted budget indicates excess revenues over expenses of \$73,675 and \$1,536,540 in Years One and Three, respectively. The budget appears reasonable.

BFA Attachment A is the 2017 and 2018 certified financial statements of HealthAlliance, Inc, which indicate the entity had negative working capital and net asset positions and generated operational deficits of \$23,432,000 in 2018 and \$9,080,000 in 2017.

BFA Attachment B is the internal financial statements of HealthAlliance, Inc. as of August 31, 2019, which indicate the entity had negative working capital and net asset positions and had an operational deficit of \$14,484,000.

WMC became the active parent co-operator of HA effective February 26, 2019. Prior to affiliating with WMC, HA had experienced seven years of consecutive volume decline resulting in significant operating losses. Comparing 2017 to 2011, HA lost 15% market share and 2,957 inpatient cases due to its inability to attract and retain providers and lack of capital to invest. With the assistance of WMC to restructure operations, improve market share penetration and achieve efficiencies, recapturing just 21% of lost volume (616 discharges) is expected to enable HA to achieve financial stability with positive cash flow. WMC has invested substantial resources (approximately \$12M yearly) to support HA while actively rebuilding their clinical programs. As such, HA with WMC's management team have identified immediate inpatient and outpatient growth opportunities, including inpatient and outpatient cardiac catheterization services, aimed at recapturing lost volume. These growth opportunities align with continued strategic investments for 2019 including cardiology, primary care, obstetrics, and oncology. HA has been receiving state subsidy since 2014 via the IAAF, VAPAP and VBP-QIP programs, and is expected to continue receiving ongoing VAPAP and VBP-QIP funding in state fiscal years 2020 and 2021 to enable service line restructuring with an end goal of establish a financially sustainable hospital in Kingston.

Conclusion

Based on the preceding, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

RNR Attachment A	Map
BFA Attachment A	HealthAlliance, Inc 2016, 2017, 2018 Certified Financial Statements
BFA Attachment B	HealthAlliance, Inc August 31, 2019 Internal Financial Statements



**Project # 192045-C
Samaritan Hospital**

Program: Hospital
Purpose: Construction

County: Rensselaer
Acknowledged: August 1, 2019

Executive Summary

Description

Samaritan Hospital of Troy NY, Inc. d/b/a Samaritan Hospital, a voluntary not-for-profit, Article 28 acute care community hospital located in Troy (Rensselaer County), requests approval to merge Memorial Hospital, Albany NY d/b/a Albany Memorial Hospital, a voluntary not-for-profit, Article 28 community hospital located in Albany (Albany County), into its operations. Samaritan Hospital will be the surviving hospital and corporation. Upon approval of the merger, the Memorial Hospital site will be known as Samaritan Hospital – Albany Memorial Campus. St. Peter's Health Partners (SPHP), a not-for-profit healthcare system in New York's Capital Region that operates numerous health facilities, is the sole member, active parent and co-operator of both hospitals. There will be no change in beds, services, or programs at this time as a result of this project.

Upon completion of this merger, Samaritan Hospital will have three hospital campuses and a net certified bed count of 442 beds. The campuses are as follows:

- Main Campus: 257 beds at 2215 Burdett Avenue, Troy;
- St. Mary's Campus: 20 beds (Chemical Dependency-Rehabilitation) at 1300 Massachusetts Avenue, Troy; and
- Albany Memorial Campus: 165 beds, at 600 Northern Blvd., Albany.

Integrating the various stand-alone hospitals of SPHP into a larger health system has been an objective of SPHP since its formation in 2011. Under SPHP's Master Facilities Plan (MFP), transforming the Memorial campus into a

hospital outpatient and/or ambulatory surgery and medical office location is under consideration. The 165-bed hospital has experienced declining average daily census for several years (40.6 in 2016 to 15.4 this year to date) with little expectation of rebounding, but outpatient volume remains significant. In 2017, the Centers for Medicare and Medicaid Services (CMS) issued guidance on the definition of a hospital, stating that in order to qualify for Medicare payments the facility must be "primarily engaged in providing inpatient services." SPHP is confident that Memorial currently qualifies as hospital. However, given the downward trend in inpatient patient care, there is growing concern as to how long Memorial will meet the CMS definition of a hospital. Memorial can ensure compliance with the regulation over the long term by merging into St. Peter's Hospital or Samaritan Hospital, as both are affiliates of SPHP. It is preferable for Memorial to merge into Samaritan, primarily because those hospitals are on the same information system (Meditech).

The MFP for the Memorial Hospital campus will take years to implement. In the meantime, the community relies greatly on the hospital's outpatient services, particularly its emergency services. The merger is expected to deliver more centralized governance, administrative and operational efficiencies by having a single management structure, reduce federal and state regulatory obligations, unify policies and procedures, and create economies of scale while enhancing centralized care for patients. Presently, SPHP, Samaritan and Albany Memorial have mirror boards. Post-merger,

SPHP and Samaritan will continue to have mirror boards and SPHP will retain the active parent reserve powers. Memorial will cease to exist as a separately licensed entity and will become a Division of Samaritan.

BFA Attachment A is the organizational charts for St. Peter's Health Partners before and after the merger.

OPCHSM Recommendation
Contingent Approval

Need Summary
There will be no change in beds or services as a direct result of this application.

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

There are no project costs or acquisition costs associated with this application.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$373,011,294	\$389,678,287
Expenses	<u>\$375,675,846</u>	<u>\$388,933,858</u>
Net Income	(\$2,664,552)	\$744,429

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 Plan of Merger Agreement, acceptable to the Department of Health. (BFA)
2. Submission of a photocopy of a list of the Board of Directors of Trinity Health, acceptable to the Department. (CSL)
3. Submission of a photocopy of an executed Resolution of the Board of Directors of Trinity Health, acceptable to the Department. (CSL)
4. Submission of a photocopy of an executed Resolution of the Board of Directors of St. Peters Health Partners, acceptable to the Department. (CSL)
5. Submission of a photocopy of an executed Resolution of the Board of Directors of Memorial Hospital, Albany, N.Y. (MHA), acceptable to the Department. (CSL)
6. Submission of a photocopy of the Certificate of Incorporation for MHA, acceptable to the Department. (CSL)
7. Submission of an Anti-Kickback Statement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an executed Resolution of the Board of Directors of Samaritan Hospital of Troy, NY (Samaritan Hospital), acceptable to the Department. (CSL)
9. Submission of a photocopy of an executed Amended and Restated Certificate of Incorporation of Samaritan Hospital, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Plan of Merger of Samaritan Hospital and MHA, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Certificate of Merger of Samaritan Hospital and MHA into Samaritan Hospital, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Project Proposal

Samaritan Hospital (Samaritan), a 257-bed, voluntary not-for-profit Article 28 acute care hospital, located at 2215 Burdett Ave in Troy (Rensselaer County), requests approval to acquire Albany Memorial Hospital (Memorial), a 165-bed hospital located approximately eight miles away, at 600 Northern Boulevard in Albany (Albany County). Both hospitals have St. Peter's Health Partners as their sole member, active parent and co-operator.

The Average Daily Census of Albany Memorial Hospital has been declining steadily.

Albany Memorial Hospital							
	2012	2013	2014	2015	2016	2017	2018
Average daily census	60.6	51.0	42.7	40.1	33.3	30.2	23.3
Total Occupancy	36.7%	30.9%	25.9%	24.3%	20.2%	18.3%	14.1%

As a result of a steady decline in its average daily census and Centers for Medicare and Medicaid Services (CMS) issuing guidance in 2017 to the State Survey Directors on the definitions of a "hospital", there is growing concern as to how long Memorial will meet the CMS definition of a hospital. Memorial can ensure compliance with the regulation over the long term by merging with Samaritan Hospital. Through this merger, Memorial aims to protect continued access to health services for area residents, including Emergency Room services which is valued greatly by the community. The merger promises to deliver significant tangible benefits to the hospitals and the communities which will improve the financial sustainability of the combined hospital, as well as the quality of care, including:

- *Governance, administrative, and operational efficiencies:* The single hospital would have one legal Board and CEO, one set of local policies and procedures, one medical and nursing staff, and many unified departments.
- *Reduction in regulatory obligations:* The reporting and other obligations imposed by a long list of federal and state regulatory agencies will have to be satisfied by one entity.
- *Coordination of care:* The merger will facilitate the coordination of care of the patients who may need services at both sites.
- *340-B Discounts:* Memorial outpatient services will benefit from the eligibility for 340-B discounts under Samaritan 340-B program.

The applicant is not requesting to decertify any beds at this time. The applicant is requesting, per 10 NYCRR §401.3(e), to operate at less than the certified capacity as the SPHPs works on a Master Facility Plan for all St. Peter's Health Partners hospitals, in anticipation of a request to reallocate the beds, if required. As a result, there would be no change to the authorized services, number or type of beds due to this application.

Prevention Agenda

The combination of the two hospitals "does nothing to change, dilute, or in any way, diminish" the activities to support their Community Service Plan or address Prevention Agenda priorities (summarized below).

Consistent with a previous CON application, the applicant identified the Prevention Agenda priorities selected for action in the most recent Community Service Plan submitted on behalf of the member hospitals. They are in alignment with the jointly-developed Community Health Improvement Plan for Rensselaer County. These priorities include:

- Preventing chronic disease, focusing on reducing obesity and diabetes in children and adults; and
- Promoting mental health and preventing substance abuse, focusing on preventing substance abuse and other mental, emotional and behavioral diseases.

The applicant specified the evidence-based interventions selected to address these priorities. Both hospitals have engaged with diverse local organizational partners in Prevention Agenda efforts to plan and/or implement appropriate interventions and will continue to do so in the merged structure. The Prevention Agenda Dashboard is being used to measure progress toward the appropriate Prevention Agenda objectives.

In their most recent Schedule H forms, both hospitals reported Community Benefit Spending in the Community Health Improvement Services and Community Benefit Operations category. In 2017, Albany Memorial Hospital spent \$357,718 on community health improvement services, representing 0.37% of total operating expenses. In 2016, Samaritan Hospital spent \$435,920 on community health improvement services, representing 0.2% of total operating expenses.

Compliance with Applicable Codes, Rules and Regulations

The Department issued a Stipulation and Order (S&O) dated August 18, 2016 and fined St. Peter's Hospital \$2,000 based on findings from a validation survey that was completed on January 7, 2016. Deficient practice was cited in the area of Food and Dietetic Services. Specifically, staff identified that the solutions used to clean the food preparation surfaces was below the required concentration to assure the areas are properly sanitized.

Conclusion

There would be no change in beds or services as a direct result of this application. 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

Plan of Merger Agreement

The applicant has submitted a draft Plan of Merger Agreement to be effectuated upon Public Health and Health Planning Council approval. The terms are summarized below:

Merging Entities:	Samaritan Hospital of Troy, Inc. and Memorial Hospital, Albany NY
Surviving Entity:	Samaritan Hospital of Troy, Inc.
Terms/Conditions:	The terms and conditions of the merger, including the manner and basis of converting membership or other interest in each constituent corporation into membership or other interest in the surviving corporation, or the cash or other consideration to be paid in exchange for membership in each constituent corporation provides that: St. Peter's Health Partners will remain the sole member of the surviving corporation; and no cash or other consideration will be paid in exchange for any membership interest.
Purchase Price:	\$0

The sole member of Samaritan Hospital is SPHP, a New York not-for-profit corporation, and the sole member of SPHP is Trinity Health Corporation, an Indiana nonprofit corporation.

Operating Budget

The applicant has submitted the current year (FYE 2018) and projected first and third year operating budgets in 2019 dollars, as summarized below:

	<u>Current</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>			
Inpatient	\$108,120,289	\$113,355,502	\$116,732,873
Outpatient	<u>\$239,470,307</u>	<u>\$247,767,276</u>	<u>\$256,330,529</u>
Net Patient Rev	\$347,590,596	\$361,122,778	\$373,063,402
Other Op. Rev*	\$13,032,265	\$12,592,745	\$13,150,062
Non-Op. Rev**	<u>(\$5,805,555)</u>	<u>(704,229)</u>	<u>\$3,464,823</u>
Total Revenues	\$354,817,306	\$373,011,294	\$389,678,287
<u>Expenses</u>			
Operating	\$340,812,705	\$359,778,581	\$373,454,321
Capital	<u>\$14,980,411</u>	<u>\$15,897,265</u>	<u>\$15,479,537</u>
Total Expenses	\$355,793,116	\$375,675,846	\$388,933,858
Net Income (Loss)	<u>(\$975,810)</u>	<u>(\$2,664,552)</u>	<u>\$744,429</u>
Discharges	11,702	11,416	11,746
Visits	966,011	1,018,235	1,074,852

*Other revenue includes: cafeteria, grant revenue, rent, and assets released from restrictions.

**Non-operating revenue: gains and loss from investment.

Utilization by payor for the current year, and anticipated first and third years is as follows:

<u>Inpatient</u>	<u>Current</u>	<u>Year One</u>	<u>Year Three</u>
Commercial-FFS	6.51%	7.10%	7.94%
Commercial- MC	13.96%	13.43%	14.27%
Medicare-FFS	30.39%	28.77%	26.98%
Medicare-MC	25.60%	26.77%	25.04%
Medicaid-FFS	4.77%	5.29%	5.10%
Medicaid-MC	17.48%	17.63%	19.68%
Private Pay	0.65%	0.46%	0.45%
Charity Care	<u>0.63%</u>	<u>0.56%</u>	<u>0.54%</u>
Total	100.00%	100.00%	100.00%
<u>Outpatient</u>			
Commercial-FFS	11.66%	11.45%	11.08%
Commercial-MC	27.08%	26.85%	26.99%
Medicare-FFS	21.25%	20.50%	20.31%
Medicare-MC	19.21%	19.89%	19.97%
Medicaid-FFS	1.89%	1.78%	1.81%
Medicaid-MC	16.66%	16.82%	17.49%
Private Pay	1.52%	1.72%	1.61%
Charity Care	<u>0.74%</u>	<u>0.98%</u>	<u>0.74%</u>
Total	100.00%	100.00%	100.00%

Budget projections are based on the following:

- While the three facilities when combined for budget reasons indicate a slight loss in the current and first year, merging the facilities will cut costs and allow for centralized management staff to run more efficient operations, which will result in a positive third-year net income.
- The Year One loss is expected to increase as Samaritan and Albany Memorial Hospital implement strategies to right-size all the facilities under one operation.
- Revenue assumptions are based on current reimbursement methodologies as well as current and historical utilization.
- Albany Memorial Hospital is experiencing a lower average daily census, creating an opportunity to right-size the facility to the community need.
- In contrast, outpatient volume appears to be rising and should provide some opportunities for growth.

Capability and Feasibility

There are no issues of capability as there are no project costs or acquisition price associated with this application.

BFA Attachment B is the 2017 and 2018 consolidated certified financial statements of St. Peter's Health Partners Albany, NY, which shows positive working capital and net asset position for both years. For 2017, SPHP achieved operating income of \$6,302,000 before other items and experienced an operating loss of \$1,752,000 before other items in 2018. Inclusive of other operating and non-operating items, SPHP achieved an excess of revenue over expenses of \$37,861,000 in 2017 and \$8,113,000 in 2018. The reason for the operating loss before other items in 2018 was due to inefficiencies in various programs and full-time salary expenses. SPHP has developed an action plan to include patient progression efficiency, voluntary separation programs and integrating electronic medical records systems to streamline patient care.

As shown on the BFA Attachment B, supplemental schedule for 2018, Samaritan Hospital of Troy achieved excess revenues over expenses of \$9,108,000 and Albany Memorial Hospital achieved an excess of revenues over expenses of \$2,505,000. Seton Health Systems Inc. d/b/a St. Mary's had an excess revenue over expenses of (\$12,589,000). The combined loss is \$976,000 which SPHP can absorb. Once the planned strategies are fully implemented and cost efficiencies are in place, the budget in Year Three indicates that the facilities will have positive net income.

BFA Attachment C is SPHP's internal financial statement as of fiscal year end June 30, 2019, which shows positive working capital and net asset positions. During 2019, SPHP shows operating income of \$2,185,000 and excess of revenues over expenses of \$24,951,000.

SPHP will actively review the overall MFP once Albany Memorial is merged into Samaritan Hospital to assess community needs and implement recommendations of consolidating beds and services.

The budget shows a first-year loss of \$2,664,552 and a third-year gain of \$744,429. SPHP completed a projected operating budget based on integration, streamlining services between campuses, cost savings initiatives, and centralizing work flow. Future initiatives for restructuring, including centralizing leadership and administrative services will help decrease costs. Right-sizing in various areas will improve sustainability in the future. The budget appears reasonable.

Conclusion

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

Attachments

- BFA Attachment A Organizational Charts – Pre & Poster Merger
- BFA Attachment B (SPHP) Consolidated Certified Financial Statements - Fiscal Years June 2017 and 2018, including Hospital Supplemental Schedules.
- BFA Attachment C (SPHP) Draft 2019 Fiscal Year End Financial Statements (June 2019)



**Project # 192123-C
Blythedale Childrens Hospital**

**Program: Hospital
Purpose: Construction**

**County: Westchester
Acknowledged: September 6, 2019**

Executive Summary

Description

Blythedale Children’s Hospital (Blythedale), an 86 bed, voluntary not-for-profit, Article 28 specialty children’s hospital located at 95 Bradhurst Avenue, Valhalla (Westchester County), requests approval to certify eight additional Traumatic Brain Injury (TBI) beds and perform requisite renovations. Blythedale is currently certified for seven TBI and three coma recovery beds. The beds as located in a dedicated Brain Injury/Coma Recovery Unit consisting of ten single-bedded rooms. This project will convert eight of the single-bedded rooms to double-bedded rooms, increasing the bed count of the Unit from ten to 18. Upon approval of this application, the Hospital will have a total of 15 TBI beds and a final certified bed count of 94 beds.

From January 2017 through May 2019 Blythedale has stated they were forced to turn away 147 children suffering from TBI – an average of more than five children every month – because the Hospital did not have enough certified TBI bed capacity to treat those patients. Of the 147 pediatric TBI patients, 118 were admitted to facilities that do not have specialized, dedicated pediatric programs.

**OPCHSM Recommendation
Contingent Approval**

Need Summary
The addition of these beds would help alleviate the high utilization rates and the lack of available beds.

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 costs of \$2,011,227 will be met through cash equity.

<u>Incremental Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$3,483,076	\$5,286,903
Expenses	\$1,664,957	\$2,171,310
Gain/(Loss)	\$1,818,119	\$3,115,593

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]

Approval conditional upon:

1. The project must be completed within three years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. The applicant is required to submit Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, prior to the applicant's start of construction for record purposes. [AER]
3. Construction must start on or before March 15, 2020 and construction must be completed by July 15, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Background

The Hospital currently has 86 beds, including 46 Medical/Surgical beds, 30 Physical Medicine and Rehabilitation (PM&R) beds, seven Traumatic Brain Injury (TBI) beds and three Coma Recovery beds. Blythedale is seeking approval to certify eight additional TBI beds. Upon approval, the Hospital will have 15 TBI beds and a total of 94 beds.

A traumatic brain injury (TBI) is defined as an alteration in brain function, or other evidence of brain pathology, caused by an external force. A non-traumatic brain injury is an alteration in brain function or pathology caused by an internal force, such as post-infectious diseases (including meningitis or Anti-NMDA receptor encephalitis (ANMDAR)), hypoxia, brain tumors and stroke. Blythedale provides both types of acquired brain injury (ABI): traumatic and non-traumatic and is the only dedicated post-acute pediatric brain injury unit in New York State.

Analysis

Bed Type	Current Beds	Request	Proposed
Coma Recovery	3		3
Medical/Surgical	46		46
Phy. Medicine and Rehab.	30		30
Traumatic Brain Injury	7	+8	15
Total	86	8	94

Source: HFIS

Average Daily Census, Length of Stay, and Occupancy							
		2017			2018		
	Beds	ADC	ALOS	Occupancy Rate	ADC	ALSO	Occupancy Rate
Med/Surg	86	66.4	44.5	77.20%	81.3	53.5	85.70%

Source: SPARCS

The table below displays a census of approximately 30 pediatric TBI patients per year in Westchester County alone. These patients tend to have a long average length of stay. The addition of eight beds will allow these patients to stay in the area and receive care at a pediatric facility.

Westchester Pediatric Residents with TBI diagnosis (21 and Under)						
Year	2013	2014	2015	2016	2017	2018
Pediatric TBI Patients	48	34	33	25	30	30

Source: SPARCS

The applicant has stated through 2019 its TBI beds have been 95% utilized and its PM&R beds were at 93% with an overall facility utilization of 88%. From January 2017 through May 2019 Blythedale has stated they were forced to turn away 147 children suffering from TBI – an average of more than five children every month – because the Hospital did not have enough certified TBI bed capacity to treat those patients. Of the 147 pediatric TBI patients, 118 were admitted to facilities that do not have specialized, dedicated pediatric programs.

It is anticipated that current year staffing is expected to increase as a result of this project from 11.1 FTEs in Year One to 14.5 FTEs in Year Three. There are no expected programmatic changes and no other change in services.

Prevention Agenda

Blythedale Children's Hospital proposes to use their platform as a child focused community engaged facility to address the Prevention Agenda goal to Prevent Chronic Diseases by Reducing Obesity in Children. This goal is in alignment with the Westchester County Prevention Agenda Coalition and the 2018 County Health Improvement Plan. The applicant will provide education to at-risk children and their families on the importance of nutrition and healthy eating, as well as to provide them with the necessary tools to establish lifelong healthy habits. The applicant will work with schools to provide on-site education as well as convening community health screening events.

The applicant states that the second Prevention Agenda goal selected by the Westchester County Prevention Agenda Coalition – Prevent Mental Health and Substance Use Disorders is not within the applicant's mission and scope of practice. Blythedale has selected another Prevention Agenda priority goal - Prevent Healthcare-Associated Infections. The applicant proposes to improve their ability to reduce health care associated infections through multiple clinical strategies and interventions.

The applicant references involvement in community wide discussions convened by the Westchester County Department of Health around the selection of county-wide Prevention Agenda priorities. However, the 2018 community health planning documents were developed separately by each institution rather than creating a combined CHA/CHIP.

The applicant provides a general list of performance measures developed to track the educational and community- based activities related to reducing obesity in children. These include numbers of materials distributed, number of attendees at health fairs, number of classroom visits and analytics related to social media but do not provide objectives for these activities.

By 2018, Blythedale will maintain hospital acquired infection rates less than 1.1 per 1,000 central line days and 1.7 per 1,000 indwelling catheter days using QI and educational strategies.

In 2017 the applicant spent \$183,119 on community health improvement services, representing 0.242% of total operating expenses.

Conclusion

The addition of these beds would help alleviate the high utilization rates and the lack of available beds. 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

Project Costs

Total project costs for the renovations is estimated at \$2,011,227 broken down as follows:

Renovation & Demolition	\$1,360,918
Design Contingency	136,092
Construction Contingency	136,092
Architect/Engineering Fees	131,112
Construction Manager Fees	34,023
Moveable Equipment	200,000
CON Application Fee	2,000
Additional Processing Fee	<u>10,990</u>
Total Project Cost	\$2,011,227

Project costs are based on a start date of March 2020, with a four-month construction period. Financing to meet the total project costs will be met with cash equity from the applicant.

Operating Budget

The applicant has submitted the incremental first and third year projected operating budget for the eight additional TBI beds, in 2019 dollars, summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Disch.</u>	<u>Total</u>	<u>Per Disch</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid FFS	\$132,707	\$265,414	\$128,931	\$386,793
Medicaid MC	\$93,416	840,745	\$87,517	1,225,233
Commercial FFS	\$125,101	<u>2,376,917</u>	\$131,246	<u>3,674,877</u>
Total Revenues		\$3,483,076		\$5,286,903
<u>Expenses</u>				
Operating	\$50,140	\$1,504,209	\$44,679	\$2,010,562
Capital	<u>\$5,358</u>	<u>160,748</u>	\$3,572	<u>160,748</u>
Total Expenses	\$55,499	\$1,664,957		2,171,310
Excess Revenues		\$1,818,119		\$3,115,593
Incremental Discharges		30		45
TBI Unit Occupancy		61.40%		89.49%

Incremental utilization by payor source for Years One and Three is summarized below:

Payor	<u>Year One</u>		<u>Year Three</u>	
	<u>Disch.</u>	<u>%</u>	<u>Disch.</u>	<u>%</u>
Medicaid FFS	2	6.67%	3	6.67%
Medicaid MC	9	30.00%	14	31.11%
Commercial FFS	<u>19</u>	<u>63.33%</u>	<u>28</u>	<u>62.22%</u>
Total	30	100.00%	45	100.00%

The following is noted with respect to the operating budget:

- Utilization is based on the incremental volume associated with the eight additional TBI inpatient beds and historical volume experience of the current TBI beds. Reimbursement rates reflect the current and projected rates of the Unit.
- The Medicaid FFS and Medicaid Managed Care rates are conservatively forecasted to be essentially unchanged.
- The non-Medicaid rates are conservatively forecasted to increase 0.5% while historically non-Medicaid rates increase 2.0% to 3.5% annually.
- Medicaid Managed Care plans pay the Hospital 100% of the published rate but in TBI cases Blythedale has a small amount of cases that pay 85% of the published rate.
- Increased operating cost include incremental salary, wages and employee benefits related to additional staff (5.7 FTE registered nurses, 2.9 FTE Aides/Orderlies, 2.3 therapists) and additional medical supplies. The incremental capital pertains to depreciation expense for project costs related to the renovation and moveable equipment.

Capability and Feasibility

The total project cost of \$2,011,227 will be met via equity from the Hospital. BFA Attachment A is the 2017 and 2018 certified financial statements of Blythedale Children's Hospital, which indicates the availability of sufficient funds for the equity contribution.

The submitted budget projects an incremental net income of \$1,818,119 and \$3,115,593 in the first and third years of operation of the additional beds, respectively. Revenues are based on the current reimbursement methodologies for TBI services. The budget appears reasonable.

As shown on BFA Attachment A, the entity had an average positive working capital position and an average positive net asset position from 2017 through 2018. Also, the entity achieved an average excess of revenues over expenses of \$4,040,346 from 2017 through 2018.

BFA Attachment B is the internal financial statements of Blythedale Children's Hospital as of the August 31, 2019. As shown, the entity had a positive working capital position and a positive net asset position and achieved an excess of revenues over expenses of \$1,645,873 through August 31, 2019.

Conclusion

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

Attachments

- BFA Attachment A 2017 and 2018 Certified Financial Statements of Blythedale Children's Hospital.
BFA Attachment B Internal Financial Statements of Blythedale Children's Hospital as of 08-31-19



**Project # 192051-C
Specialists' One-Day Surgery Center, LLC**

Program: Diagnostic and Treatment Center **County:** Onondaga
Purpose: Construction **Acknowledged:** July 26, 2019

Executive Summary

Description

Specialists' One-Day Surgery, LLC (SODS) is the operator of a proprietary Article 28 freestanding ambulatory surgery center (FASC) in Syracuse (Onondaga County). Prior to opening its extension clinic facility at 5801 East Taft Road, Syracuse, SODS operated a dual-single-specialty (Orthopedics and Pain Management) FASC at 190 Intrepid Lane, Syracuse. Under CON 172083 and effective March 27, 2019, SODS renovated and reconfigured its Intrepid Lane facility and opened the East Taft Road site, moving Orthopedic services to this new location. Pain Management services remain at the Intrepid Lane site, which is certified for single specialty – pain management services. Per this application, SODS requests approval to certify a second specialty, Pain Management, at the East Taft Road site to become a dual single-specialty FASC (Orthopedics and Pain Management).

The applicant indicates that a small number of pain management procedures currently performed at the Intrepid Lane site require anesthesia. Since the anesthesia service line was relocated to the East Taft Road site, the Intrepid Lane site is required to make separate arrangements for anesthesia which becomes costly and creates scheduling inefficiencies. SODS wants the flexibility to permit its current pain management medical staff to perform pain management cases at the East Taft Road site on an as needed basis. No additional staff and

no modifications of the East Taft Road site will be required to accommodate pain management procedures. There will be no change in services at the Intrepid Lane site and most pain management cases will continue to be performed at there.

**OPCHSM Recommendation
Contingent Approval**

Need Summary
This project will enhance access to pain management surgery services for the residents of Onondaga County.

Program Summary
Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary
Total project costs of \$14,503 will be funded via cash from accumulated funds.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$67,608	\$67,608
Expenses	12,300	12,300
Gain/(Loss)	\$55,308	\$55,308

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]

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Background

Specialists' One-Day Surgery Center currently operates two ambulatory surgery centers, one offering orthopedic surgery and one offering pain management surgery services. The applicant is requesting to add a second specialty (pain management) to its orthopedic surgery site so that a small number of pain management procedures (approximately 10) which require anesthesia can be performed more easily and efficiently.

The Center was designed and constructed to meet the standards of a multi-specialty surgery center. Currently, it operates eight (8) operating rooms, each of which are at least 410 square feet in area. The Center has the capacity to handle additional pain management cases in addition to the surgical cases currently being performed and would like the flexibility to the medical staff.

It is anticipated that there will be no change in the current staffing to accommodate projected incremental increase in cases. Dr. Alan Lemley will continue to serve as the Medical Director and the existing transfer and affiliation agreement with St. Joseph's Hospital Health Center will remain in effect.

Analysis

The service area is Onondaga County. The table below show the number of patient visits at ambulatory surgery centers in Onondaga County for 2017 and 2018, which increased 17.8 percent year-over-year.

ASC Type	Facility Name	Total Patient Visits	
		2017	2018
Multi	Camillus Surgery Center ¹	2,462	1,901
Gastroenterology	Digestive Disease Center of Central NY ¹	11,389	19,887
Gastroenterology	Endoscopic Procedure Center	6,005	5,986
Gastroenterology	Endoscopy Center of Central NY	4,148	7,435
Pain Management	Heritage One-Day Surgery	16,851	17,977
Pain Management	Specialists' One-Day Surgery Center	14,778	16,685
Orthopedics	Specialists' One-Day Surgery Center (opened 3/27/19)	N/A	N/A
Multi	Specialty Surgery Center of Central NY ¹	12,685	13,644
Gastroenterology	Syracuse Endoscopy Associates	6,762	6,590
Ophthalmology	Syracuse Surgery Center	1,491	1,790
Gastroenterology	University Gastroenterology at the Philip G. Holtzapple Endoscopy Center	2,160	1,694
Orthopedics	Upstate Orthopedics Ambulatory Surgery Center	5,501	5,609
Total Visits		84,232	99,198

¹ 2018 data is an estimation, based upon partial year information

Compliance with Applicable Codes, Rules and Regulations

The medical staff will continue to ensure that procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and/or expertise. The facility's admissions policy will include anti-discrimination regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures will be performed in accordance with all applicable federal and state codes, rules and regulations, including standards for credentialing, anesthesiology services, nursing, patient admission and discharge, a medical records system, emergency care, quality assurance and data requirements.

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Conclusion

Approval of this project will enhance access to pain management surgery services for the residents of Onondaga County. 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

Total Project Cost and Financing

Total project costs for the acquisition of moveable equipment is estimated at \$14,503, broken down as follows:

Movable Equipment	\$12,435
Application Fees	\$2,000
Additional Processing Fees	<u>\$68</u>
Total Project Cost	\$14,503

The project cost will be funded via cash from the Company's accumulated funds. BFA Attachment B provides the 2017 - 2018 certified financial statements of Specialists' One-Day Surgery, LLC, which show sufficient resources to meet the equity requirement for total project cost.

Operating Budget

The applicant submitted the current year operations for pain management services, and the projected first- and third-year operating budgets, in 2019 dollars, summarized below:

<u>Revenues</u>	Current Year		Year One		Year Three	
	<u>Per Proc.</u>	<u>Total</u>	<u>Per Proc.</u>	<u>Total</u>	<u>Per Proc.</u>	<u>Total</u>
Medicaid-MC	\$3,204	\$6,408	\$3,204	\$6,408	\$3,204	\$6,408
Medicare-FFS	\$6,700	\$13,400	\$6,700	\$13,400	\$6,700	\$13,400
Commercial-FFS	\$9,000	\$36,000	\$9,000	\$36,000	\$9,000	\$36,000
Private Pay	\$5,700	<u>\$11,400</u>	\$5,700	<u>\$11,400</u>	\$5,700	<u>\$11,400</u>
Total		\$67,208		\$67,208		\$67,208
<u>Expenses</u>						
Operating	\$1,230	\$12,300	\$1,230	\$12,300	\$1,230	\$12,300
Capital	<u>0</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
	\$1,230	\$12,300	\$1,230	\$12,300	\$1,230	\$12,300
Net Income		<u>\$54,908</u>		<u>\$54,908</u>		<u>\$54,908</u>
Procedures		10		10		10

Incremental revenues and expenses associated with pain procedures at the East Taft Road site are expected to be nominal and immaterial.

Utilization by payor source for the current year, and years one and three is summarized below:

<u>Payor</u>	<u>Current Year</u>		<u>Year One</u>		<u>Year Three</u>	
	<u>Proc.</u>	<u>%</u>	<u>Proc.</u>	<u>%</u>	<u>Proc.</u>	<u>%</u>
Medicaid-MC	2	20%	2	20%	2	20%
Medicare-FFS	2	20%	2	20%	2	20%
Commercial-FFS	4	40%	4	40%	4	40%
Private Pay	2	20%	2	20%	2	20%
Total	10	100%	10	100%	10	100%

The following is noted with respect to the submitted budget:

- Revenue assumptions are based upon the current reimbursement rates received by the applicant at the 190 Intrepid Lane ASC.
- Expense assumptions are based upon current experience and consist of medical and surgical supply costs. There will be no need for additional staff to handle pain management cases. The current medical staff who perform cases at the Intrepid Lane site will perform pain management procedures at the East Taft Road site on an as needed basis.
- Utilization assumptions are based on the current cases at 190 Intrepid Lane site.
- Breakeven is approximately two procedures (20% of first year procedures).

Capability and Feasibility

Total project costs of \$14,503 will be funded in cash from the SODS's accumulated funds. The working capital requirement is estimated at \$2,050, based on two months of first year incremental expenses. Funding will come from SODS's internally generated funds including those that otherwise would be available for distribution to its members. BFA Attachment B is the 2017 - 2018 certified financial statements of Specialists' One-Day Surgery, LLC, which shows positive working capital, positive net assets and positive net income of \$8,968,470 in year 2018. BFA Attachment C is the entity's internal financials as of June 30, 2019, which shows positive working capital, positive net assets and net income of \$3,170,208.

The submitted budget indicates net income of \$54,908 during Year One and Year Three after certification of the pain management services at the East Taft Road site. The budget appears reasonable.

Conclusion

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

Supplemental Information

Surrounding Hospital Responses

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas.

St. Joseph's Hospital Health Center -- **No Response**

301 Prospect Avenue
Syracuse, New York 13203

Crouse Hospital -- **No Response**

736 Irving Avenue
Syracuse, New York 13210

University Hospital SUNY Health Science Center -- **No Response**

750 East Adams Street
Syracuse, New York 13210

DOH Comment

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

Attachments

- BFA Attachment A Certified Financial Statements of Specialists' One-Day Surgery, LLC for 2017 and 2018
- BFA Attachment B Internal Financial Statements of Specialists' One-Day Surgery, LLC as of June 30, 2019



**Project # 152243-C
Northern Westchester Hospital**

Program: Hospital
Purpose: Construction

County: Westchester
Acknowledged: November 10, 2015

Executive Summary

Description

Northern Westchester Hospital (NWH), a 245-bed, voluntary not-for-profit, Article 28 acute care hospital located at 400 Main Street, Mount Kisco (Westchester County), requests approval to certify Cardiac Catheterization – Percutaneous Coronary Intervention (PCI) and Cardiac Catheterization - Electrophysiology (EP) services, and perform requisite renovations, on the Mount Kisco campus. The proposed program will be operated with clinical oversight from Lenox Hill Hospital (LHH) in accordance with the terms of an executed clinical service agreement. LHH, a 634-bed, acute care hospital located on Manhattan's Upper East Side, is a full-service cardiac surgery center that provides PCI and cardiac surgery services. Both hospitals are members of Northwell Health, Inc., a not-for-profit corporation located in Nassau County, and are co-operated by Northwell Healthcare, Inc., whose sole corporate member and passive parent is Northwell Health, Inc.

This project will allow NWH to become the regional destination for patients requiring PCI through coordination with LHH. The Cardiac Cath/EP suite will be located on the second floor (Level 2) of the Wallace Pavilion next to NWH's recently relocated Interventional Radiology (IR) service (CON 172409-L). The proposed 1,709 square foot suite will be directly adjacent to surgery, providing an integrative platform aligning all procedures requiring anesthesia on Level 2 of the Wallace Pavilion.

OPCHSM Recommendation
Contingent Approval

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018, Westchester County residents received 733 treatments outside of the Hudson Valley region. Northern Westchester Hospital, projects 115 emergency PCI procedures in Year One and beyond.

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

Project costs of \$3,623,197 will be funded with \$362,320 equity from NWH and a bond issuance for \$3,260,877 at 6.5% interest for a 30-year term. Citigroup Global Markets, Inc. has provided a letter of interest to underwrite the bond financing noting that if the financing is completed on a tax-exempt basis, the bonds will be issued through the Dormitory Authority of the State of New York (DASNY).

<u>Incremental</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$13,592,700	\$13,637,100
Expenses	\$10,211,100	\$10,284,700
Net Income	\$3,381,600	\$3,352,400

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 a bond resolution acceptable to the Department of Health. Included with the submission must be a sources and uses statement and debt amortization schedule, for both new and refinanced debt. (BFA)

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before January 15, 2020 and construction must be completed by October 15, 2020, 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 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 12, 2019

Need Analysis

Background

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in year one of service. Emergency PCI includes any procedure not scheduled and not elective. In the Hudson Valley Health Services Area, seven facilities currently provide PCI services. In 2018, 1,221 Hudson Valley Residents were treated outside of the HSA for currently defined emergency PCI procedures. The six Hudson Valley applicants on the Public Health and Health Planning Council-PHHPC December Agenda that seek certification of Cardiac Catheterization-Percutaneous Coronary Intervention services all project, at minimum, 36 emergency PCI procedures in year-one.

In 2018, Westchester County residents received 733 treatments outside of the Hudson Valley region. Northern Westchester Hospital, projects 115 emergency PCI procedures in year one and beyond. Accompanying patient selection criteria for Electrophysiology procedures has been submitted.

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

Table 1: 2018 Emergency (709.14: 09/25/19) PCI's Performed on Hudson Valley Residents: By: County, By Operational Hudson Valley Facilities, By: Location of Treatment.											
Patient County of Residence	Operational Facilities in the Hudson Valley Region							Resident Outmigration			
	Good Samaritan Suff. (Rockland)	Orange Regional (Orange)	St Luke's Cornwall Newburgh (Orange)	Vassar Brothers (Dutchess)	New York Presbyterian Lawrence (Westchester)	Westchester Med (Westchester)	White Plains (Westchester)	Total	County Residents Treated: All Locations	County Residents Receiving Emergency PCI Treatment in Hudson Valley	County Residents Leaving Hudson Valley for Emergency PCI Treatment
Delaware				4			0	4	131	4	127
Dutchess		3	21	461	4	37	1	527	575	527	48
Orange	90	358	190	24	3	9	0	674	777	674	103
Putnam			2	30	10	55	7	104	137	104	33
Rockland	268	2	2	1	1	11	2	287	412	287	125
Sullivan		141		5		4	0	150	163	150	13
Ulster	3	19	26	263		9	0	320	359	320	39
Westchester		2		6	173	253	331	765	1,498	765	733
Total H. V. Residents receiving Emergency PCIs in Region	361	525	241	794	191	378	341	2,831	4,052	2,831	1,221

Table 2: Applicant Facilities Projected Emergency PCI's

Project	Facility	County	Projected Emergency PCIs	
			Year One	Year Three
152243	Northern Westchester Hospital	Westchester	115	115
162211	New York-Presbyterian Hudson Valley Hospital	Westchester	50	64
162148	Nyack Hospital	Rockland	100	100
171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region.

Northern Westchester Hospital has projected 115 Emergency PCI procedures by Year One of service.

The goals of this project are to:

- Improve patient access to high-quality, coordinated diagnostic cardiac catheterization and PCI procedures to residents in both Westchester and Putnam Counties, including the underserved residents of the service area.
- Improve cardiac health outcomes for the residents of the service area who currently experience health disparities and poor cardiac health outcomes.
- Provide high quality oversight of procedures performed in the new laboratory as a result of a clinical services agreement with Lenox Hill Hospital.
- Decrease outmigration of interventional cardiology cases from Northern Westchester and Putnam Counties to facilities in Connecticut and Manhattan.
- Facilitate Northwell Health in transforming its delivery system in order to transition from its current Fee-For-Service Payment model to an accountable Value-Based Payment (VBP) model.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Program Description

The program will be coordinated (via an executed clinical service agreement) with Lenox Hill Hospital (LHH), a 634-bed acute care hospital on Manhattan's Upper East Side that offers a full-service cardiac surgery center and is also a member of Northwell Health. Lenox Hill Hospital will facilitate integration of expertise and resources for the cardiac catheterization laboratory located at NWH and will provide clinical leadership, day-to-day supervision and quality oversight. Further, all existing policies and procedures currently in place at LHH will be incorporated into the operation of the lab at NWH and patients who require surgery will be transferred to LHH or Westchester Medical Center.

The proposed lab will include:

- One adult PCI/EP cardiac catheterization lab
- 24/7 Interventional staff coverage provided by LHH full-time faculty
- Telemedicine capabilities enabling review of cardiac catheterization laboratory studies by LHH as needed.

- Onsite Medical Director provided by Lenox Hill Hospital.
- Surgical back-up provided by Lenox Hill Hospital (with more critically ill patients to be transferred to Westchester Medical Center)
- The existing ICU/CCU unit will house five (5) dedicated CCU bays for cardiac catheterization and EP patients for recovery and continuation of care.

Upon approval, Northern Westchester Hospital will have the following services added to their operating certificate:

- Cardiac Catheterization – Percutaneous Coronary Intervention (PCI)
- Cardiac Catheterization – Electrophysiology (EP)

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and electrophysiology services and they have assured the Department that their program will meet all of the requirements of 405.29(e)(1), 405.29(e)(2) and 405.29(e)(5).

Compliance with Applicable Codes, Rules and Regulations

The Department issued a Stipulation and Order (S&O) dated November 21, 2016 and fined Northern Westchester Hospital \$10,000 based on an investigation of the death of a newborn due to the code team not being called in a timely manner via the proper procedure. Deficient practice was cited in the area of Nursing Services.

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

Northern Westchester Hospital states that a PCI-capable cardiac catheterization lab would further advance the local Prevention Agenda in that it would aim to improve timely access to high-quality treatment and management of cardiac disease within a clinical setting. Cardiac intervention services provided to patients in Northern Westchester Hospital would fall within the wider continuum of high-quality cardiac care that all Northwell Health patients have access to within its network for providers.

The applicant provides a list of initiatives and objectives are aligned with the goals of the Prevention Agenda 2013-2017. These include preventing chronic and vaccine preventable diseases; promoting initiatives that focus on primary and secondary prevention; healthy women, children and infants; mental health; promoting access to quality health care and reducing health disparities; and preventing chronic and preventable diseases. It is unclear from the documentation if these are also the goals selected by the Westchester County Prevention Agenda Community Coalition. The applicant does not plainly describe involvement in the community-wide health planning activities with the Westchester County Health Department.

Northern Westchester Hospital selects its metrics from the Prevention Agenda dashboard. The applicant provided the following measures as demonstrating an improvement between 2016 and 2017:

- Age-adjusted preventable hospitalizations rate per rate per 10,000 (Age 18+ years)
- Age-adjusted heart attack hospitalization rate per 10,000 population
- An increase on process improvement initiatives to increase the ratio of follow-up appointments for new patients

In 2014 (the latest electronic filing available) the applicant spent \$0 on community health improvement services, representing 0% of total operating expenses.

Conclusion

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

Clinical Services and Quality Oversight Agreement

The applicant has submitted an executed Clinical Services and Quality Oversight Agreement:

Execution Date:	October 21, 2015
Service Provider:	Lenox Hill Hospital located at 100 East 77 th Street, New York, NY
Facility Operator:	Northern Westchester Hospital located at 400 Main Street, Mount Kisco, NY
Services rendered:	Back-up to laboratory patients who require Cardiac Surgery Center Services; quality improvement program (jointly); inclusion in Northwell's interventional database; training for personnel on the database; participation in a joint annual study on financial impact; involvement in research studies; inclusions in registries and database; quality assurance activities; at least 10 meetings per year between health professionals; and coverage in labs for 365 days per year, 24 hours per day and ongoing education and training.
Term:	5 years with one-year renewals each year thereafter.

NWH joined Northwell Health, Inc. on January 1, 2015. As NMH and LHH are both members of Northwell Health, Inc., there are no fees associated with the agreement.

The applicant has confirmed that the agreement remains valid and will not take effect until NMH receives CON approval by the Department of Health to establish a cardiac catheterization program at the Mount Kisco campus. The agreement provides that NWH shall be responsible for the day-to-day operations of the Cath Lab and that both parties shall jointly develop a quality improvement program. NWH will establish a telemedicine link that provides LHH representatives with the ability to review Laboratory studies in a timely manner.

Total Project Cost and Financing

Total project costs for renovations and movable equipment are estimated at \$3,623,197, as follows:

Renovation & Demolition	\$760,000
Design Contingency	70,000
Construction Contingency	70,000
Planning Consultant Fees	20,000
Architect/Engineering Fees	60,000
Construction Manager Fees	38,000
Other Fees	22,000
Movable Equipment	2,388,356
Financing Costs	173,033
Application Fee	2,000
Processing Fee	<u>19,808</u>
Total Project Cost	\$3,623,197

Project costs are based on a six-month construction starting January 2020.

The applicant's financing plan appears as follows:

Equity	\$362,320
Bond Issuance (6.5% interest, 30-year term)	<u>\$3,260,877</u>
Total	\$3,623,197

Citigroup Global Markets, Inc. has provided a letter of interest to underwrite the bond financing noting that if the financing is completed on a tax-exempt basis, the bonds will be issued through DASNY.

Operating Budget

The applicant has submitted an incremental operating budget, in 2019 dollars, for the first and third years, as summarized below:

	<u>Year One</u>		<u>Year Three</u>	
<u>Inpatient Revenues:</u>	<u>Per Disc.</u>	<u>Total</u>	<u>Per Disc.</u>	<u>Total</u>
Commercial - MC	\$53,069	\$3,714,800	\$52,523	\$3,729,100
Medicare - FFS	\$12,472	1,359,500	\$12,409	1,365,000
Medicare - MC	\$18,453	627,400	\$18,000	630,000
Medicaid - FFS	\$16,380	81,900	\$18,075	72,300
Medicaid - MC	\$21,492	279,400	\$21,569	280,400
Private Pay	\$14,545	<u>160,000</u>	\$14,618	<u>160,800</u>
Total Inpt. Rev.		\$6,223,000		\$6,237,600
<u>Outpatient Revenues:</u>	<u>Per Proc.</u>	<u>Year One</u>	<u>Per Proc.</u>	<u>Year Three</u>
Commercial - MC	\$19,927	\$4,423,700	\$19,918	\$4,441,800
Medicare - FFS	\$5,635	1,938,300	\$5,640	1,945,900
Medicare - MC	\$6,605	719,900	\$6,631	722,800
Medicaid - FFS	\$3,754	48,800	\$3,769	49,000
Medicaid - MC	\$4,870	194,800	\$4,890	195,600
Private Pay	\$1,300	<u>44,200</u>	\$1,306	<u>44,400</u>
Total Outpt. Rev.		\$7,369,700		\$7,399,500
Total Revenue		\$13,592,700		\$13,637,100
<u>Expenses:</u>				
Operating	\$12,590.55	\$9,594,000	\$12,661.65	\$9,673,500
Capital	<u>\$809.84</u>	<u>617,100</u>	<u>\$800.00</u>	<u>611,200</u>
Total	\$13,400.39	\$10,211,100	\$13,461.65	\$10,284,700
Net Income		<u>\$3,381,600</u>		<u>\$3,352,400</u>
Discharges		242		244
Procedures		762		764
Avg Cost/Procedure		\$13,400.39		\$13,461.65

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

	<u>Year One</u>		<u>Year Three</u>	
<u>Inpatient</u>	<u>Disch.</u>	<u>%</u>	<u>Disch.</u>	<u>%</u>
Commercial - MC	70	28.9%	71	29.1%
Medicare - FFS	109	45.0%	110	45.1%
Medicare - MC	34	14.0%	35	14.3%
Medicaid - FFS	5	2.1%	4	1.6%
Medicaid - MC	13	5.4%	13	5.3%
Private Pay	<u>11</u>	<u>4.5%</u>	<u>11</u>	<u>4.5%</u>
Total	242	100.0%	244	100.0%

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

<u>Outpatient</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Proc.</u>	<u>%</u>	<u>Proc</u>	<u>%</u>
Commercial - MC	222	29.1%	223	29.2%
Medicare - FFS	344	45.1%	345	45.2%
Medicare - MC	109	14.3%	109	14.3%
Medicaid - FFS	13	1.7%	13	1.7%
Medicaid - MC	40	5.2%	40	5.2%
Private Pay	34	4.5%	34	4.5%
Total	762	100.0%	764	100.0%

Revenue, expense and utilization assumptions are based on the experience of existing cardiac catheterization lab programs within the System. In particular, the applicant looked at the experience of developing the cardiac program at Southside Hospital in Bay Shore, Long Island, and adjusted for the projected Northern Westchester volume and patient utilization.

Capability and Feasibility

The applicant will fund the total project cost of \$3,623,197 with \$362,320 in equity from NWH and a bond issuance for \$3,260,8770 at 6.5% interest for a 30-year term. Citigroup Global Markets, Inc. has provided a letter of interest to underwrite the bond financing. If the financing is completed on a tax-exempt basis, the bonds will be issued through DASNY. The Northwell Healthcare, Inc.'s CFO has provided a letter indicating their commitment to providing financial support for the program to serve the needs of the community. BFA Attachment A is the certified financial statements of Northern Westchester Hospital for 2018 and their internal financial statements as of June 30, 2019, which indicates the availability of sufficient resources for this project.

Working capital of \$1,714,117 based on two months of third year expenses will come from hospital operations.

The submitted budget represents the incremental budget related to the proposed PCI capable cardiac catheterization and EP suite, and not the hospital as a whole. The budget projects a net gain for the cardiac services for the first and third years of \$3,381,600 and \$3,352,400, respectively. Revenues are based on prevailing payment methodologies and current payment rates. Expenses are based on the experience of other hospitals within the Northwell system.

The certified and internal financial statements presented as BFA Attachment A indicate the availability of sufficient resources to meet equity requirements and maintain the current project. As shown, the Hospital has maintained positive working capital, positive net asset position and had an average net gain for all periods shown.

Conclusion

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

Attachments

- RNR Attachment A Map
- BFA Attachment A Northern Westchester Hospital's 2018 certified financial statements and internal financial statements as of June 30 ,2019
- BFA Attachment B Northwell Health Inc. Organizational Chart



Project # 162211-C
NewYork-Presbyterian/Hudson Valley Hospital

Program: Hospital
Purpose: Construction

County: Westchester
Acknowledged: September 22, 2016

Executive Summary

Description

Hudson Valley Hospital Center d/b/a New York-Presbyterian Hudson Valley Hospital (NYP/HV), a 128-bed, voluntary not-for-profit, Article 28 acute care hospital located at 1980 Crompond Rd, Cortlandt (Westchester County), requests approval to certify Cardiac Catheterization – Electrophysiology (EP) and Cardiac Catheterization – Percutaneous Coronary Intervention (PCI) services and renovate space to construct a new suite to house one Cardiac Catheterization Lab and one laboratory for EP and other minor procedures. The applicant will modify 8,262 square feet of space on the third floor of the original hospital building to create the new suite.

NYP Community Programs, Inc. (NYP), a wholly owned subsidiary of The New York and Presbyterian Hospital (NYPH), became the sole member and active parent/co-operator of NYP/HV in January 2015. One of the main goals of the relationship was to establish a coordinated and integrated system with the objective of improving quality and increasing access at the regional level for the communities served by NYP/HV.

NYP/HV has a formal clinical sponsorship agreement with NYP/Columbia University Irving Medical Center (NYP/Columbia). By integrating the cardiac resources of NYP/Columbia and coordinating care from an integrated system perspective, NYP/HV will be able to expand NYP/Columbia's cardiac program, broadening access to critical cardiac services in NYP/HV's service area, while enhancing clinical quality and outcomes by adopting common protocols, quality measures, and safety standards.

OPCHSM Recommendation
Contingent Approval

Need Summary

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in Year One of service. In 2018, Westchester County residents received 733 treatments outside of the Hudson Valley region. New York Presbyterian, Hudson Valley Hospital projects 50 emergency PCI procedures in Year One and 64 in Year Three.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

Total project costs of \$13,073,500 will be met via accumulated funds.

<u>Incremental</u>	<u>First Year</u>	<u>Third Year</u>
Revenues	\$8,965,316	\$9,993,879
Expenses	<u>\$9,547,565</u>	<u>\$11,289,034</u>
Gain/(Loss)	(\$582,249)	(\$1,295,155)

	<u>In 000's</u>		
<u>Enterprise</u>	<u>Current Year</u>	<u>First Year</u>	<u>Third Year</u>
Revenue	\$4,182,124	\$4,191,089	\$4,192,118
Expenses	<u>\$4,018,780</u>	<u>\$4,028,328</u>	<u>\$4,030,069</u>
Gain	\$163,344	\$162,762	\$162,049

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 Design Development and State Hospital Code (SHC) Drawings, as described in BAER Drawing Submission Guidelines DSG-1.0 and 2.18 LSC Chapter 18 Healthcare Facilities Public Use for review and approval. [DAS]
3. Submission of documentation that a data manager has been hired, acceptable to the Department. [HSP]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before February 3, 2020 and construction must be completed by October 16, 2020, 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 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.

Council Action Date

December 12, 2019

Need Analysis

Background

New York Title 10 Cardiac Services Regulation 709.14, effective September 25, 2019, requires facilities seeking to add percutaneous coronary intervention, PCI, services to project a minimum of 36 emergency PCI procedures in year one of service. Emergency PCI includes any procedure not scheduled and not elective. In the Hudson Valley Health Services Area, seven facilities currently provide PCI services. In 2018, 1,221 Hudson Valley Residents were treated outside of the HSA for currently defined emergency PCI procedures. The six Hudson Valley applicants on the Public Health and Health Planning Council-PHHPD December Agenda that seek certification of Cardiac Catheterization-Percutaneous Coronary Intervention services all project, at minimum, 36 emergency PCI procedures in Year One.

In 2018, Westchester County residents received 733 treatments outside of the Hudson Valley region. New York Presbyterian, Hudson Valley Hospital projects 50 emergency PCI procedures in Year One and 64 in Year Three. Accompanying patient selection criteria for Electrophysiology procedures has been submitted.

Analysis

Please refer **RNR Attachment A** - Hudson Valley PCI and Emergency PCI Procedures by County, by Resident, by Existing Provider, and by Applicant Projection.

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Table 2: Applicant Facilities Projected Emergency PCI's

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			Year One	Year Three
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162148	Nyack Hospital	Rockland	100	100
171415	Northern Dutchess Hospital	Dutchess	51	51
172251	Putnam Hospital Center	Putnam	36	36
191260	Health Alliance Hospital Mary's Ave Campus	Ulster	103*	103

**Based on the transfer of Acute Myocardial Infarction with and without complications.*

In 2018, residents of the Hudson Valley underwent 4,052 emergency PCI treatments. Of these, 2,831 procedures were performed within the Hudson Valley Region and 1,221 were performed out of the region. New York-Presbyterian/Hudson Valley Hospital projects 50 Emergency PCI procedures by Year One of operation.

By providing PCI-capable Cardiac Cath and EP services, NYP/Hudson Valley proposes to achieve the following goals:

- Improve regional access to advanced cardiac services including diagnostic cardiac catheterization, PCI, and EP services for the communities served by NYP/Hudson Valley;
- Improve cardiac health outcomes for residents of the NYP/Hudson Valley service area; and
- Provide a continuum of care for patients already treated at NYP/Hudson Valley.

Conclusion

Additional PCI programs will decrease the number of patients who have to leave the region in which they live to receive this service.

Program Analysis

Project Proposal

The proposed program will operate with clinical oversight from New York-Presbyterian/Columbia University Medical Center (NYPCUMC) in accordance with the terms of an executed clinical sponsorship agreement. New York-Presbyterian/Columbia University Medical Center is a 1007-bed, academic facility located at 622 West 168th Street in Manhattan (New York County) that is a full-service cardiac surgery provider.

NYPHVM will renovate existing space on the first floor. Staffing is expected to increase by 15.2 FTEs in the first year after completion and increase to 18.9 FTEs by the third year of operation.

The project will result in NYPHVM's operating certificate changing to add the following certified services:

- Cardiac Catheterization - Percutaneous Coronary Intervention (PCI)
- Cardiac Catheterization - Electrophysiology (EP)

The Applicant has submitted a written plan that demonstrates their ability to comply with all of the standards for PCI Capable Cardiac Catheterization Laboratories and Cardiac Electrophysiology (EP).

Compliance with Applicable Codes, Rules and Regulations

This facility has no outstanding Article 28 surveillance or enforcement actions and, based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

The hospital will make special efforts to reach underserved populations in their primary service area. The target locations were specified in the application by ZIP codes (i.e., includes sections of Westchester, Putnam, Dutchess, and Orange Counties) and the demographics for the hospital's service were described. The high-risk population was specified according to high unemployment, median household income and no insurance. Access to this population is provided through community initiatives, engagement with the Prevention Agenda and having a medical office in Peekskill. Financial, linguistic and cultural barriers make it difficult for these populations to receive basic medical care and cardiac services. Increased access to care for these populations will improve diagnosis and treatment of cardiac risks and provide a continuum of care. The applicant provided a detailed breakdown for each of these metrics.

The applicant described in sufficient detail:

1. the interventions being implemented to support local Prevention Agenda goals;
2. engagement of local community partners in Prevention Agenda efforts; and
3. data being used to track progress.

Most of these activities emphasize health education (e.g., cooking demonstrations, farmers' markets, health fairs), rather than policy and environmental changes. Effort to form and sustain strategic partnerships, serve as an anchor institution in the community, and train OB staff on the benefits of breastfeeding are examples of the role that the hospital should play in promoting healthy behaviors. A greater emphasis on these actions would strengthen the hospital's role in advancing the Prevention Agenda priorities.

In 2017 the applicant spent \$1,370,603 on community health improvement services, representing 0.668% of total operating expenses.

Conclusion

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

Total Project Cost and Financing

Total project cost for renovation/demolition, moveable equipment, and construction is estimated at \$13,073,500, broken down as follows:

Renovation & Demolition	\$3,600,000
Site Development	\$15,500
Design Contingency	\$360,000
Construction Contingency	\$360,000
Architect/Engineering Fees	\$498,439
Other Fees	\$992,921
Movable Equipment	\$7,173,140
Application Fee	\$2,000
Additional Fee for Projects	<u>\$71,500</u>
Total Project Cost with Fees	\$13,073,500

Project costs are based on an eight-month construction starting February 2020. The applicant will finance the total project cost via \$13,073,500 equity.

Operating Budget

The applicant submitted an incremental operating budget, in 2019 dollars, for Years One and Three:

<u>Revenues</u>	<u>Year One</u>	<u>Year Three</u>
Total Inpatient Rev	\$4,595,160	\$5,189,247
Total Outpatient Rev	<u>\$4,370,156</u>	<u>\$4,804,632</u>
Total Revenue	\$8,965,316	\$9,993,879
<u>Inpatient Expenses</u>		
Operating	\$4,916,487	\$5,441,522
Capital	<u>\$285,899</u>	<u>\$532,816</u>
Total Inpt Expense	\$5,202,386	\$5,974,338
<u>Outpatient Expenses</u>		
Operating	\$3,916,328	\$4,515,473
Capital	<u>\$428,849</u>	<u>\$799,223</u>
Total Outpt Expense	\$4,345,177	\$5,314,696
Total Expense	\$9,547,563	\$11,289,034
Net Income/(Loss)	<u>(\$582,249)</u>	<u>(\$1,295,155)</u>
<u>Utilization (Procedures)</u>		
Inpatient	200	212
Outpatient	<u>547</u>	<u>580</u>
Total	747	792
Avg Cost Per Procedure	\$12,781.21	\$14,253.83

The following is noted with respect to the operating budget:

- Revenues are based on prevailing payment rates by payor for cardiac catheterization procedures. The inpatient and outpatient payment rates are based upon the experience of NYP for cardiac services under Medicare and Medicaid payment methodologies, and commercial payor contracts that are based on negotiated rates.
- Utilization is based on the population characteristics of NYP/HV's service area, which includes sections of Westchester, Putnam, Dutchess and Orange Counties. The incidence and mortality rates from cardiovascular disease for these residents evidence the need for PCI and EP services.

- Expenses are based on the experience of NYP and include incremental labor costs for staff FTEs (physician’s assistants, registered nurses and technician/specialist), as well as the capital cost related to the expansion project.
- Utilization by payor source is as follows:

<u>Inpatient</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Disch</u>	<u>%</u>	<u>Disch</u>	<u>%</u>
Commercial FFS	59	29.50%	63	29.72%
Medicare FFS	77	38.50%	82	38.68%
Medicare MC	29	14.50%	31	14.62%
Medicaid FFS	4	2.00%	4	1.89%
Medicaid MC	28	14.00%	29	13.68%
Private Pay/Other	3	1.50%	3	1.41%
Total Inpatient	200	100.00%	212	100.00%

<u>Outpatient</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Visits</u>	<u>%</u>	<u>Visits</u>	<u>%</u>
Commercial FFS	103	29.68%	109	29.62%
Medicare FFS	133	38.33%	141	38.32%
Medicare MC	50	14.41%	54	14.67%
Medicaid FFS	7	2.02%	8	2.17%
Medicaid MC	48	13.83%	50	13.59%
Private Pay/Other	6	1.73%	6	1.63%
Total Outpatient	347	100.00%	368	100.00%

Capability and Feasibility

The total project cost of \$13,073,500 will be met entirely through accumulated funds. The submitted incremental budget demonstrates net losses of \$582,249 and \$1,295,155 in Year One and Year Three, respectively. The enterprise budget shows a net income of \$162,761,751 and \$162,048,845. The budget appears reasonable. As shown on BFA Attachment A, the facility has enough funds to cover the operating losses of the new service line.

BFA Attachment A is the 2017-2018 certified and internal financial statements of NYP/HV as of July 31, 2019, which shows positive working capital and net asset positions for the period. The facility also generated an average net income of \$1,646,500 for the 2017-2018 period and a net loss of \$2,309,000 for the period ended July 31, 2019. The losses in 2018 and 2019 were caused by investments the hospital and medical group made in primary care and physician specialties, including the recruitment of physicians. The operating losses will be offset and funded by working capital provided by ongoing hospital operations of New York-Presbyterian Hospital.

BFA Attachment B is the 2018 certified and internal financial statements of New York Presbyterian Hospital as of August 31, 2019, which shows positive working capital and net asset positions for the period shown. The facility also generated a net income of \$198,441,000 for 2018 and a net income of \$184,785,000 for the period ended August 31, 2019.

Conclusion

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

Attachments

- RNR Attachment A Map
- BFA Attachment A 2017-2018 certified and internal financial statements of NYP/Hudson Valley Hospital as of July 31, 2019
- BFA Attachment B 2018 certified and internal financial statements of New York Presbyterian Hospital as of August 31, 2019



Project # 121223-C
Excellent Home Care Services, LLC

Program: Certified Home Health Agency
Purpose: Construction

County: Kings
Acknowledged: April 18, 2012

Executive Summary

Description

Excellent Home Care Services, LLC (Excellent), an existing Special Population Certified Home Health Agency (CHHA) serving Bronx, Kings, New York, Queens and Nassau Counties, requests approval to become a General Purpose CHHA to serve the same counties.

On December 8, 2011, the Public Health Council adopted an amendment to Section 760.5 of Title 10 NYCRR. This emergency regulation authorized the Commissioner of Health to issue a request for applications (RFA) to establish new certified home health agencies or expand the approved geographic service areas and/or approved population of existing CHHA's. Excellent submitted an application in response to the competitive RFA and was awarded RFA approval. This CON application is in response to the RFA approval.

In 2018, approximately eighty percent (80%) of Excellent's patient population was comprised of OPWDD patients. Excellent proposes that by converting to a General Purpose CHHA, the agency will be able to expand its patient population, which in turn would allow for increased financial stability and ultimately enable Excellent to continue to maintain its commitment to serving the OPWDD population.

Concurrently under review is CON 191075 in which the current operators, Benjamin Landa (50%) and the Guttman Estate (50%), seek approval to transfer 100% membership interest in Excellent to Excel Health LLC (50%) and Superb Health LLC (50%).

OPCHSM Recommendation Approval

Need Summary
The CON determination of need was based on the applicant's response to the RFA.

Program Summary
This proposal will have no impact on the counties served or services provided by Excellent Home Care Services, LLC. Excellent will continue to serve the OPWDD population while broadening their focus to include those outside that population.

Financial Summary
There are no project costs associated with this application. The projected budget is as follows:

Table with 3 columns: Category, Year One, Year Three. Rows: Revenues, Expenses, Net Income.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval conditional upon:

1. Pursuant to 10 NYCRR 762.2(l), the applicant shall implement the project that is the subject of this application within 90 days of receipt of the Commissioner's approval of the application and be providing services in the entire geographic area approved within one year of the Council's recommendation for approval. Failure to implement an approved application within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the Commissioner's approval. [CHA]

Council Action Date

December 12, 2019

Need Analysis

Background

On December 8, 2011 the Public Health and Health Planning Council adopted an amendment to Section 750.5 of Title 10, NYCRR authorizing the Commissioner of Health to issue a request for applications (RFA) to establish new certified home health agencies (CHHAs) or expand existing CHHAs. Public need was based on established criteria in section 709.1(a) of Title 10 and that approval of the application will facilitate implementation of Medicaid Redesign Initiatives to shift Medicaid beneficiaries from traditional fee-for-service programs to managed care, managed long term care systems, integrated health systems or similar care coordination models or that approval will ensure access to CHHA services in counties with fewer than 2 existing CHHAs.

Solicitation

The RFA for the establishment of new or expansion of existing CHHAs was released on January 25, 2012 with RFA applications due on March 9, 2012 and CON applications due on April 20, 2012. Applicants were permitted to submit questions to the Department to seek additional clarification regarding this process. The Department's answers were provided to all applicants prior to the submission deadline, to ensure consistent information was shared regarding the process.

Applicants that were not presented to the Public Health and Health Planning Council with a recommendation for approval at either the August 2012 or October 2012 meetings were considered deferred. The department notified RFA applicants that we are exercising our authority under the RFA Section VII.D.5 to seek clarifications and revisions of applications from those applicants whose applications have been deferred. Letters dated September 17, 2012 and September 27, 2012 were sent to these applicants through NYSECON and included information related to the review and evaluation criteria and characteristics of approved applicants.

Additionally, the opportunity to arrange a meeting or phone conference with the Division of Home and Community Based Services to discuss the RFA criteria that was used to evaluate each application was made available to each applicant in 2012.

Competitive Review

The CON determination of need was based on the applicant's response to the RFA which includes any additional information submitted by the applicant in response to the aforementioned September 17th and 27th letters. The applications were reviewed on criteria that included, but were not limited to:

- Organizational capacity to successfully implement the MRT initiatives and potential of the proposal to support the goals of the Department in advancing MRT initiatives;
- Knowledge and experience in the provision of home health services;
- Demonstration of public need based on 709.1(a) as well as a description of community need and the health needs of the community supported by data;
- Potential of the approved application to produce efficiencies in the delivery of home care services to the home care population;
- Comprehensive and effective quality assurance plan which described how the agency will use data to implement an ongoing quality assessment and performance improvement program that leads to measurable and sustained improvement in performance.

Excellent Home Care Services, LLC provided the following details regarding how the agency would operate in support of several Medicaid Redesign Team (MRT) initiatives:

MRT #5 Reduce and Control Utilization of Certified Home Health Agency Services.

Excellent states that they will continue working towards preventing unnecessary utilization, which is a particular concern for the high-risk and high-cost population currently served by the CHHHA. As an existing CHHA, Excellent already has the necessary infrastructure and relationships with other health care providers to ensure continued efficiency and effectiveness upon conversion to a General Purpose CHHA.

MRT #89 Health Homes for High Cost, High Need Enrollees

This MRT goal is particularly relevant to Excellent given its Special Population designation. The OPWDD population served by Excellent often requires a higher volume of services. Excellent is currently a partner in three health Homes and is working to become a part of Health Homes in other counties. Excellent's participation promotes continuity of care and a seamless transition between hospital, home care, and community programs in which Excellent's clients may participate.

MRT #90 Mandatory Enrollment in MLTC Plans/ Health Home Conversion

Excellent Home Care Services, LLC currently has contracts with four Managed Long Term Care Plans (MLTCPs) and is working on securing additional contracts. Excellent intends to work closely with its contracted MLTCPs in order to meeting Medicaid Redesign Team initiatives.

MRT #191 Decrease the Incidence and Improve the Treatment of Pressure Ulcers.

Excellent is a participant in the Gold Stamp Program to Reduce Pressure Ulcers. The Centers for Medicare and Medicaid Services (CMS) collects and reports data regarding the quality of patient care for certified home health agencies and compares it to both the state and national averages. As of July 31, 2019, the New York State and National Average for the quality indicator "How often patients developed new or worsened pressure ulcers" is 0.4%. Excellent exceeds the state and national average for this indicator, with a measurement of 0.0%.

The applicant has stated that their clinically sophisticated program of care, which is focused on disease states and management, emphasizes coordination of care, leads to a personalized plan of care for each patient and is able to reduce avoidable hospital and nursing home admissions and readmissions while maintaining and improving patient health. The disease-centered plan of care is supported by the use of an Electronic Medical Record (EMR) and enables Excellent to focus on each client's core health issues in a unique and individualized manner. Excellent's health IT system has helped the agency control utilization and adapt to reimbursement changes.

Excellent Home Care Services, LLC provided data from a variety of sources as well as a detailed analysis of the data that demonstrated public need as specified in 10 NYCRR 709.1(a) and community need in each of the counties proposed. The applicant projected growth in the elderly populations, persons receiving income support, disabled elderly population, mortality rates and Prevention Quality Indicator (PQI) rates by race/ethnicity.

Program Analysis

Review Summary

This application was previously presented for consideration in May 2013 and January 2014 in response to the Department's Request for Applications (RFA). In both instances the application was deferred by the Establishment and Project Review Committee of PHHPC.

Per the applicant, Excellent is proposing to convert to a General Purpose CHHA in order to strengthen and stabilize the agency's operating capabilities by allowing the addition of new patients, which previously had to be turned away due to the Special Population designation. The applicant sites low reimbursement rates as a major obstacle to maintaining operations and states that these low rates have placed the agency in financial jeopardy and at risk of closure. In 2018, approximately eighty percent (80%) of Excellent's patient population was OPWDD patients. Excellent proposes that by converting to a General Purpose CHHA, the agency will be able to expand its patient population, which in turn would allow for increased financial stability and ultimately enable Excellent to continue to maintain its commitment to serving the OPWDD population.

This proposal will not change the counties served or services provided by Excellent Home Care Services, LLC. Excellent will continue to serve the OPWDD population and will also begin their approved services of Nursing, Physical Therapy, Occupational Therapy, Home Health Aide, Personal Care Aide, Speech & Language Pathology, Respiratory Therapy, Medical Social Work, Medical Supplies, Equipment and Appliances and Nutrition to client's outside of the OPWDD population.

Excellent Home Care Services, LLC has made significant progress toward becoming compliant with their conditional approval to serve the developmentally disable population. In 2010, patients from the special population made up 30% of the total number of patients served by Excellent. In 2012, that number grew to approximately 58%. The percentage has continued to grow, with reports of 67% in 2015, 78% in 2016, 81% in 2017 and 82% in 2018.

Facility Compliance/Enforcement

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

CHHA Quality of Patient Care Star Ratings as of August 1, 2019	
New York Average: 3.5 out of 5 stars National Average: 3.5 out of 5 stars	
CHHA Name	Quality of Care Rating
Excellent Home Care Services, LLC	3 out of 5 stars

Conclusion

Excellent Home Care Services, LLC is currently in compliance with all applicable codes, rules and regulations.

Financial Analysis

Operating Budget

The applicant submitted their current year results (2018), and their projected first- and third-year operating budgets, in 2019 dollars as summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>	<u>Total</u>	<u>Total</u>	<u>Total</u>
Commercial-FFS	\$1,269,491	\$1,318,360	\$1,843,276
Medicare-MC	\$6,409,306	\$7,027,270	\$8,044,174
Medicaid-FFS	\$27,289,745	\$29,556,098	\$33,285,542
Medicaid-MC	<u>\$5,842,611</u>	<u>\$6,368,365</u>	<u>\$7,233,530</u>
Total Revenue	\$40,811,153	\$44,270,093	\$50,406,522
<u>Expenses</u>			
Operating	\$39,788,448	\$42,523,392	\$46,715,686
Capital	<u>\$423,611</u>	<u>\$423,611</u>	<u>\$423,611</u>
Total Expenses	\$40,212,059	\$42,947,003	\$47,139,297
Net Income	<u>\$599,094</u>	<u>\$1,323,090</u>	<u>\$3,267,225</u>
Total Visits *	70,573	83,133	103,804
Total Hours **	1,132,996	1,208,046	1,331,546

*Nursing, PT, OT, Speech Pathology, Medical Social Services

**Hours are for Home Health Aide

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

<u>Payor</u>	<u>Current Year</u>	<u>First Year</u>	<u>Third Year</u>
Commercial-FFS	6.97%	6.15%	5.22%
Medicare-MC	38.32%	35.59%	32.54%
Medicaid-FFS	46.13%	48.51%	51.17%
Medicaid-MC	7.41%	8.46%	9.63%
Charity Care	1.17%	1.30%	1.44%
Total	100%	100%	100%

The following is noted with respect to the submitted budget:

- Revenues, expenses and utilization are based on historical experience. The projected Year One and Year Three increases reflect the expansion in utilization expected as if CON 121223 is approved to convert from a Special Population CHHA to a General Purpose CHHA.
- Capital cost includes annual rent expense of \$399,964 (verified per the 2018 certified financial statements) that are expected to continue upon re-negotiation of the expired lease.
- According to the 2018 cost report, the average cost per hour is \$25.53 for Home Health Aide Hours. Medicare, Medicaid, and Commercial revenues are based on an episodic payment methodology. Projected Medicaid revenue is based on the 2018 CHHA Medicaid payment rate as proxy.
- Utilization is based on existing historical services and the current footprint it currently services using historical data and projections based on increased need as projected under companion CON 121223.
- The CHHA has an existing charity care policy which will continue to be utilized after the transfer of membership interest.

Capability and Feasibility

There are no project costs associated with this application. The submitted budget indicates a net income of \$1,323,090 and \$3,267,225 in the first and third year, respectively. Revenues are based on the current reimbursement methodologies for the current services provided. The submitted budget is reasonable based on the population expansion approval of this application will enable.

BFA Attachment A is the 2017 and 2018 certified financial statements of Excellent Home Care Services, LLC, which indicate the facility achieved positive net asset and working capital positions and generated positive net income for the periods shown. BFA Attachment B is their internal financial statement as of July 31, 2019, which shows a positive net asset position of \$4,610,328, a positive working capital position of \$8,450,819 and net income of \$3,099,393.

The working capital requirement will be funded via operations as provided in CON 191075, which is concurrently under review.

Attachments

BFA Attachment A	2017 and 2018 Certified Financial Statements
BFA Attachment B	Internal Financial Statements (January 1, 2019 – July 31, 2019)



Project # 191123-E Preferred Certified, LLC

Program: Certified Home Health Agency Purpose: Establishment

County: Bronx Acknowledged: March 7, 2019

Executive Summary

Description

Preferred Certified, LLC, an existing New York limited liability company, requests approval to be established as the new operator of Park Gardens CHHA, a proprietary, Article 36 certified home health agency (CHHA) located at 6677-B Broadway, Bronx (Bronx County). The CHHA is currently owned and operated by Park Gardens Rehabilitation and Nursing Center LLC, which also operates a 200-bed residential health care facility located at 6585 Broadway, Riverdale (Bronx County). The CHHA is certified to serve Bronx, New York and Westchester counties and is licensed to provide the following services: Audiology, Home Health Aide, Homemaker, Housekeeper, Medical Social Services, Medical Supplies/Equipment and Appliances, Nursing, Nutritional, Personal Care, Occupational Therapy, Physical Therapy, Respiratory Therapy, and Speech-Language Pathology Therapy. Upon Public Health and Health Planning Council (PHHPC) approval of this application, the agency will be called Preferred Certified. There will be no change in counties served or services provided.

On June 13, 2018, Park Gardens Rehabilitation and Nursing Center LLC and Preferred Certified, LLC entered into an Asset Purchase Agreement (APA) for the sale and acquisition of the CHHA operations and certain assets for a purchase price of \$250,000. The APA will close upon approval by the Public Health and Health Planning Council (PHHPC). Concurrently, the applicant executed an Interim Consultative Agreement (ICA) and a Management Agreement (MA) proposal to manage the day-to-day activities of the CHHA. The applicant has been managing the CHHA under the terms of the ICA

since June 13, 2018, then subsequently under the MA which received Department of Health approval on August 28, 2018. The MA will continue in full force until PHHPC approval of the change in ownership.

Ownership of the CHHA before and after the requested change is as follows:

Table with 2 columns: Member, % under Current Operator Park Gardens Rehabilitation and Nursing Center LLC. Row: Solomon Abramczyk, 100%

Table with 2 columns: Members, % under Proposed Operator Preferred Certified, LLC. Rows: Samuel Ari Weiss (66.67%), Shmuel Berry Weiss (33.33%)

OPCHSM Recommendation Contingent Approval

Need Summary The change in ownership of the CHHA will not result in any changes to the counties being served or the services provided.

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

Financial Summary

There are no project costs associated with this proposal. The purchase price for the assets is \$250,000 to be met via equity.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,277,452	\$2,300,226
Expenses	<u>1,549,306</u>	<u>1,570,969</u>
Net Income	\$728,146	\$729,257

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. Provide a copy of the Articles of Organization of Preferred Certified LLC, acceptable to the Department. (CSL)
2. Provide a copy of the lease for the premises, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Proposal

Preferred Certified, LLC a limited liability company, requests approval to become the new operator of Park Gardens Rehabilitation and Nursing Center, LLC d/b/a Park Gardens CHHA under Article 36 of the Public Health Law.

Under an approved Management Agreement, Preferred Certified, LLC has been managing the day-to-day activities of Park Gardens Rehabilitation and Nursing, LLC d/b/a Park Gardens CHHA since August 28, 2018 and are now seeking approval to be established as the new operator of Park Gardens CHHA. Upon approval of this project, the Management Agreement will be terminated. Additionally, the name of the CHHA will change from Park Gardens Rehabilitation and Nursing Center, LLC d/b/a Park Gardens CHHA to Preferred Certified.

Park Gardens Rehabilitation and Nursing Center, LLC d/b/a Park Gardens CHHA serves Bronx, New York and Westchester counties from an office located at 6677B Broadway, Bronx, 10471. Upon approval of this project, the CHHA will be located at 5223 Broadway, Bronx, 10463. The CHHA is licensed to provide the following services, which will not change after approval: Audiology, Home Health Aide, Homemaker, Housekeeper, Medical Social Services, Medical Supplies/Equipment and Appliances, Nursing, Nutritional, Personal Care, Occupational Therapy, Physical Therapy, Respiratory Therapy, and Speech-Language Pathology Therapy.

In 2017, Park Gardens Rehabilitation and Nursing Center, LLC d/b/a Park Gardens CHHA was unable to provide charity care due to low utilization and higher than expected operating expenses. The new proposed operator, Preferred Certified, LLC has committed to providing one percent (1%) charity care in Year One and two percent (2%) by Year Two of project implementation. Preferred Certified, LLC plans to implement a new business plan for the CHHA which includes stronger community outreach, increased advertising and building a strong referral system to achieve this goal.

Character and Competence Review

The membership of Preferred Certified, LLC is as follows:

Samuel A. Weiss – Managing Member, 66.67%

President, NAE Edison, LLC d/b/a Edison Home Health Care (LHCSA)

Affiliations

- NAE Edison, LLC d/b/a Edison Home Health Care (LHCSA)
- Assistcare Home Health Services LLC d/b/a Preferred Home Care Of New York (LHCSA)
- The W Group of Goshen d/b/a Goshen Manor (ACF) (October 2017 – Present)
- The W Assisted Living at New Broadview (ACF) (February 2018 – Present)
- New Broadview Manor Home for Adults LHCSA (February 2018 – Present)

Shmuel B. Weiss – CEO Member, 33.33%

President/CEO, Assistcare Home Health Services LLC d/b/a Preferred Home Care of New York (LHCSA)

Affiliations

- Assistcare Home Health Services LLC d/b/a Preferred Home Care of New York (LHCSA)
- New Broadview Manor Home for Adults LHCSA (February 2018 – Present)
- The W Group of Goshen d/b/a Goshen Manor (ACF) (October 2017 – Present)
- The W Assisted Living at New Broadview (ACF) (February 2018 – Present)

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The information provided by the Division of Adult Care Facilities and Assisted Living Surveillance and the Division of Home and Community Based Services has indicated that the applicant has provided sufficient

supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

CHHA Quality of Patient Care Star Ratings as of September 30, 2019 New York Average: 3.5 out of 5 stars National Average: 3.5 out of 5 stars	
CHHA Name	Quality of Care Rating
Park Gardens Rehabilitation and Nursing Center, LLC d/b/a Park Gardens CHHA	1.5 out of 5 stars

Conclusion

The establishment of Preferred Certified, LLC as the new operator will result in no changes to the services or service area of the CHHA. Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a certified home health agency.

Financial Analysis

Asset Purchase Agreement (APA)

The applicant has submitted an executed APA for the purchase of the CHHA:

Date:	June 13, 2018
Purpose:	To purchase all rights of the Seller to own and operate the CHHA, and all of the CHHA's assets.
Seller:	Park Gardens Rehabilitation and Nursing Center LLC
Buyer:	Preferred Certified, LLC
Assets Acquired:	All of Seller's right, title and interest in the following: CHHA business and operation; the name "Park Gardens CHHA" and "Park Gardens Home Care" and all other trade names, logos, trademarks, service marks and intellectual property rights; policies, procedures manual and computer software; telephone and fax numbers, domain names and social media accounts used by the business; all patient records relating to the business; copies of all other books and records relating to the business; seller's Medicare and Medicaid provider agreements and provider numbers; all licenses, registrations, CONs, authorizations, permits and any other regulatory approvals held or owned by seller relating to the ownership or operation of the business and the assets; all cash and cash equivalents; all rights to accounts receivable for services rendered by seller on and after the Closing Date; all insurance claims and all other assets of any kind.
Assumed Liabilities:	Buyer shall not assume any obligations, expense or liability of the Seller.
Purchase Price:	\$250,000
Payment of the Purchase Price:	\$250,000 cash at Closing.

The applicant will fund the purchase price via proposed members' equity. BFA Attachment A is the net worth statements of the proposed members, which shows sufficient equity.

The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/r surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of October 22, 2019, the facility had no outstanding Medicaid liabilities.

Lease Rental Agreement

The applicant has submitted an executed lease (modified and extended) for the site that they will occupy, which is summarized below:

Date:	July 1, 2015
Premises:	Store front office space located at 6677B Broadway, Bronx, NY 10471
Landlord:	6677 Broadway RMR LLC
Tenant:	Park Gardens Rehabilitation and Nursing Center LLC
Term:	5 years
Rent:	\$60,482.42 for the first year with a 2.5% increase each year thereafter

The landlord's predecessor-in-interest, Baron 551 LLC, and the Tenant entered into a lease agreement dated March 23, 2010, regarding store front space located at 6677A and 6677B Broadway, Bronx. This original lease, which expired on June 30, 2015, was modified and extended for a term of five years commencing on July 1, 2015. This current master lease agreement expires on June 30, 2020.

The applicant has attested that the lease is an arm's length arrangement, as the landlord and tenant have no relationship.

Sublease Agreement

The applicant has submitted an executed sublease for the site they will occupy, summarized below:

Date:	February 1, 2019
Premises:	Store front office space located at 6677B Broadway, Bronx, NY 10471.
Landlord:	6677 Broadway RMR LLC
Tenant:	Park Gardens Rehabilitation and Nursing Center LLC
Subtenant:	Preferred Certified, LLC
Term:	Lease term commenced on February 1, 2019 and expires June 30, 2020
Rent:	\$2,713.87 per month. (\$32,566.44 annually)

The existing Sublease Agreement will remain in place until June 30, 2020. After PHHPC approval the CHHA will be located at 5223 Broadway, Bronx, 10463

Operating Budget

The applicant has submitted the current year (2018) results and an operating budget for the first and third years, in 2019 dollars, which is summarized below:

	<u>Current</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>			
Medicare FFS	\$6,101	\$795,774	\$803,732
Medicaid FFS	0	141,262	142,674
Private Pay	162	0	0
All Other #	<u>86,072</u>	<u>1,340,416</u>	<u>1,353,820</u>
Total Revenues	\$92,335	\$2,277,452	\$2,300,226
<u>Expenses</u>			
Operating	\$246,340	\$1,516,740	\$1,538,403
Capital	<u>32,491</u>	<u>32,566</u>	<u>32,566</u>
Total Expenses	\$278,831	\$1,549,306	\$1,570,969
Net Income (Loss)	<u>(\$186,496)</u>	<u>\$728,146</u>	<u>\$729,257</u>
Utilization: (Visits)*	576	14,359	14,653
Utilization: (Hours)**	3	27,259	27,531

* Nursing, PT, OT, SP, and Medical Social Services

** Home Health Aide hours

Managed Care and MLTC

The following is noted with respect to the submitted budget:

- The applicant indicated that the low utilization and revenue in 2018 were due to the current operator's focus on selling and ceasing its operation of the CHHA.
- Year One and Year Three payor rates are based on the average \$160 of revenue per visit reflected in the 2018 cost report (i.e., \$92,335 of revenue in 2018 divided by 576 total visits in 2018).
- Upon approval of this application, Preferred Certified, LLC intends to increase the CHAA's utilization by acquiring additional contracts with the following MLTC plans: Metropolitan Jewish Health System, Visiting Nurse Services and ArchCare. The applicant expects to enroll 100 new patients from the community through existing and new MLTC plans and from the applicant's existing referral sources in order to support the projected increase in utilization in Year One. The referral sources include: The W Assisted Living at Riverdale, a 256-bed Adult home that includes a 200-bed-ALP; Edison Home Health Care, a Licensed Home Care Service Agency (LHCSA); Preferred Home Care of New York, a LHCSA; and The W Senior Living at Goshen, a 120-bed Adult Home.
- The applicant expects to achieve the first-year net operating income as follows:
 - Securing patient referrals from facilities and agencies that are affiliated with members of the applicant as stated above, thus increasing visits and hours.
 - Enrolling new patients through MLTC plans that will support the projected increase in utilization.
 - Increasing staff and providing ongoing staff training, in-service education and re-education of the RN staff in order to ensure that patients are monitored properly and receiving appropriate services, and that increased volume can be handled when received.

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

<u>Payor</u>	<u>Current</u>	<u>Year One</u>	<u>Year Three</u>
Medicare FFS	6.60%	34.57%	34.22%
Medicaid FFS	0.17%	6.14%	6.07%
Charity Care	0.00%	1.06%	2.07%
All Other	<u>93.23%</u>	<u>58.24%</u>	<u>57.63%</u>
	100.00%	100.00%	100.00%

Charity care is expected to be 2% by Year Three. The applicant states their policy is to assess individuals based on income to determine eligibility for reduced fees and/or charity care. Their commitment includes providing uncompensated services to uninsured patients lacking the financial resources to pay.

Capability and Feasibility

Preferred Certified, LLC will acquire the CHHA's operations for \$250,000 funded by members' equity. BFA Attachment A is the net worth statements of the proposed members, which shows sufficient equity.

The working capital requirement is estimated at \$258,218 based on two months of first year expenses and will be funded from the proposed members' equity. BFA Attachment, the members' net worth statements, reveals sufficient resources to meet the working capital needs. BFA Attachment C is the pro forma balance sheet, which shows the entity will start with \$258,218 in equity.

The submitted budget projects a net income of \$728,146 and \$729,257 in the first- and third-year budgets, respectively. The budget appears reasonable.

BFA Attachment B is the financial summary for Park Gardens Rehabilitation and Nursing Center. The applicant indicated that the current operator's 2018 certified financial statements were prepared on a consolidated basis for the RHCF and CHHA. In 2018, the Park Gardens Rehabilitation and Nursing Center maintained an operating net income of \$505,314.

Conclusion

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

Attachments

BFA Attachment A Personal Net Worth Statement- Proposed Members of Preferred Certified, LLC
BFA Attachment B Financial Summary for Park Gardens Rehabilitation & Nursing Center LLC
BFA Attachment C Pro Forma Balance Sheet of Preferred Certified, LLC

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to establish Preferred Certified, LLC as the new operator of the Certified Home Health Agency located at 6677-B Broadway, Bronx currently operated as Park Gardens CHHA, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

191123 E

Preferred Certified, LLC

APPROVAL CONTINGENT UPON:

1. Provide a copy of the Articles of Organization of Preferred Certified LLC, acceptable to the Department. (CSL)
2. Provide a copy of the lease for the premises, acceptable to the Department. (CSL)

APPROVAL CONDITIONED UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



Project # 191212-B
Atlantic SC, LLC d/b/a Atlantic Surgery Center

Program: Diagnostic and Treatment Center **County:** Suffolk
Purpose: Establishment and Construction **Acknowledged:** April 29, 2019

Executive Summary

Description

Atlantic SC, LLC d/b/a Atlantic Surgery Center, an existing New York limited liability company whose sole member is Nitin Mariwalla, M.D., requests approval to establish and construct a single-specialty Article 28 freestanding ambulatory surgery center (FASC) specializing in gastroenterology services. The Center will be located in a to-be-constructed building at 1145 Montauk Highway, West Islip (Suffolk County). Lola 1145 Realty, LLC, the property owner, will construct the FASC and lease the premises to the applicant. There is a relationship between landlord and tenant in that Dr. Mariwalla is the sole member of both entities.

Dr. Mariwalla is a neurosurgeon with a medical practice in West Islip. He will be an owner/operator of the FASC and will serve as its Medical Director. Seven gastroenterologists of Island Gastroenterology Consultants, P.C., a Suffolk County based medical practice, have provided a letter of interest to perform procedures at the Center. Collectively, the physicians are currently performing approximately 10,500 procedures annually that will be performed in the ASC. Of these procedures, about 10,000 are currently being performed at other ASCs and about 500 are performed in a hospital setting. The physicians are all Board-certified and have admitting privileges at Good Samaritan Hospital Medical Center where the applicant intends to have a Transfer and Affiliation Agreement for back-up and emergency services. Good Samaritan

Hospital Center is located 0.4 miles from the proposed facility.

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

Need Summary
The number of projected procedures is 7,500 in Year One and 10,352 in Year Three with Medicaid at 15.0% and Charity Care at 3.0%.

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

Financial Summary
Total project costs of \$3,582,708 will be funded as follows: \$750,000 of member's equity; a \$2,000,000 bank construction loan, self-amortizing for a 10-year term (landlord); and an \$832,708 bank loan for fit-out and equipment, self-amortizing for 10-year term (applicant). Peapack-Gladstone Bank has provided a letter of interest for the respective financings with interest rates indexed at the Bank's five-year Cost of Funds (current indicative rate of 4% interest). The proposed budget is as follows:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$4,789,409	\$6,477,598
Expenses	\$3,356,925	\$3,934,271
Net Income	\$1,432,484	\$2,543,327

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a 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]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed loan commitment (landlord) for the building's construction, acceptable to the Department of Health. [BFA]
6. Submission of an executed loan commitment (applicant) for equipment and fit-out costs, acceptable to the Department of Health. [BFA]
7. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
8. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by August 31, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]
4. The staff of the facility must be separate and distinct from 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]
6. 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 12, 2019

Need Analysis

Need Analysis

The service area is Suffolk County. The table below shows the number of patient visits at ambulatory surgery centers in Suffolk County for 2017 and 2018.

Specialty Type	Facility Name	Patient Visits	
		2017	2018
Gastro/Pain Manage	Advanced Surgery Center of Long Island	7,107	7,876
Gastroenterology	Digestive Health Center of Huntington, Inc	3,020	3,155
Gastroenterology	Great South Bay Endoscopy Center, LLC	5,838	6,198
Gastroenterology	Island Digestive Health Center	5,771	5,565
Gastroenterology	Island Endoscopy Center, LLC ²	5,573	0
Multi	Long Island Ambulatory Surgery Center	15,857	15,265
Orthopedics	Long Island Hand and Orthopedic Surgery Center	751	651
Multi	Melville Surgery Center	6,243	6,542
Multi	North Shore Surgi-Center ¹	0	0
Multi	Port Jefferson ASC (opened 2/13/18)	N/A	N/A
Multi	Progressive Surgery Center, LLC ³	1,008	1,208
Multi	South Shore Surgery Center ³	5,007	8,160
Multi	Suffolk Surgery Center, LLC ²	6,107	0
	Totals	62,282	54,620

¹ No SPARCS data was found for 2017 or 2018.

² No SPARCS data was found for 2018.

³ 2018 data is an estimation, based upon partial year information.

The number of projected procedures is 7,500 in Year One and 10,352 in Year Three. The applicant estimates that approximately 95% of the projected procedures are currently being performed at other freestanding ambulatory surgery centers. The table below shows the projected payor source utilization for Years One and Three.

Payor	Year One		Year Three	
	Volume	%	Volume	%
Commercial Ins	3,525	47.0%	4,865	47.0%
Medicare	2,625	35.0%	3,623	35.0%
Medicaid	1,125	15.0%	1,553	15.0%
Charity Care	225	3.0%	311	3.0%
Total	7,500	100.0%	10,352	100.0%

To serve the underinsured population, the center intends to obtain contracts with the following Medicaid Managed Care plans: Affinity Health, Health First, Neighborhood Health and United Healthcare Community. The proposed center will reach out to Hudson River Healthcare – Amityville and Long Island Selected Healthcare (LISH) at Central Islip, both FQHCs, to provide service to the under-insured. The center will adopt a financial assistance policy with a sliding fee scale once operational. The applicant is committed to serving all persons in need without regard to ability to pay or source of payment.

Conclusion

Approval of this project will allow for the additional access to gastroenterology ambulatory surgery services for the communities within Suffolk County.

Program Analysis

Facility Information

Proposed Operator	Atlantic SC, LLC
Doing Business As	Atlantic Surgery Center
Site Address	1145 Montauk Highway West Islip, NY 11795 (Suffolk County)
Surgical Specialties	Single Specialty: Gastroenterology
Operating Rooms	0
Procedure Rooms	5
Hours of Operation	Monday through Friday from 8:00 am – 6:00 pm
Staffing (1 st / 3 rd Year)	11.2 FTEs / 15.2 FTEs
Medical Director	Nitin Mariwalla, M.D.
Emergency, In-Patient & Backup Support Services Agreement and Distance	Expected to be provided by: Good Samaritan Medical Center 0.4 miles / 1 minute
After-hours access	The patient and responsible party will be informed of the afterhours care including the contact information for their physician and the ASC. The discharge instruction and the answering machine message will also provide instructions to call the patient's Medical Doctor if the surgery center is closed or 911 in the event of an emergency.

Character and Competence

Dr. Mariwalla is the sole member and proposed Medical Director. He is a Neurosurgeon with over 11 years of experience. He has managed a private practice for approximately two years. He is responsible for the hiring of staff, billing practices, and delivery of surgical services. He received his medical degree from Tulane University School of Medicine. He completed his residency and Cerebrovascular Fellowship at Emory University. He currently resides on the Medical Advisory Board, World Wide Task Force for Syringomyelia and Chiari and is a Physician Advisor for Interfaith Outreach Home.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

Atlantic Surgery Center aims to promote access to primary care services by aligning themselves with Good Samaritan Hospital Medical Center and notifying any patient that comes to the Center without a primary care physician of the primary care services offered by the hospital affiliates. The Center plans for outreach to underserved communities by participating in community health events and local religious institutions to make these facilities aware of the services provided and the Center's relationship with the local hospital. The Center proposes to serve uninsured persons and persons without the ability to pay the entire charge by providing a sliding scale fee.

The center is committed to implementing an electronic medical record (EMR) system and will consider joining a regional health information organization (RHIO) or qualified health information exchange (HIE).

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

Lease Rental Agreement

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

Date:	January 1, 2019
Premises:	8,400 sq. ft located at 1145 Montauk Highway, West Slip, NY 11795
Landlord:	Lola 1145 Realty, LLC
Tenant:	Atlantic SC, LLC
Term:	10 Years with renewal options for two (2) additional five-year terms.
Rent:	\$168,000 per year (\$14,000 per month) increased 2% annually.
Provisions:	Tenant will pay its proportion of taxes, insurance, common area expenses (including snow removal), HVAC costs and utilities. Improvements made by tenant will be at tenant's expense.

The lease agreement is a non-arm's length arrangement. The applicant has provided an affidavit attesting that there is a relationship between landlord and tenant in that Dr. Mariwalla is the sole member of both entities. The lease reflects current rates for similar property. Letters for two New York State licensed realtors were provided attesting to the rent being of fair market value.

Total Project Costs and Financing

Total project costs for construction, fit-out and the acquisition of moveable equipment is estimated at \$3,582,708, broken down as follows:

Renovation & Development	\$2,056,320
Design Contingency	102,816
Construction Contingency	102,816
Architect/Engineering Fees	164,506
Other Fees	204,000
Movable Equipment	894,499
Financing Costs	15,499
Interim Interest Expense	20,666
CON Application Fee	2,000
Additional CON Processing Fee	<u>19,586</u>
Total Project Cost	\$3,582,708

Project costs are based on a construction start date of March 2020, with a six-month construction period.

The applicant's plan for financing is as follows:

Equity (Applicant Member)	\$750,000
Loan (Landlord, 10-year term, 4% interest, 10-year amortization)	\$2,000,000
Loan (Tenant, 10-year term, 4% interest, 10-year amortization)	<u>\$832,708</u>
Total Project Financing	\$3,582,708

BFA Attachment A is the applicant's personal Net Worth Statement, which indicates sufficient liquid resources exist to fund the equity requirement for project costs. Peapack-Gladstone Bank submitted a letter of interest for the respective financings at the stated terms with interest rates indexed at the Bank's five-year Cost of Funds (current indicative rate of 4% interest).

Operating Budget

The applicant has submitted their first-and third-year operating budget, in 2019 dollars, summarized below.

	Year One		Year Three	
	Per Visit	Revenues	Per Visit	Revenues
<u>Revenues</u>				
Commercial FFS	\$845.28	\$2,979,608	\$814.48	\$3,962,455
Medicare FFS	\$595.34	\$1,562,764	\$595.26	\$2,156,615
Medicaid MC	\$543.93	\$611,926	\$543.76	\$844,458
Bad Debt		-\$108,219		-\$146,068
Other *		<u>-\$256,670</u>		<u>-\$339,862</u>
Total Revenues		\$4,789,409		\$6,477,598
<u>Expenses</u>				
Operating Expense	\$341.36	\$2,560,215	\$302.10	\$3,127,330
Capital Expense	<u>\$106.23</u>	<u>\$796,710</u>	<u>\$77.95</u>	<u>\$806,941</u>
Total Expense	\$447.59	\$3,356,925	\$380.05	\$3,934,271
Net Income		<u>\$1,432,484</u>		<u>\$2,543,327</u>
Total Procedures		7,500		10,352

* NYS gross receipt tax on revenue (Health Facility Cash Receipts Assessment).

Utilization for by payor sources is anticipated as follows:

Payor	Year One	Year Three
Commercial FFS	47%	47%
Medicare FFS	35%	35%
Medicaid MC	15%	15%
Charity Care	<u>3%</u>	<u>3%</u>
Total	100%	100%

The following assumptions were considered for the operating budget:

- Volume is based on the historical experience of the physicians of Island Gastroenterology Consultants, P.C., a Suffolk County medical practice. Seven of the practices' physicians have provided a letter of intent to perform surgery at the Center and have collectively submitted a letter in support of utilization projections.
- Medicare revenues are based on the 2019 Medicare fee schedule. Commercial revenues are based on the physicians' past commercial payor rate experience for the types of gastroenterology cases they would perform at the center. Medicaid revenues are based on the recent APG rates listed on the Department of Health website.
- Expense and utilization assumptions reflect the physicians' experience in operating through private practice, as well as with Island Gastroenterology Consultants, P.C.
- Data by CPT code detailing case mix and volume was provided to support payment rates and revenue projections. It is estimated that 28% of the procedures will be endoscopies, 37% will be esophagogastroduodenoscopies, 23% will be colonoscopies, 6% will be polyp removals, and 6% of the procedures will include endoscopic ultrasound. The budget appears reasonable given the payment and expense rates for these types of procedures performed at the FACS.

Capability and Feasibility

Total project costs of \$3,582,708 will be funded as follows: \$750,000 of member's equity; a \$2,000,000 bank construction loan, self-amortizing for a 10-year term (landlord); and an \$832,708 bank loan for fit-out and equipment, self-amortizing for 10-year term (applicant). Peapack-Gladstone Bank has provided a letter of interest for the respective financings with interest rates indexed at the Bank's five-year Cost of Funds (current indicative rate of 4% interest).

Working capital requirements are estimated at \$655,712 based on two months of third year expenses. The applicant will fund the working capital needs via equity. BFA Attachment A is the member's net

worth statement which indicates the availability of sufficient funds for the stated levels of equity. BFA Attachment B is the pro forma balance sheet of Atlantic SC, LLC as of the first day of operations, which indicates a positive member equity position of \$655,712.

Atlantic SC, LLC d/b/a Atlantic Surgery Center projects net income of \$1,432,484 and \$2,543,327 in the first and third years, respectively. Revenues are based on the current 2019 Medicare fee schedule, the Medicaid APG rates and the Commercial rates experience of the physicians in their private medical practice. The budget appears reasonable.

Conclusion

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Supplemental Information

Surrounding Hospital Responses

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas. There follows a summary of the applicant's response to DOH's request for information on the proposed facility's volume of surgical cases, the sources of those cases, and on how staff will be recruited and retained by the ASC.

Southside Hospital -- **No Response**
301 East Main Street
Bay Shore, New York 11706

Good Samaritan Hospital Medical Center -- **No Response**
1000 Montauk Highway
West Islip, New York 11795

DOH Comment

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

Attachments

BHFP Attachment	Map
BFA Attachment A	Net Worth Statement of the Proposed Member of Atlantic SC, LLC
BFA Attachment B	Pro Forma Balance Sheet – Atlantic Surgery Center, LLC
BFA Attachment C	Organizational Chart of the Proposed Member/Facility

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 12th day of December 2019, 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 ambulatory surgery center for gastroenterology to be located at 1145 Montauk Highway, West Islip, 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:

191212 B

Atlantic SC, LLC d/b/a Atlantic Surgery 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 a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a 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]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed loan commitment (landlord) for the building's construction, acceptable to the Department of Health. [BFA]
6. Submission of an executed loan commitment (applicant) for equipment and fit-out costs, acceptable to the Department of Health. [BFA]
7. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
8. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]

APPROVAL CONDITIONAL UPON:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by August 31, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]
4. The staff of the facility must be separate and distinct from 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]
6. 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]

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



Project # 192021-B
Northeast Endoscopy

Program: Diagnostic and Treatment Center
Purpose: Establishment and Construction
County: Suffolk
Acknowledged: July 15, 2019

Executive Summary

Description

Northeast Endoscopy, LLC (the Center), an existing New York limited liability company, requests approval to establish and construct a single specialty, Article 28 freestanding ambulatory surgery center (FASC) specializing in gastroenterology procedures to be located at 235 N. Belle Mead Road, East Setauket (Suffolk County). The Center will be housed in approximately 12,000 square feet of leased space in the single-story building and will have three procedures rooms, eight preoperative bays, ten recovery areas, and the requisite support spaces. Vinayak Ganapati, LLC is the property owner. There is a relationship between landlord and tenant in that the entities have identical membership.

The proposed ownership of the Center is as follows:

Table with 2 columns: Member, %
Proposed Operator: Northeast Endoscopy, LLC
Members: Shri Varhdman Mahavir, LLC (100%), Niles Mehta, M.D. (50%), Preeti Mehta, M.D. (50%)

Dr. Niles Mehta, who is Board-certified in Gastroenterology, will serve as Medical Director. The applicant intends to enter into a Transfer and Affiliation Agreement with Long Island Community Hospital.

Drs. Niles and Preeti Mehta will be practicing physicians at the Center and have provided letters indicating their commitment to perform 1,400 procedures in the first year of project

implementation. The physicians have a combined 90% ownership interest in New Hyde Park Endoscopy, an Article 28 FASC located in Nassau County that opened in January 2018 and is operating at near capacity. The primary purpose of this project is to accommodate the physicians' existing patients who live in Suffolk County and travel to Nassau County to utilize their services. This new Center will be more convenient for their patients who reside in Suffolk County and will also provide needed additional gastroenterological surgical services to all residents of Suffolk County.

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

Need Summary
The number of projected procedures is 1,400 in Year One and 1,486 in Year Three with payor utilization of Medicaid at 13.0% and Charity Care at 2.0%.

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 cost is \$5,272,625 and will be met via \$147,403 members' equity, a landlord contribution of \$3,802,754, and a personal loan from Kanak Golia (father of Dr. Preeti Mehta) for \$1,322,468 with no loan terms and no expectation of repayment. The landlord contribution will be funded via \$83,905 equity (landlord) and a personal loan from Kanak Golia to the realty entity for \$3,718,849 with no interest terms and no expectation of repayment.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,063,040	\$2,125,350
Expenses	<u>\$1,870,816</u>	<u>\$1,943,010</u>
Net Income	\$192,224	\$182,340

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. (RNR)
3. Submission of a 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)
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed lease agreement, acceptable to the Department of Health. (BFA)
6. Submission of an executed personal loan commitment for project costs (applicant), acceptable to the Department of Health. (BFA)
7. Submission of an executed personal loan agreement for project costs (landlord), acceptable to the Department of Health. (BFA)
8. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
9. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
10. Submission of an executed lease agreement, acceptable to the Department of Health. [CSL]

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by September 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. (RNR)
4. The staff of the facility must be separate and distinct from 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]
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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]
6. 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 12, 2019

Need and Program Analysis

Project Proposal

Proposed Operator	Northeast Endoscopy, LLC
Doing Business As	Northeast Endoscopy
Site Address	235 North Belle Mead Road East Setauket, NY 11733 (Suffolk County)
Surgical Specialties	Single Specialty: Gastroenterology
Operating Rooms	0
Procedure Rooms	3
Hours of Operation	Monday through Friday from 7:30 am – 3:30 pm
Staffing (1st / 3rd Year)	8.0 FTEs / 8.0 FTEs
Medical Director	Nilesh Mehta, M.D.
Emergency, In-Patient & Backup Support Services Agreement and Distance	Expected to be provided by: Long Island Community Hospital 12.9 miles / 27 minute
After-hours access	If the patient requires assistance while during hours when the Center is not in operation, the patient will have the phone number of an on-call service, which will be available 24 hours per day, seven (7) days per week, to immediately refer the patient to the Center's on-call physician, who will be a member of the Center's credentialed medical staff.

Analysis

The service area is Suffolk County. The population of Suffolk County in 2010 was 1,493,350 with 625,791 individuals (41.9%) who are 45 and over, which are the primary population group utilizing gastroenterology services. Per projection data from the Cornell Program on Applied Demographics, this population group (45 and over) is estimated to grow to 714,044 by 2025 and represent 47.8% of the projected population of 1,494,816.

The table below shows the number of patient visits at ambulatory surgery centers in Suffolk County for 2017 and 2018.

Specialty Type	Facility Name	Patient Visits	
		2017	2018
Gastro/Pain Manage	Advanced Surgery Center of Long Island	7,107	7,876
Gastroenterology	Digestive Health Center of Huntington, Inc	3,020	3,155
Gastroenterology	Great South Bay Endoscopy Center, LLC	5,838	6,198
Gastroenterology	Island Digestive Health Center	5,771	5,565
Gastroenterology	Island Endoscopy Center, LLC ²	5,573	0
Multi	Long Island Ambulatory Surgery Center	15,857	15,265
Orthopedics	Long Island Hand and Orthopedic Surgery Center	751	651
Multi	Melville Surgery Center	6,243	6,542
Multi	North Shore Surgi-Center ¹	0	0
Multi	Port Jefferson ASC (opened 2/13/18)	N/A	N/A
Multi	Progressive Surgery Center, LLC ³	1,008	1,208
Multi	South Shore Surgery Center ³	5,007	8,160
Multi	Suffolk Surgery Center, LLC ²	6,107	0
	Totals	62,282	54,620

¹No SPARCS data was found for 2017 or 2018.

²No SPARCS data was found for 2018.

³2018 data is an estimation, based upon partial year information.

The number of projected procedures is 1,400 in Year One and 1,486 in Year Three. The applicant states that all the projected procedures are currently being performed at New Hype Park Endoscopy (a freestanding ambulatory surgery center in Nassau County). The primary purpose of this project is to accommodate the patients of the participating physicians who reside in Suffolk County. The table below shows the projected payor source utilization for Years One and Three.

Projections	Year One		Year Three	
	Volume	%	Volume	%
Commercial	1,092	78.0%	1,159	78.0%
Medicare FFS	84	6.0%	89	6.0%
Medicare MC	14	1.0%	15	1.0%
Medicaid FFS	14	1.0%	15	1.0%
Medicaid MC	168	12.0%	178	12.0%
Charity Care	28	2.0%	30	2.0%
Total	1,400	100.0%	1,486	100.0%

To serve the underinsured population, the center intends to obtain contracts with the following Medicaid Managed Care plans: Health First and Fidelis. The doctors involved in this proposed center also own New Hyde Park Endoscopy in Nassau County. The doctors currently work with the Joseph P. Addabbo Family Health Center to refer patients and will seek a second referral agreement from the health center to serve the under-insured in Suffolk County. The center will reach out to Long Island Select Healthcare (LISH) to serve the under-insured individuals in the service area. The center will adopt a financial assistance policy with a sliding fee scale once operational. The applicant is committed to serving all persons in need without regard to ability to pay or source of payment.

Character and Competence

The following table details the membership interest of Northeast Endoscopy, LLC:

Name	Interest
Shri Vardhman Mahavir LLC	100.00%
<i>Nilesh Mehta M.D. (50%)</i>	
<i>Preeti Mehta M.D. (50%)</i>	
Total	100.0%

Dr. Nilesh Mehta M.D. is the proposed Medical Director. He is a Gastroenterologist with over 15 years of experience. He has been the president of a digestive disease practice for approximately 10 years. He received his medical degree from MGM Medical College. He completed his Internal Medicine residency at Harlem Center Hospital and a Gastroenterology residency at State University Hospital Health Science Center. He is board-certified in Gastroenterology.

Dr. Preeti Mehta M.D. is a Gastroenterologist with over 17 years of experience. She received her medical degree from the Icahn School of Medicine at Mount Sinai. She completed her Internal Medicine residency at North Shore University Hospital. She completed her Gastroenterology residency at State University of New York Health Science Center. She is board certified in Internal Medicine with a subspecialty in Gastroenterology.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

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

Northeast Endoscopy aims to promote access to primary care services by educating their patients regarding the availability of primary care services offered by local providers, including the outpatient primary care services offered by Long Island Community Hospital, the proposed back-up hospital for the Center. The Center plans for outreach to underserved developing a patient referral agreement with Joseph Addabbo Family Health Center, A Federally Qualified Health Center (FQHC) that they have a close working relationship with through their existing FASC in Nassau County. The Center also plans to reach out to other FQHCs that are located near the proposed Center. The Center will accept all Commercial Medicaid plans. The Center has an operating budget that projects that 2% of the cases will be for charity care. The Center is committed to the development of a formal outreach program directed to the members of the local community, particularly those who are underserved. The purpose of the program will be to inform the community members of the benefits derived from, and the latest advances made in, gastroenterology.

The Center plans to utilize an Electronic Medical Record (EMR) system and to fully integrate and exchange information with an established Regional Health Information Organization (RHIO) with the capability for clinic referral and event notification. The Center does not plan to become part of an Accountable Care Organization or Medical Home.

Conclusion

Approval of this project will allow for the improved access to gastroenterology ambulatory surgery services for the communities within Suffolk County. Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

Financial Analysis

Lease Rental Agreement

The applicant has submitted a draft lease rental agreement for the site that they will occupy, the terms are summarized below:

Premises:	12,000 square feet located at 235 N. Belle Mead Road, East Setauket
Lessor:	Vinayak Ganapati, LLC
Lessee:	Northeast Endoscopy, LLC
Term:	15 years with one additional five-year term.
Rental	\$480,000 annually (\$40 per sq. ft.)
Provisions	Tenant is responsible for utilities and pro-rata share of real estate taxes.

The applicant has submitted an affidavit indicating that the lease agreement will be a non-arm's length lease arrangement as there is identical ownership in the operations and realty companies. The applicant submitted letters from two New York real estate brokers attesting to the reasonableness of the per square foot rental.

Total Project Cost

The total project cost for the renovation and moveable equipment, is estimated as \$5,272,625, broken down as follows:

Renovation & Demolition	\$2,863,016
Design Contingency	286,302
Construction Contingency	286,302
Architect/Engineering Fees	286,312
Other Fees	80,822
Movable Equipment	1,439,041
Application Fee	2,000
Processing Fee	<u>28,830</u>
Total Project Cost	\$5,272,625

Project costs are based on a six-month construction period.

The applicant's financing plan appears as follows:

Equity (Applicant)	\$147,403
Loan to Applicant from Kanak Golia (father of Preeti Mehta)	\$1,322,468
Landlord Contribution - Equity	\$83,905
Landlord Contribution - Loan from Kanak Golia	<u>\$3,718,849</u>
Total	\$5,272,625

Kanak Golia has provided a letter indicating he is willing to provide a personal loan to the applicant to be used to pay for the project costs. The loan has no interest or other terms and there is no expectation of repayment. A separate letter from Kanak Golia was provided indicating his willingness to provide a personal loan to Vinayak Ganapati, LLC (realty) to fund the landlord's contribution. This loan also has no interest or other terms and there is no expectation of repayment. Mr. Golia has submitted documentation to verify liquid assets are available to fund the loans.

BFA Attachment A is the applicant members' net worth statement which shows sufficient liquid resources to fund the equity requirement.

Operating Budget

The applicant submitted an operating budget for the first and third years, in 2019 dollars, summarized below:

<u>Revenues</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Proc.</u>	<u>Total</u>	<u>Per Proc.</u>	<u>Total</u>
Commercial - FFS	\$1,649.73	\$1,801,509	\$1,601.31	\$1,855,919
Medicare - FFS	\$1,116.00	93,744	\$1,085.11	96,575
Medicare - MC	\$1,116.00	15,624	\$1,073.07	16,096
Medicaid - FFS	\$970.43	13,586	\$933.07	13,996
Medicaid - MC	\$824.86	<u>138,577</u>	\$802.04	<u>142,764</u>
Total Revenue		\$2,063,040		\$2,125,350
<u>Expenses</u>				
Operating	\$786.40	\$1,100,953	\$789.47	\$1,173,147
Capital	<u>\$549.90</u>	<u>769,863</u>	<u>\$518.08</u>	<u>769,863</u>
Total	\$1,336.30	\$1,870,816	\$1,307.54	\$1,943,010
Net Income		<u>\$192,224</u>		<u>\$182,340</u>
Total Procedures		1,400		1,486

Utilization by payor during the first and third years is as follow:

<u>Payor</u>	<u>Year One</u>	<u>Year Three</u>
Commercial - FFS	78.0%	78.0%
Medicare - FFS	6.0%	6.0%
Medicare - MC	1.0%	1.0%
Medicaid - FFS	1.0%	1.0%
Medicaid - MC	12.0%	12.0%
Charity	<u>2.0%</u>	<u>2.0%</u>
Total	100.0%	100.0%

The following is noted with respect to the submitted budget:

- Revenue, expense and utilization assumptions are based on the combined historical experience of the proposed members. Historical experience includes their combined 90.005% ownership interest in New Hyde Park Endoscopy, an Article 28 FASC.
- Anticipated procedure volume by CPT code and related revenue by payor (APGs for Medicaid) were provided and appear reasonable.
- The FASC will employ 8 FTEs including 2 FTE Technician/Specialists, 3 FTE RNs and 1 FTE LPN staff.
- The applicant members, both Board-certified Gastroenterologists, have provided letters of interest demonstrating their commitment to perform 1,400 procedures in the first year with an anticipation of 3% growth each year thereafter.

Capability and Feasibility

Total project cost is \$5,272,625 and will be met via \$147,403 members' equity, a landlord contribution of \$3,802,754, and a personal loan from Kanak Golia (father of Dr. Preeti Mehta) for \$1,322,468 with no loan terms and no expectation of repayment. The landlord contribution will be funded via \$83,905 equity (landlord) and a personal loan from Kanak Golia to the realty entity for \$3,718,849 with no interest terms and no expectation of repayment. Mr. Golia has provided a letter indicating that he is willing to provide the respective personal loans at the stated terms and has submitted documentation to verify that liquid assets are available. BFA Attachment A is the applicant members' net worth statement, which shows sufficient liquid resources to fund the equity requirement for project costs.

Working capital requirements are estimated at \$323,835 based on two months of third year expenses and will be funded entirely via equity from the proposed members. BFA Attachment A is the applicant members' net worth statement, which shows sufficient liquid resources to fund the equity requirement for working capital. BFA Attachment B is the pro forma balance sheet as of the first day of operation, which indicates a positive net asset position of \$471,238.

The submitted budget projects net income of \$192,224 and \$182,340 during the first and third years, respectively. Revenue, expense and utilization assumptions are based on the combined historical experience of the proposed members. The budget appears reasonable

Conclusion

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Supplemental Information

Surrounding Hospital Responses

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas.

St. Charles Hospital -- No Response

200 Belle Terre Road
Port Jefferson, New York 11777

Stony Brook University Hospital -- No Response

Health Sciences Center Suny
Stony Brook, New York 11794

John T Mather Memorial Hospital -- No Response

75 North Country Road
Port Jefferson, New York 11777

DOH Comment

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

Attachments

BFA Attachment A	Net Worth Statement
BFA Attachment B	Pro Forma Balance Sheet
BHFP Attachment	Map

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 12th day of December 2019, 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 ambulatory surgery center specializing in gastroenterology to be located at 235 North Belle Mead Road, East Setauket, 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:

192021 B

Northeast Endoscopy

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]
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 - a. Data displaying actual utilization including procedures;
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 - 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)
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed lease agreement, acceptable to the Department of Health. (BFA)
6. Submission of an executed personal loan commitment for project costs (applicant), acceptable to the Department of Health. (BFA)
7. Submission of an executed personal loan agreement for project costs (landlord), acceptable to the Department of Health. (BFA)
8. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
9. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
10. Submission of an executed lease agreement, acceptable to the Department of Health. [CSL]

APPROVAL CONDITIONAL UPON:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by September 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. (RNR)
4. The staff of the facility must be separate and distinct from 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]
6. 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]

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



Project # 192069-B
**Crotona Parkway SC, LLC d/b/a Crotona Parkway
Ambulatory Surgery Center**

Program: Diagnostic and Treatment Center **County:** Bronx
Purpose: Establishment and Construction **Acknowledged:** August 16, 2019

Executive Summary

Description

Crotona Parkway SC, LLC d/b/a Crotona Parkway Ambulatory Surgery Center (Crotona), an existing New York limited liability company, requests approval to establish and construct a multi-specialty Article 28 freestanding ambulatory surgery center (FASC) to be located at 1976 Crotona Parkway, Bronx (Bronx County). The proposed center will be housed in approximately 11,000 square feet of leased space. The lease will be non-arm's length as there is relationship between the landlord and tenant. The FASC will include five procedure rooms, two operating rooms, pre-op and recovery rooms, and the requisite support areas.

The proposed members are as follows:

Crotona Parkway SC, LLC	
Members	%
Leonid Reyfman, M.D.	50%
Boleslav Kosharskyy, M.D.	50%

Leonid Reyfman, M.D., who is Board-Certified in Anesthesiology, will serve as Medical Director. The FASC will enter into a Transfer and Affiliation Agreement with St. Barnabas Hospital, located 1.3 miles (10 minutes' travel time), for back-up and emergency care services.

OPCHSM Recommendation

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

Need Summary

The number of projected procedures is 2,800 in Year One and 3,864 in Year Three, with Medicaid at 10.0% and Charity Care at 2.0% each year.

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 total project cost of \$5,044,633 will be met via \$1,008,927 members' equity, and a bank loan for \$4,035,706 at 5% interest for a ten-year term. Peapack-Gladstone Bank has provided a letter of interest.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$3,188,328	\$4,399,894
Expenses	<u>3,187,851</u>	<u>3,861,427</u>
Net Income	\$477	\$538,467

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed lease agreement, acceptable to the Department of Health. (BFA)
3. Submission of an executed loan commitment for project costs, acceptable to the Department of Health. (BFA)
4. Submission of an executed working capital loan commitment, acceptable to the Department of Health. (BFA)
5. 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)
6. 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
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7. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
8. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
9. Submission of a photocopy of a property lease, acceptable to the Department. (CSL)
10. Submission of the Articles of Organization of Crotona Parkway SC, LLC, acceptable to the Department. (CSL)
11. Submission of the Operating Agreement of Crotona Parkway SC, LLC, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within two years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before April 1, 2020 and construction must be completed by November 30, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
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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/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]
6. 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.

Council Action Date

December 12, 2019

Need and Program Analysis

Program Description

Crotona Parkway SC, LLC d/b/a/ Crotona Parkway Ambulatory Surgery Center seeks approval for the establishment and construction of a freestanding, multi-specialty ambulatory surgery center, initially providing plastic, orthopedic, urology and pain management services.

Proposed Operator	Crotona Parkway SC, LLC
Doing Business As	Crotona Parkway Ambulatory Surgery Center
Site Address	1976 Crotona Parkway Bronx, New York 10460 (Bronx County)
Surgical Specialties	Multi-Specialty
Operating Rooms	2
Procedure Rooms	5
Hours of Operation	Monday through Friday 8:00 am to 6:00 pm
Staffing (1st / 3rd Year)	9.2 FTEs / 13.2 FTEs
Medical Director	Leonid Reyfman M.D.
Emergency, In-Patient & Back-up Support Services Agreement and Distance	St. Barnabas Hospital 1.3 miles / 10 minutes
After-hours access	Instructions will be provided on the patient's discharge instructions for the patient to call their own Medical Doctor or 911 when the surgery center is closed. The message on the answering machine will also provide instructions for the patient to contact their surgeon, primary care physician, or 911.

Analysis

The service area consists of Bronx County. The table below shows the number of patient visits for ambulatory surgery centers in Bronx County for 2017 and 2018.

Specialties	Facility Name	Total Patient Visits	
		2017	2018
Gastroenterology	Advanced Endoscopy Center	10,901	11,010
Multi	Downtown Bronx ASC ¹	312	2,092
Multi	Ambulatory Surgery Center of Greater New York	8,881	8,054
Multi	Avicenna ASC, Inc ²	2,984	
Multi	East Tremont Medical Center ²	2,544	
Multi	Empire State Ambulatory Surgery Center	3,997	3,828
Ophthalmology	Eye Surgery Center of New York	2,407	4,272
Gastroenterology	Mid-Bronx Endoscopy Center (opened 8/11/17)	939	4,524
Gastroenterology	New York GI Center, LLC	11,327	18,555
Total Visits		44,292	52,335

¹ 2018 is an estimation, based upon partial year information

² No SPARCS data located for 2018

The number of projected procedures is 2,800 in Year One and 3,864 in Year Three, with 10% Medicaid and 2% charity care each year. These projections are based on the current practices of participating surgeons. The applicant estimates that of the current procedures, 80% are being done in other ASC's, 5% are being done in an office-based setting and the remaining 15% are being done in hospitals.

Character and Competence

The proposed members and managers of Crotona Parkway SC, LLC are:

Member	Interest
<i>Leonid Reyfman, M.D.</i>	50.0%
<i>Boleslav Koshavarskyy, M.D.</i>	50.0%
Total	100.0%

A Character and Competence Review was conducted on the members of Crotona Parkway SC, LLC.

Dr. Leonid Reyfman, M.D. is a board-certified Anesthesiologist. He is the proposed Medical Director and board member. He is the Director of Pain Physicians NY for over 10 years. He is also the Site Director of Pain Medicine at SUNY Downstate Medical Center for over 12 years. He was the previous Medical Director of Island Ambulatory Surgery Center. He completed his medical degree at Ross University School of Medicine in Dominica. He received his pharmacy degree from the Arnold & Marie Schwarz College of Pharmacy in Brooklyn. He completed his residency in Internal Medicine at Maimonides Medical Center. He completed his fellowship in Anesthesiology at State University of New York Downstate in Brooklyn.

Dr. Boleslav Kosharskyy, M.D. is self-employed for 14 years in the Bronx. He is board certified in Anesthesiology with sub-certifications in Pain Medicine and Hospice and Palliative Medicine. He is the current President and founder of a pain medicine practice. He has established three main offices. He received his medical degree from Freie University Berlin in Germany. He completed his residency in Pain Medicine at State University Hospital Upstate in Syracuse. He completed his residency in Anesthesiology at Boston University Medical Center in Boston. He is an Associate Medical Director of Pain Medicine and Director of Anesthesia for Joint Replacement at Montefiore Medical Center. He established the regional anesthesia service at the Joint Replacement Center. He has written policies and procedures for perioperative patients. He has supervised four attending physicians, fellows, and residents. He co-managed the operating theater and the recovery room. As the associate Director he participated in the establishment of the outpatient treatment center for patients with chronic pain. He lead quality assurance and improvement and co-managed a group of five attending physicians, fellows, and residents.

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. Kosharskyy disclosed one settled malpractice case. The claim alleged that on February 2, 2010, resuscitative efforts were rendered to a newborn with low intrauterine APGAR scores. The plaintiff alleged that the newborn suffered severe brain injury due to failure to assure a safe vaginal delivery. There were multiple co-defendants in the case. The case was settled on May 4, 2016. A total payout was assessed for \$8 million dollars. Dr. Kosharskyy's insurer paid \$1 million dollars.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

The Applicant is committed to serving patients without the ability to pay the full charge or who is uninsured. The Applicant is committed to serving all persons in need of services and there will be no discrimination based on personal characteristics or ability to pay. There is a financial assistance policy with a sliding fee schedule. The patients will be made aware of the sliding scale discount policy through prominent displays in the common area and on the site's websites. The Applicant has indicated that as part of its commitment to outreach to serve the underinsured population will include negotiation of contracts with several Medicaid Managed Care plans including Fidelis, Health First, MetroPlus and United Healthcare Community Plan. The Center plans to contact staff at St Barnabas Hospital to discuss a collaborative relationship to meet the needs of the under-served population. The Center also intends to contact Urban Health Plan (FQHC) to develop collaborate relationships to provide service to the under-insured in their service area. The Applicant will participate in community health events and with local religious institutions to ensure that the local organizations are aware of the services available and of the ASC's relationship with St. Barnabas. If the patient does not have a relationship with a primary care physician, the Center will provide a list of local primary care physicians, including names and telephone numbers.

The Applicant plans on using an electronic medical record (EMR) system and will consider participating in one or more Accountable Care Organizations (subject to its eligibility to do so) and may also consider participating in a regional health information organization (RHIO) and/or Health Information Exchange (HIE).

Conclusion

Approval of this project will provide increased access to multi-specialty ambulatory surgery services in an outpatient setting for the residents of Bronx 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

Total Project Cost and Financing

The total project cost for renovations and movable equipment is \$5,044,633, broken down as follows:

Renovation & Demolition	\$3,044,577
Design Contingency	152,229
Construction Contingency	152,229
Architect/Engineering Fees	213,120
Other Fees	231,750
Movable Equipment	999,833
Financing Costs	94,848
Interim Interest Expense	126,464
Application Fee	2,000
Processing Fee	<u>27,583</u>
Total Project Cost	\$5,044,633

Project costs are based on a construction start date of April 1, 2020, with an eight-month construction period.

The financing for this project will be as follows:

Members' Equity	\$1,008,927
Bank loan (5% interest, 10-yr. term)	<u>4,035,706</u>
Total	\$5,044,633

Peapack-Gladstone Bank has provided a letter of interest for the bank loan. BFA Attachment A shows sufficient resources to meet the equity requirement.

Lease Agreement

The applicant has submitted a draft lease for the site to be occupied, summarized below:

Premises:	Approx. 7,700 sq. ft. (2 nd floor) plus 3,000 sq. ft. (3 rd floor) of the building located at 1976 Crotona Parkway, Bronx, NY or
Landlord:	1976 Crotona LLC
Tenant:	Crotona Parkway ASC, LLC
Term:	10 years with the right to renew for 2 additional 5-year terms
Rental:	\$269,500 base rent for the 1st year, with 3% per annum increases years 2 - 10
Provisions:	Tenant is responsible for utilities and any tenant work

The applicant has submitted an affidavit stating that there is a relationship between the landlord and tenant in that Dr. Reyfman has 24% ownership and Dr. Kosharsky has 4% ownership in 1976 Crotona LLC. The applicant has submitted letters from two NYS licensed realtors attesting to the reasonableness of the per square footage rental.

Operating Budget

The applicant has submitted an operating budget, in 2019 dollars, for Years One and Three:

	<u>Year One</u>		<u>Year Three</u>	
<u>Revenues</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Commercial - FFS	\$1,631.61	\$1,050,758	\$1,631.10	\$1,450,046
Commercial - MC	\$1,182.58	1,158,924	\$1,182.93	1,599,315
Medicare - FFS	\$806.58	587,188	\$806.29	810,320
Medicaid - FFS	\$1,103.74	154,523	\$1,104.88	213,242
Medicaid - MC	\$1,103.74	154,523	\$1,104.88	213,242
Private Pay	\$735.82	<u>82,412</u>	\$733.74	<u>113,729</u>
Total Revenue		\$3,188,328		\$4,399,894
<u>Expenses</u>				
Operating	\$678.54	\$1,899,899	\$667.59	\$2,579,585
Capital	<u>\$459.98</u>	<u>1,287,952</u>	<u>\$331.74</u>	<u>1,281,842</u>
Total	\$1,138.52	\$3,187,851	\$999.33	\$3,861,427
Net Income (Loss)		\$477		\$538,467
Total Patient Visits		2,800		3,864

Utilization by payor source for Year One and Year Three is as follows:

<u>Payor</u>	<u>Year One</u>	<u>Year Three</u>
Commercial - FFS	23.0%	23.0%
Commercial - MC	35.0%	35.0%
Medicare - FFS	26.0%	26.0%
Medicaid - FFS	5.0%	5.0%
Medicaid - MC	5.0%	5.0%
Private Pay	4.0%	4.0%
Charity	<u>2.0%</u>	<u>2.0%</u>
Total	100.0%	100.0%

The following is noted with respect to the submitted budget:

- Rates are based on the 2019 Medicare rate schedule for the services by CPT-4 Code to be provided. Commercial Fee-for-Service is approximately twice the Medicare fee schedule, Commercial Managed Care is one and a half times the Medicare fee schedule.
- Expenses are based upon historical data from previous cost reports of similar ambulatory surgery centers and experience of the applicant who participates in other ambulatory surgery centers.
- The numbers and mix of staffing were determined by the historical experience of the proposed operators.
- Utilization is based upon physicians submitting letters of intent to perform the estimated number of procedures at the FASC.

Capability and Feasibility

The total project cost of \$5,044,633 will be met via \$1,008,926 members' equity, and a bank loan for \$4,035,706 at 5% interest with a ten-year term. Peapack-Gladstone Bank has provided a letter of interest.

Working capital requirements are estimated at \$643,572 based on two months of third year expenses. The working capital will be funded via members' equity of \$321,786 and a bank loan for \$321,786 for a three-year term at 5% interest. Peapack-Gladstone Bank has provided a letter of interest. BFA Attachment A is the proposed members' personal net worth statements, which indicate sufficient resources to fund the equity requirements.

The submitted budget projects a net income of \$477 (breakeven) and \$538,467 during Years One and Three of operations, respectively. Revenue assumptions are driven by physicians submitting letters of intent to perform procedures, and the rates are projected based on CMS published rates for FASCs. Expenses are based upon historical data from previous cost reports of similar ambulatory surgery centers and experience of the applicant who participates in other ambulatory surgery centers. The budget appears reasonable.

BFA Attachment B is the Pro-Forma balance sheet, which shows the operation will start with \$321,786 in members' equity.

Conclusion

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Supplemental

Surrounding Hospital Responses

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas.

SBH Health System -- **No Response**

4422 Third Avenue
Bronx, New York 10457

BronxCare Hospital Center -- **No Response**

1650 Grand Concourse
Bronx, New York 10457

BronxCare Hospital Center -- **No Response**

1276 Fulton Avenue
Bronx, New York 10456

DOH Comment

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

Attachments

BFA Attachment A	Net Worth Statement of Proposed Members
BFA Attachment B	Pro-Forma Balance Sheet
BHFP Attachment	Map

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 12th day of December 2019, 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 multi-specialty ambulatory surgery center, initially providing plastic, orthopedic, urology and pain management services, to be located at 1976 Crotona Parkway, Bronx, 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:

192069 B

FACILITY/APPLICANT:

Crotona Parkway SC, LLC d/b/a Crotona Parkway Ambulatory Surgery 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 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 lease agreement, acceptable to the Department of Health. (BFA)
3. Submission of an executed loan commitment for project costs, acceptable to the Department of Health. (BFA)
4. Submission of an executed working capital loan commitment, acceptable to the Department of Health. (BFA)
5. 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)
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APPROVAL CONDITIONAL UPON:

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Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov [HSP]
6. 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.

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



**Project # 191286-B
Perfect Health Medical, LLC**

Program: Diagnostic and Treatment Center **County:** Kings
Purpose: Establishment and Construction **Acknowledged:** May 31, 2019

Executive Summary

Description

Perfect Health Medical LLC, an existing New York limited liability company whose sole member is Joel Deutsch, requests approval to establish and construct an Article 28 Diagnostic and Treatment Center (D&TC) to be located at 4424-4426 18th Avenue, Brooklyn (Kings County). The D&TC will be housed in approximately 5,450 sq. ft. of lease space on the first-floors (3,700 sq. ft.) and basement levels (1,750 sq. ft.) shared between two contiguous two-story buildings. The space is currently being utilized by an existing private medical practice, QHC Upstate Medical, P.C. (QHC), which is 100% owned by Seth Kurtz, M.D. Upon Public Health and Health Planning Council (PHHPC) approval of this application, the private practice will cease operations and the space will be converted to the D&TC with only minor construction needed to implement the conversion. The applicant requests certification for Medical Services – Primary Care and Medical Services – Other Medical Specialties to provide primary medical care, behavioral health, cardiovascular, gastrointestinal and podiatry services.

Mr. Joel Deutsch is the sole member/manager of Perfect Health Medical LLC. Perfect Health Boro Park LLC, a management services organization (MSO) 100% owned by Joel Deutsch, currently provides administrative services to QHC, holds the building leases, and owns certain assets and liabilities associated with the operation of QHC (leasehold improvements, equipment, etc.). Through this project the depreciated assets of Perfect Health Boro Park LLC will be acquired by Perfect Health Medical, LLC. On May 20, 2019, Perfect

Health Boro Park LLC and Perfect Health Medical LLC executed a sale purchase agreement detailing the assets being transferred for a purchase price of \$908,885. The agreement will be effectuated upon PHHPC approval. Perfect Health Boro Park LLC will sub-lease the space to Perfect Health Medical LLC with all costs being passed down from the Master Lease.

Dr. Kurtz, who is Board-Certified in Pediatrics and Emergency Medicine, will serve as Medical Director and will be a practicing physician at the Center. The conversion from a private practice to an Article 28 facility is expected to enhance access to care to all residents in an area that has a high Medicaid and uninsured population.

The Center will have a Transfer Agreement for backup and emergency services with Maimonides Medical Center, located 1.4 miles or approximately 11 minutes' travel time from the proposed Center.

OPCHSM Recommendation
Contingent Approval

Need Summary
The number of projected visits is 28,359 in Year One and 30,668 in Year Three with Medicaid at 56% 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 total project cost of \$249,064 will be funded with \$24,906 member's equity and a \$224,158 promissory note for a 15-year term with interest estimated at 3.5%. The sale purchase agreement for the assets will be financed via a \$908,885 promissory note for a 15-year term at 3.5% interest. David Janklowicz, an independent third party and personal friend to the applicant, has submitted a letter of interest for the promissory notes at the stated terms, as well as his personal net worth statement indicating sufficient resources to fund the

transactions. Mr. Janklowicz will also fund the applicant's working capital financing needs via a promissory note for a 3-year term at 3.5% interest. Mr. Janklowicz will have no other financial interest in the project.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,709,002	\$2,929,606
Expenses	<u>\$2,569,514</u>	<u>\$2,619,362</u>
Net Income	\$139,488	\$310,244

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 promissory note for the asset purchase agreement (Bill of Sale and Obligations Undertaking), acceptable to the Department of Health. (BFA)
3. Submission of an executed promissory note for the capital loan commitment, acceptable to the Department of Health. (BFA)
4. Submission of an executed promissory note for working capital, acceptable to the Department of Health. (BFA)
5. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0, including satisfaction of currently open ProjNet Questions during the State Hospital drawing review. [AER]
6. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
7. Submission of the Articles of Organization of Perfect Health, LLC, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before February 1, 2020 and construction must be completed by March 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
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 12, 2019

Need and Program Analysis

Project Proposal

Perfect Health Medical LLC, an existing New York State limited liability company (LLC), seeks approval to establish and construct an Article 28 diagnostic and treatment center to be located at 4424-4426 18th Avenue in Brooklyn (Kings County). The proposed center, which is currently operating as a private medical practice, will provide primary medical care services, behavioral health, specialty medical services (cardiovascular and gastrointestinal), and podiatric services.

Proposed Operator	Perfect Health Medical LLC
To Be Know As	Perfect Health Medical LLC
Site Address	4424-4426 18 th Avenue Brooklyn, New York 11204 (Kings County)
Specialties	Medical Services – Primary Care Medical Services-Other Medical Specialties
Hours of Operation	Sunday-Thursday 9 AM-6 PM Friday 9 AM-1 PM Same day appointments for urgent and non-urgent patients.
Staffing (1st Year / 3rd Year)	16.35 FTEs / 16.95 FTEs
Medical Director(s)	Seth D. Kurtz, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Maimonides Medical Center 1.4 miles / 11 minutes away

Background and Analysis

The primary service area is comprised the neighborhoods of Borough Park, Bensonhurst, Flatbush and Midwood which includes the following zip codes: 11204, 11218, 11219, 11228, 11214, 11223 and 11230 in Kings County. The primary service area of Kings County and Borough Park have higher rates of hospitalization due to Ambulatory Care Sensitive Conditions (ACSCs) including: uncontrolled diabetes, lower-extremity amputation among patients with uncontrolled diabetes, hypertension and urinary tract infections. The Center will implement a number of initiatives that align with the New York State Prevention Agenda to help combat the high rates of these ACSCs in the primary service area.

The center is in Borough Park which is home to one of the largest Hasidic Jewish communities inside the United States. The center will contain seven exam rooms, an x-ray room and a special-purpose cardiology exam room, as well as appropriate support space. The center will provide primary care, behavioral health, cardiovascular, gastrointestinal and podiatric services. The center is projecting 56% Medicaid utilization. .

Per HRSA, Borough Park is a designated Health Professional Shortage Area for Primary Care services and a Medical Underserved Area/Population. The number of projected visits is 28,359 in Year One and 30,668 in Year Three.

The applicant is committed to serving all persons in need without regard to ability to pay or source of payment.

Character and Competence

Mr. Joel Deutsch is the sole member/manager of Perfect Health Medical LLC. He has spent two years serving as the Director of a primary care practice which overall responsibilities included planning, organizing, and managing the day to day operations. He also oversees the financial feasibility, strategic planning, patient satisfaction, and quality care efforts of the practice. In this role, he assists with staff recruitment and retention. Prior to this employment, Mr. Deutsch has experience in healthcare as an employee of the Mount Sinai Health System as a patient care representative. He advocated for patients to ensure they received quality care. He educated patients to make sure they understood their procedures and ensured compliance with their plan of care.

Dr. Seth D. Kurtz earned his medical degree from the SUNY Downstate College of Medicine in Brooklyn and completed an emergency medicine fellowship at Lincoln Medical Mental Health Center and a pediatrics fellowship at Maimonides Medical Center. He is board-certified in pediatrics and emergency medicine and has 12 years of experience operating primary care practices. Dr. Kurtz will serve as the center's medical director.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

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

Approval for this project will provide for the improved access for a variety of medical services for the residents of Borough Park, Bensonhurst, Flatbush and Midwood as well as the surrounding communities within 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

Total Project Costs and Financing

Total project costs for renovation is estimated at \$249,064 broken down as follows:

Renovation & Demolition	\$133,250
Design Contingency	\$13,325
Construction Contingency	\$13,325
Architect/Engineering Fees	\$15,990
Other Fees (Consultant)	\$65,480
Financing Costs	\$3,362
Interim Interest	\$981
Application Fee	\$2,000
Additional Processing Fee	<u>\$1,351</u>
Total Project Cost	\$249,064

Project costs are based on a construction start date of February 1, 2020, with a one-month construction period.

The applicant's financing plan is as follows:

Member's Equity	\$24,906
Promissory note (15-year term, 3.5% interest)	<u>\$224,158</u>
Total	\$249,064

BFA Attachment A is a summary of the sole member's personal net worth, which indicates sufficient liquid resources to fund the equity requirement for project costs. David Janklowicz, an independent third party and personal friend to the applicant, has submitted a letter of interest for the promissory note at the stated terms, as well as his personal net worth statement verifying the available liquid resources to fund the transaction.

Bill of Sale and Obligations Undertaking Agreement

The applicant has submitted an executed asset purchase agreement to acquire the assets of Perfect Health Boro Park LLC. The terms are summarized below:

Date:	May 20, 2019
Seller:	Perfect Health Boro Park LLC
Buyer:	Perfect Health Medical LLC
Clinic Address:	4424-4426 18 th Avenue, Brooklyn (Kings County)
Asset Acquired:	All leasehold improvements including security system, furniture, computers and software/programs, medical equipment inventory, medical supplies, copyrights of seller, names, title, trademarks, goodwill, causes of actions related to trademarks, books, records, promotional materials, business market surveys, sales correspondence, tax records, accounting and legal matters related to the business, mailing lists, all causes of action related to the business or recovery of assets, intellectual property, vendor information, and web-site.
Excluded Assets:	Accounts payable, expenses incurred by seller based on claims, obligations or liabilities against seller on or after closing date, obligations for capitalized leases, borrowed money, claims, debts, liabilities to include bonuses, salaries, wages, commissions, incentives, wage continuation, 401K plans, cafeteria plans, childcare, retirement, profit-sharing or similar arrangement, any indemnification obligations to pay expenses out of the arrangement including accountings, lawyers, or advisors, legal suites liabilities, storage, transportation. All cash, bank accounts and short-term investments as of the closing date. All income tax refunds and tax deposits of the seller and the minute books and tax returns of the Seller.
Assumption of Liabilities:	Liabilities arising because of events after the closing date that are subject to the ordinary course of business. Buyer assumes no debt, liability or obligations of seller as stated in the agreement.
Purchase Price:	\$908,885 to be paid after approval of this project.
Payment of Purchase Price:	\$908,885 due at closing

The purchase price will be financed via a promissory note for a 15-year term at 3.5% interest. David Jankowicz, an independent third party and personal friend to the applicant, has submitted a letter of interest for the promissory note at the stated terms, as well as his personal net worth statement verifying the available liquid resources to fund the transaction.

Lease Structure

The proposed D&TC will be on the first floor and basement levels shared between two buildings located at 4424 and 4426 18th Avenue in Brooklyn. The two buildings are owned by two separate trusts, each of which has a master lease agreement with Perfect Health Boro Park LLC.

Master Lease Rental Agreement (Master Lease Agreement #1)

The applicant has submitted an executed lease for the space located in the building at 4424 18th Avenue. The terms are summarized below:

Date:	July 1, 2016
Premises:	3,450 sq. ft. including basement located at 4424-18 th Avenue, Brooklyn, NY 11204
Lessor:	Yosef Isaacs, Trustee of the BI Family Trust
Lessee:	Perfect Health Boro Park LLC
Term:	10 Years (One 5-year renewal option)
Rent:	\$120,000 annually (\$34.78 per sq. ft.) Base rent will increase 5% bi-annually
Provisions:	Tenant will pay 75% pro rata share of taxes to landlord.

The lease is an arm's length arrangement. The applicant has submitted an affidavit attesting that there is no relationship between the landlord and tenant. The sublease provides that this building's first-floor space of approximately 2,250 sq. ft. will be apportioned for patient care services. The residual 1,200 sq. ft. located in the basement will to be utilized for D&TC storage, staff lounge, electrical rooms and closets.

Master Lease Rental Agreement (Master Lease Agreement #2)

The applicant has submitted an executed master lease for the space located in the building at 4426 18th Avenue. The terms are summarized below:

Date:	July 24, 2016 as amended September 3, 2019
Premises:	2,000 sq. ft. including basement located at 4426 18 th Avenue, Brooklyn, NY 11204
Lessor:	Connie Pittas, Trustee of Kostas and Connie Pittas Irrevocable Trust UAD
Lessee:	Perfect Health Boro Park LLC
Term:	10 Years (One 5-year renewal option).
Rent:	\$72,000 annually (\$44.66 per sq. ft.) Base rent will increase 5% bi-annually.
Provisions:	Pro-rata share at 40% for taxes/assessments will be paid by tenant. Tenant responsible for insurance and utilities. The tenant is permitted to sublet with notice to the landlord.

The lease is an arm's length arrangement. The applicant has submitted an affidavit attesting that there is no relationship between the landlord and tenant. The sublease provides that the building's first-floor space of approximately 1,450 square feet will be apportioned for patient care services. The residual 550 sq. ft. located in the basement will be used for D&TC storage, staff lounge, electrical rooms and closets. The September 3, 2019 amendment added the 550 additional sq. ft. of basement space with no change in term or rent expense.

Sublease Agreement

The applicant submitted an executed sublease agreement for the proposed D&TC space that encompasses both buildings. The terms are summarized below:

Date:	May 20, 2019
Premises:	Approx. 5,450 sq. ft. including basement located at 4424 and 4426 18 th Avenue, Brooklyn, NY 11204 (3,700 sq. ft. first floor & 1,750 sq. ft. basement)
Sublessor:	Perfect Health Boro Park LLC
Sublessee:	Perfect Health Medical LLC
Term:	5/20/2019 to 7/24/2031 (12 years, 2 months)
Rent:	\$176,747 annually (\$54.00 per sq. ft.) Base rent will increase 5% bi-annually.
Provisions:	Utilities are the responsibility of the Sublessee. Basement space will be use by the D&TC for storage, staff lounge, electrical rooms and closets.

The sublease agreement is non-arm's length as there is identical membership between the sublessor and sublessee entities. The applicant has submitted letters from two New York licensed realtors attesting to the rental rate being of fair market value and that the leased space reflects current rates for property similar to this location and size.

Operating Budget

The applicant submitted their first-and third-year operating budgets, in 2019 dollars, summarized below:

Revenues	Year One		Year Three	
	Per Visit	Total	Per Visit	Total
Commercial FFS	\$108.56	\$61,554	\$108.56	\$66,547
Commercial MC	\$92.28	\$209,374	\$92.28	\$226,445
Medicare FFS	\$97.97	\$694,607	\$97.97	\$751,136
Medicare MC	\$83.27	\$118,083	\$83.27	\$127,660
Medicaid MC	\$101.63	\$1,614,044	\$101.63	\$1,745,558
Private Pay *	\$20.00	\$11,340	\$20.00	\$12,260
Total Revenue		\$2,709,002		\$2,929,606

<u>Expenses</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Operating	\$78.24	\$2,218,707	\$76.07	\$2,332,979
Capital	\$12.37	\$350,807	\$9.34	\$286,383
Total Expenses	\$90.61	\$2,569,514	\$84.41	\$2,619,362
Net Income		<u>\$139,488</u>		<u>\$310,244</u>
Total Visits		28,359		30,668

*Private pay is a discounted charge for people who cannot afford care.

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

<u>Payor</u>	<u>Year One</u>	<u>Year Three</u>
Commercial FFS	2%	2%
Commercial MC	8%	8%
Medicare FFS	25%	25%
Medicare MC	5%	5%
Medicaid MC	56%	56%
Private Pay	2%	2%
Charity Care	2%	2%

Revenue and expense assumptions are based on the historical experience of the existing private practice calculated with QHC volumes. The Medicare FFS and MC rates are based upon the Medicare fee schedule, along with an expected collection rate adjustment based on the experience of the private practice. The Medicaid APG reimbursement methodology for an Article 28 D&TC operation is the basis of the Medicaid MC rate (all Medicaid visits are expected to be MC). Utilization is projected based on historical and current visits of QHC and the projected need for ambulatory primary healthcare in this medically underserved area.

Capability and Feasibility

The total project cost of \$249,064 will be met with member's equity of \$24,906 and a \$224,158 promissory note for a 15-year term at 3.5% interest (estimated). The sale purchase agreement for the assets will be financed via a \$908,885 promissory note for a 15-year term at 3.5% interest. David Janklowicz, an independent third party and personal friend to the applicant, has submitted a letter of interest for the promissory notes at the stated terms, as well as his personal net worth statement indicating sufficient resources to fund the transactions. BFA Attachment A is the personal net worth statement of the applicant member, which indicates sufficient funds for his equity contribution.

Working capital requirements are estimated at \$436,560 based on two months of third year expenses and will be provided via \$218,280 equity from the applicant member and a \$218,280 promissory note from Mr. Janklowicz for a 3-year term at 3.5% interest rate. BFA Attachment A indicates the applicant member has sufficient liquid resources. Mr. Janklowicz has submitted his personal net-worth statement documenting sufficient equity for all transactions. BFA Attachment B is the pro forma balance sheet of Perfect Health Medical, LLC as of the first day of operations, which indicates a positive member equity position of \$243,186.

The submitted budget indicates a net income of \$139,488 and \$310,244 in Years One and Three, respectively. Revenues are based on the historical experience of QHC and current APG rates and Medicare fee schedule rates for ambulatory primary care services. Year One utilization is slightly lower due to the start-up operations of the newly established facility. The submitted budget appears reasonable.

Conclusion

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

Attachments

BFA Attachment A	Member Net-Worth
BFA Attachment B	Pro-forma Balance Sheet
BFA Attachment C	Organizational Chart
RNR Attachment A	Map

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 12th day of December 2019, 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 to be located at 4424-4426 18th Avenue, Brooklyn to provide primary medical care, behavioral health, specialty medical services and other medical specialites to include cardiovascular, gastrointestinal and podiatry services, 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:

191286 B

FACILITY/APPLICANT:

Perfect Health Medical, LLC

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 promissory note for the asset purchase agreement (Bill of Sale and Obligations Undertaking), acceptable to the Department of Health. (BFA)
3. Submission of an executed promissory note for the capital loan commitment, acceptable to the Department of Health. (BFA)
4. Submission of an executed promissory note for working capital, acceptable to the Department of Health. (BFA)
5. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0, including satisfaction of currently open ProjNet Questions during the State Hospital drawing review. [AER]
6. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
7. Submission of the Articles of Organization of Perfect Health, LLC, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application and an expiration of the approval. [PMU]
2. Construction must start on or before February 1, 2020 and construction must be completed by March 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
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*.



**Project # 192118-B
NY Med of Brooklyn, LLC**

Program: Diagnostic and Treatment Center **County:** Kings
Purpose: Establishment and Construction **Acknowledged:** September 16, 2019

Executive Summary

Description

NY Med of Brooklyn, LLC, an existing New York limited liability company, requests approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) to be located at 765 Nostrand Avenue, Brooklyn (Kings County). The D&TC will be housed in approximately 2,805 square feet of leased space. The lease will be an arm’s length agreement as there is no relationship between landlord and tenant. The applicant requests certification for Medical Services – Primary Care and Medical Services – Other Medical Specialties to provide primary health care, other medical specialties care and physical medicine/rehabilitation services including physical therapy. The facility will include four exam rooms, six private therapy cubicles open to a small rehabilitation gym, and the requisite support spaces. Upon Public Health and Health Planning Council (PHHPC) approval of this application, the D&TC will be known as NY Med of Brooklyn.

The ownership of the Center is as follows:

<u>Proposed Operator</u>	
NY Med of Brooklyn, LLC	
<u>Members</u>	
Russell Greenseid, D.C.	28.333%
Matthew B. Weiss, D.C.	28.333%
Steven Soifer, D.C.	28.334%
Sebastian Lattuga, M.D.	7.500%
Steven Touliopoulos, M.D.	7.500%

Ari Bernstein, M.D., who is Board-Certified in Internal Medicine, will serve as Medical Director. The applicant will seek a Transfer and Affiliation Agreement with Interfaith Medical Center.

**OPCHSM Recommendation
Contingent Approval**

Need Summary

NY Med of Brooklyn LLC proposes to certify a diagnostic and treatment center in Kings County to provide the following certified services: Medical Services - Primary Care and Medical Services – Other Medical Specialties. The number of projected visits is 5,386 in Year One and 10,659 in Year Three.

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 \$1,089,504 will be met via accumulated funds of the proposed members. NY Med of Brooklyn, LLC has submitted an affidavit that they will provide funding, if necessary, to cover any net operating losses.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$770,912	\$1,525,763
Expenses	<u>\$810,382</u>	<u>\$1,240,098</u>
Net Income	(\$39,470)	\$285,665

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
3. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
4. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
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]

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by June 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The 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]
4. 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]
5. 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.

Council Action Date

December 12, 2019

Need and Program Analysis

Background

The primary service area is Bedford – Stuyvesant in northern Kings County. The population of Kings County was 2,504,700 in 2010 and is projected to grow to 2,810,876 by 2025, an increase of 12.2%.

The proposed center will provide Primary Medical Care Services, Orthopedics, Gastroenterology, Pain Management, Pulmonology, Oncology, Endocrinology, Cardiology, Urology, and Physical Medicine and Rehabilitation and will be certified for Primary Care and Other Medical Specialties. The number of projected visits is 5,386 in Year One and 10,659 in Year Three. The center is projecting Medicaid utilization of 35% for the first and third year.

Proposed Operator	NY Med of Brooklyn, LLC
To Be Known As	NY Med of Brooklyn
Site Address	765 Nostrand Avenue Brooklyn, NY 11216 (Kings County)
Specialties	Medical Services – Primary Care Medical Services-Other Medical Specialties
Hours of Operation	Monday through Friday 8:00 AM to 6:00 PM As volume or need indicates the applicant will add Saturday 8:30 AM to 6:00 PM
Staffing (1st Year / 3rd Year)	9.44 FTEs / 14.65 FTEs
Medical Director(s)	Ari Bernstein, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Interfaith Medical Center-One Brooklyn Health System 1.5 miles / 6 minutes away

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 is higher than the New York State rate.

Hospital Admissions per 100,000 Adults for Overall PQIs		
2016 PQI Rates	Service Area	New York State
All PQI's	1,576	1,363

Source: DOH, 2019

Per HRSA, areas of Kings County are designated as a Health professional Shortage Area and a Medically Underserved Area/population as follows:

- Crown Heights- Bedford-Stuyvesant: Health Professional Shortage Area for Primary Care services
- Bedford-Stuyvesant Service Area: Medically Underserved area

The applicant is committed to serving all persons in need without regard to ability to pay or source of payment.

Character and Competence

The members of NY Med of Brooklyn, LLC are:

Name	Interest
Russell Greenseid, <i>Manager/Member</i>	28.333%
Sebastian Lattuga, <i>Manager/Member</i>	7.500%
Steven Soifer, <i>Manager/Member</i>	28.334%
Steven Touiopoulos, <i>Manager/Member</i>	7.500%
Matthew Weiss, <i>Manager/Member</i>	28.333%

Mr. Russell Greenseid is a practicing Chiropractor and Manager of a practice for 20 years. His responsibilities include managing day to day responsibilities such as hiring, fiscal duties, enacted office protocol, and developing an office manual. He has trained new chiropractors and taught employees to work in a multidisciplinary setting. He is responsible for business development, growth, and advertising campaigns.

Dr. Sebastian Lattuga, M.D. is the Medical Director of his primary care facility. His responsibilities include managing and promoting patient care; recruits, trains, and supervises physicians and assistants with medical knowledge, professionalism, and continuing education; liaisons with other medical and non-medical departments to develop and improved policy, protocols, and procedures; evaluates budget; and investigates and maintains compliance with all federal and state regulation and codes.

Mr. Steven Soifer is an Owner and Operator of a Diagnostic and Treatment facility. He previously was employed as a Healthcare Manager of a managed care organization for over 11 years. He is a licensed Chiropractor.

Dr. Steven Toulipoulos, M.D. is a practicing Orthopedic Physician at a group practice. He received his medical degree from State University of New York Downstate Medical Center in Brooklyn. He completed his orthopedic residency at Kings County Hospital Center and his orthopedic surgery residency at Lenox Hill Hospital. He is board certified in Orthopaedic Surgery.

Mr. Matthew Weiss is an Owner and Operator of a Diagnostic and Treatment Center for over six years. He is the Chief Operating Officer on an Article 28 Diagnostic and Treatment Center. He is a licensed Chiropractor. He is responsible for the day to day operations of the facility, the financial management, human resources, customer relations, and quality assurance and improvement. He previously oversaw the business operations and day to day management of a managed care organization for over 11 years.

Dr. Ari Bernstein, M.D. is the proposed Medical Director. He is currently an Internal Medicine and Urgent Care Physician of an Article 28 Diagnostic and Treatment Center. He assists the current Medical Director with the day to day responsibilities and oversight of the facility. He was previously employed as an Emergency Medicine Physician. His responsibilities included supervising medical staff, physician assistants, and medical residents. He was the physician in charge of the Emergency Department during his scheduled shifts. He is Board Certified in Internal Medicine. He graduated with his medical degree from St. George's University School of Medicine in Grenada. He completed his Internal Medicine residency at New York Presbyterian Queens.

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. Bernstein disclosed being named in a malpractice case filed in the summer (July/August) of 2017 which alleged misdiagnosis of a bowel perforation post op. Dr. Bernstein was the Emergency Department physician when the patient arrived at complaining of abdominal pain and surgical site pain one post op from abdominal surgery. Dr. Bernstein called the surgeon down to see the patient immediately. The surgeon did an official consult and the patient was discharged with post-op pain. The patient alleges that they went to another hospital later in the day and required surgery for a bowel perforation. The case against Dr. Bernstein (and the surgeon) is pending.

Dr. Lattuga disclosed being named in three pending malpractice cases. The three pending malpractice cases are in the discovery phase. On June 18, 2013, the patient alleged that the failure to properly treat an impending cerebral vascular accident. On September 12, 2017, the patient alleged a negligent cervical spinal fusion. On December 20, 2018, the patient alleged a negligent spinal surgery. Dr. Lattuga also disclosed being named in three closed malpractice cases. On November 1, 2011 a patient alleged negligent cervical spine surgery. The case was settled in 2018 with no finding of malpractice and an indemnity of \$240,000 paid. On October 11, 2013, a patient alleged negligent spinal surgery. The case was closed in 2016 with no findings of malpractice and no indemnity paid. On June 25, 2015, a patient alleged negligent spinal fusion and laminectomy. The case was closed in 2018 with no finding of malpractice and no indemnity paid.

Dr. Touliopoulos disclosed being named in two pending malpractice suits (August 2017 and September 2018). One patient alleged that she required a revision knee replacement due to complications arising from initial total knee replacement. The second patient alleges a cerebrovascular accident occurred postoperatively.

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. Approval for this project will provide for the additional access to a variety of medical services for residents with the Bedford-Stuyvesant area as well as the surrounding communities in Kings County.

Financial Analysis

Total Project Cost and Financing

Total project cost for renovations and moveable equipment is \$1,089,504, broken down as follows:

Renovation & Demolition	\$695,250
Design Contingency	69,525
Construction Contingency	69,525
Architect /Engineering Fees	54,000
Other Fees	55,000
Moveable Equipment	123,255
Telecommunications	15,000
CON Fee	2,000
Additional Processing Fee	<u>5,949</u>
Total Project Cost	\$1,089,504

Project costs are based on a construction start date of March 1, 2020, and a three-month construction period.

Total project cost will be met via accumulated funds of the proposed members. BFA Attachment A provides the net worth statement of the proposed members of NY Med of Brooklyn, LLC, which shows sufficient liquid assets overall to meet the equity requirements of this application.

Lease Agreement

The applicant has submitted an executed lease agreement, the terms of which are summarized below:

Date:	July 1, 2019
Premises:	2,805 square feet of space at 765 Nostrand Avenue, Brooklyn NY 11216
Landlord:	Hazel Blue Nostrand, LLC
Tenant:	NY Med of Brooklyn, LLC
Rental:	Fixed rent \$90,000 annually (\$7,500 per month) with a 3% increase at the end of the first lease year and each successive lease year thereafter.
Term:	10 years with three five-year renewal options at a 5% fixed rent escalation.
Provisions:	Tenant shall be responsible for maintenance, taxes, insurance and utilities.

The applicant submitted an affidavit that the lease is an arm's length agreement. The applicant has submitted letters from two New York realtors attesting to the rent reasonableness.

Operating Budget

The applicant has submitted their first-year and third-year operating budget, in 2019 dollars:

	Year One		Year Three	
<u>Revenues</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
Commercial FFS	\$165.00	\$248,815	\$164.97	\$492,446
Medicare FFS	\$135.14	36,353	\$134.99	71,948
Medicare MC	\$108.01	116,329	\$107.99	230,234
Medicaid FFS	\$168.88	91,027	\$169.00	180,158
Medicaid MC	\$126.80	170,676	\$126.75	337,797
Private Pay	\$199.84	<u>107,712</u>	\$199.98	<u>213,180</u>
Total Revenue		\$770,912		\$1,525,763
 <u>Expenses</u>				
Operating	\$124.79	\$672,099	\$102.86	\$1,096,415
Capital	<u>25.67</u>	<u>138,283</u>	<u>13.48</u>	<u>143,683</u>
Total Expenses	\$150.46	\$810,382	\$116.34	\$1,240,098
Net Income/loss		<u>(\$39,470)</u>		<u>\$285,665</u>
Visits		5,386		10,659
Cost/Visit		\$150.46		\$116.34

Utilization by payor source during first and third years is broken down as follows:

Payor	Year One		Year Three	
	Visits	%	Visits	%
Commercial FFS	1,508	28%	2,985	28%
Medicare FFS	269	5%	533	5%
Medicare MC	1,077	20%	2,132	20%
Medicaid FFS	539	10%	1,066	10%
Medicaid MC	1,346	25%	2,665	25%
Private Pay	539	10%	1,066	10%
Charity Care	<u>108</u>	<u>2.0%</u>	<u>212</u>	<u>2.0%</u>
Total	5,386	100%	10,659	100%

The following is noted with respect to the submitted budget:

- The Medicaid Fee-for-Service rate is based on the Medicaid APG payment methodology's base rate plus the cost of capital, as obtained from the Bureau of D&TC Reimbursement. The applicant used the clinic base rate of \$169.02 for a conservative estimate of the FFS per visit rate.
- Medicaid Managed Care is assumed to be 75% of the Medicaid APG Fee for Service rate. The Center intends to reach out to United Health Care, Fidelis, Healthfirst and Affinity for Medicaid Managed Care contracting.
- Commercial Insurance and Medicare Fee for Service is based on the Medicare Part B fee schedule. Medicare Managed Care is based on 80% of the Medicare FFS rate.

Capability and Feasibility

The total project cost is \$1,089,504 and will be met via accumulated funds of the proposed members.

Working capital requirements are estimated at \$206,683 based on two months of third-year expenses and will be satisfied via equity from the proposed members of NY Med of Brooklyn, LLC. BFA Attachment A is the net worth of the proposed members, which indicates the availability of sufficient funds for stated levels of equity. BFA Attachment B, the pro forma balance sheet for the applicant, indicates that the facility will initiate operations with members' equity of \$1,296,187

The submitted budget projects a net loss of \$39,470 for the first year and a net income of \$285,665 for the third year. Revenues are based on prevailing reimbursement methodologies for D&TCs. NY Med of Brooklyn, LLC has submitted an affidavit that they will provide funding, if necessary, to cover any net operating losses. The budget appears reasonable.

Based on the preceding, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	Net Worth Statement of NY Med of Brooklyn, LLC
BFA Attachment B	Pro Forma Balance Sheet, NY Med of Brooklyn, LLC
BHFP Attachment	Map

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 12th day of December 2019, 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 construction of a new diagnostic and treatment center to be located in leased space at 765 Nostrand Avenue, Brooklyn, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

192118 B

NY Med of Brooklyn

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
3. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
4. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-1.0. [AER]
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]

APPROVAL CONDITIONAL UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. Construction must start on or before March 1, 2020 and construction must be completed by June 1, 2020, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the start date this shall constitute abandonment of the approval. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [PMU]
3. The 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]
4. 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]

5. 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.

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



Project # 192013-E
Fairview Nursing Care Center, Inc.

Program: Residential Health Care Facility
Purpose: Establishment

County: Queens
Acknowledged: August 2, 2019

Executive Summary

Description

Fairview Nursing Care Center, Inc., a proprietary business corporation that operates a 200-bed, Article 28 residential health care facility (RHCF) located at 69-70 Grand Central Parkway, Forest Hills (Queens County), requests approval to transfer 99% ownership interest to one new shareholder from one withdrawing shareholder and one remaining shareholder. Current shareholder Abraham N. Klein died in 2012 bequeathing all his ownership interest in the Center to his wife, Sarah Dinah Klein, the Executrix of his estate. Due to Ms. Klein's advanced age and her wish to transfer economic interest in the corporation to their son, Yaakov Klein, all of Abraham Klein's 100 shares (50% stock interest) in Fairview Nursing Care Center, Inc. and 98 shares (49% stock interest) of Ms. Klein's ownership interest will be transferred to Yaakov Klein. There will be no change in beds or services provided.

Ownership of the Fairview Nursing Care Center, Inc. before and after the requested change is as follows:

<u>Stockholders</u>	<u>Current</u>	<u>Proposed</u>
Sara Dina Klein	50%	1%
Abraham Klein (Estate)	50%	0%
Yaakov Klein	---	99%
Total	100%	100%

Yaakov Klein currently has 40% ownership interest in KFG Operating Two, LLC, a New York limited liability company that operates Bensonhurst Center for Rehabilitation and Healthcare, a 200-bed, Article 28 RHCF located at 1740 84th Street, Brooklyn (Kings County).

OPCHSM Recommendation

Contingent Approval

Need Summary

There is no need review of this application.

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

There are no project costs associated with this application. The aggregate purchase price for the 198 shares is \$24,750,000 and will be funded via two promissory notes—one at \$12,500,000 for Abraham Klein's shares and one at \$12,250,000 for Sara Klein's shares. There is no down payment. The promissory notes are interest only at 2% for 10 years, after which they will either be refinanced, or the terms will be extended. Upon Ms. Klein death, her two shares (1% ownership interest) will be gifted to Yaakov Klein and the outstanding balance of the promissory notes will be forgiven.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$34,913,000	\$34,516,000
Expenses	<u>30,667,032</u>	<u>30,920,032</u>
Gain	\$4,245,968	\$3,595,968

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 photocopy of the amended bylaws, acceptable to the Department. (CSL)
2. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Program Analysis

Facility Information

	Existing	Proposed
Facility Name	Fairview Nursing Care, Inc.	Same
Address	69-70 Grand Central Parkway Forest Hills, NY 11375	Same
RHCF Capacity	200	Same
ADHCP Capacity	100 (offsite)	Same
Type of Operator	Corporation	Same
Class of Operator	Proprietary	Same
Operator	Sara Dina Klein 50% Abraham Noach Klein (Estate) 50%	Yaakov Klein 99% Sara Dina Klein 1.0%

No changes in the program or physical environment are proposed in this application.

Character and Competence - Assessment

Yaakov Klein has a bachelor's degree from Yeshiva Machzikei Hadas. He has been employed as the Director of Operations at Fairview Nursing Care Center, Inc. since 2013. Prior to this he was employed as a teacher in Israel. Mr. Klein discloses the following health facility interests:

Bensonhurst Center for Rehabilitation and Healthcare (50%) 02/2012 to present

A review of the above facilities indicates there were no enforcements or Civil Money Penalties for the period of ownership.

Quality Review

Facility	Ownership Since	Overall	Health Inspection	Quality Measure	Staffing
Fairview Nursing Care Center <i>(subject facility)</i>	Current	****	***	*****	**
Bensonhurst Center for Rehabilitation and Healthcare	Current	*****	*****	*****	**
	02/2012	***	***	****	***

Data date: 10/2019

Conclusion

No negative information has been received concerning the character and competence of the proposed applicants.

Financial Analysis

Stock Purchase Agreements

The applicant has submitted executed Stock Purchase Agreements (SPA) to acquire the stock interests of the RHCF. The agreements will become effectuated upon Public Health and Health Planning Council (PHHPC) approval of this CON. The terms are summarized below:

Date:	October 3, 2019
Seller:	The Estate of Abraham N. Klein
Purchaser:	Yaakov Klein
Terms:	100 shares of common stock for \$12,500,000 at 2% per year (interest only) on the outstanding sum for a period of 10 years. After 10 years, the loan will be reviewed and either refinanced or the term will be extended. There is no down payment.
Purchase Amount:	\$12,500,000 via promissory note

Date:	October 3, 2019
Seller:	Sara Dina Klein
Purchaser:	Yaakov Klein
Terms:	98 shares of common stock for \$12,250,000 at 2% per year (interest only) on the outstanding sum for a period of 10 years. After 10 years the loan will be reviewed and either refinanced or the term will be extended. There is no down payment.
Purchase Amount:	\$12,250,000 via promissory note

The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of October 29, 2019, the facility had no outstanding Medicaid overpayment liabilities.

Promissory Notes

The applicant has submitted executed Promissory Notes to purchase the stock interests of the RHCF. The Promissory Notes will become effectuated upon PHHPC approval of this CON. The terms are summarized below:

Date:	October 3, 2019
Obligor:	Yaakov Klein
Obligee:	Estate of Abraham Klein
Terms:	A loan to be financed by the obligee at 2% interest (interest only) on the outstanding sum for a period of 10 years. After the 10 years the loan will be reviewed and either refinanced or the term will be extended. There will be no down payment.
Amount:	\$12,500,000

Date:	October 3, 2019
Obligor:	Yaakov Klein
Obligee:	Sara Dina Klein
Terms:	A loan to be financed by the obligee at 2% interest (interest only) on the outstanding sum for a period of 10 years. After the 10 years the loan will be reviewed and either refinanced or the term will be extended. There will be no down payment.
Amount:	\$12,250,000

Operating Budget

The applicant has provided an operating budget, in 2019 dollars, for the current, first and third years subsequent to the change of ownership. The budget is summarized below:

	Current Year (2018)		Year One		Year Three	
	Per Diem	Total	Per Diem	Total	Per Diem	Total
<u>Inpatient Revenue</u>						
Commercial-MC	\$418.60	\$2,479,816	\$418.52	\$2,499,000	\$418.56	\$1,912,000
Medicare	\$671.12	11,613,785	\$671.08	11,703,000	\$671.23	11,235,000
Medicaid	\$342.41	15,298,597	\$342.40	15,417,000	\$342.65	16,389,000
Private Pay	\$449.48	733,095	\$449.18	738,000	\$449.63	424,000
Total Inpt Revenue		\$30,125,293		\$30,357,000		\$29,960,000
<u>Outpatient Revenue</u>	<u>Per Vst.</u>	<u>Total</u>	<u>Per Vst.</u>	<u>Total</u>	<u>Per Vst.</u>	<u>Total</u>
Commercial-FFS	\$146.73	\$3,227,525	\$146.73	\$3,286,000	\$146.73	\$3,286,000
Medicaid-FFS	\$126.35	1,247,719	\$126.34	1,270,000	\$126.34	1,270,000
Total Outpt Revenue		\$4,475,244		\$4,556,000		\$4,556,000
Other Opr Revenue		15,154		0		0
Total Revenue		\$34,615,691		\$34,913,000		\$34,516,000
<u>Inpatient Expense</u>	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>
Operating	\$328.08	\$22,814,631	\$329.60	\$23,098,000	\$332.65	\$23,312,000
Capital	36.22	2,518,738	36.25	2,540,032	36.30	2,544,032
Total Inpt Expense	\$364.30	\$25,333,369	\$365.84	\$25,638,032	\$368.96	\$25,856,032
<u>Outpatient Expense</u>	<u>Per Vst.</u>	<u>Total</u>	<u>Per Vst.</u>	<u>Total</u>	<u>Per Vst.</u>	<u>Total</u>
Operating	\$126.03	\$4,016,816	\$126.24	\$4,096,000	\$126.73	\$4,112,000
Capital	28.47	907,324	28.75	933,000	29.34	952,000
Total Outpt Expense	\$154.50	\$4,924,140	\$154.99	\$5,029,000	\$156.07	\$5,064,000
Total Expense		\$30,257,509		\$30,667,032		\$30,920,032
Net Income		\$4,343,028		\$4,245,968		\$3,595,968
<u>Utilization</u>						
Patient Days		69,539		70,079		70,079
Outpatient Visits		31,872		32,447		32,447
Occupancy %		95.26%		96.00%		96.00%
Break-even		81.53%		82.57%		84.48%

The following is noted with respect to the submitted budget:

- Private pay is comprised of revenue from cash or a subsidiary policy.
- Medicaid revenue is based on the facility's current 2018 Medicaid Regional Pricing rate.
- Medicare revenues include fee-for-service, managed care, and Medicare Part B
- The Medicare, Medicaid, and private pay/other rates are based on the facility's actual 2018 rates.
- The current year reflects the facility's 2018 revenues and expenses based on 2018 certified financials.
- Breakeven utilization is projected at 82.57% or 59,514 patient days for Year One, and 84.48% or 61,668 patient days for Year Three.
- The facility's Medicaid rate effective July 1, 2019, which was approved on October 9, 2019, is now revised downward to \$303.87 (reflects updated case mix). The current lower rate will therefore, impact year one and year three projections reducing first and third year revenues by \$1,734,949 and \$1,854,898, respectively.

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

<u>Payor</u>	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
Commercial	8.52%	8.52%	6.52%
Medicare	24.89%	24.88%	23.88%
Medicaid	64.25%	64.25%	68.25%
Private Pay	2.35%	2.34%	1.35%
Total	100.00%	100.00%	100.00%

- The facility's Medicaid admissions of 9.0% in 2017 and 11.9% in 2018 did not exceed Queens County's 75% threshold rates of 23.8% for 2017 and 24.6% in 2018. Fairview Nursing Care Center, Inc. is located in a neighborhood with a median household income that is higher than the average threshold. In an effort to reach lower than average household income families, the applicant has implemented a marketing program and an outreach effort to the broader community that it serves. These efforts will include meeting with local community organizations as well as all of the referring healthcare provider organizations to the Center.

Capability and Feasibility

There are no project costs associated with this application. The submitted budget indicates a net income of \$4,245,968 and \$3,595,968 for the first and third years, respectively, subsequent to the change in membership interest. BFA Attachment E is the revised first-year and third-year budgets based on the July 2019 current Medicaid rate for the facility promulgated October 9, 2019. As shown, budgeted revenues would decrease by \$1,734,949 in Year One and \$1,854,898 in Year Three, resulting in a net operating income of \$2,511,019 and \$1,741,07, respectively. The budget appears reasonable.

Working capital requirements are estimated at \$5,111,172, which is equivalent to two months of first year expenses and will be met through operations. BFA Attachment B is Fairview Nursing Care Center, Inc.'s financial summary. As of June 30, 2019, current assets (\$24,101,111) less current liabilities (\$6,786,562) equals \$17,314,549, which is sufficient to fund working capital needs.

As shown on BFA Attachment B, the facility maintained a positive working capital position, a positive net asset position, and an average net operating income of \$5,302,824 for the years 2017 and 2018. As of June 30, 2019, the facility maintained a positive working capital position, a positive net asset position, and had a net operating income of \$6,936,204.

BFA Attachment C is the financial summary of Bensonhurst Center for Rehabilitation and Healthcare, Yaakov Klein's affiliated home. The facility maintained a positive working capital position, a net asset position, and a net operating income of \$7,850,065 in 2018.

Conclusion

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

Attachments

- BFA Attachment A Net Worth Statement of Proposed Members
- BFA Attachment B Financial Summary - Fairview Nursing Care Center, Inc.
- BFA Attachment C Affiliated Nursing Home - Bensonhurst Center for Rehabilitation and Healthcare
- BFA Attachment D Revised First and Third Year budgets based on 2019 Medicaid Rate

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 12th day of December 2019, 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 99% ownership interest to one new shareholder from one withdrawing shareholder and one remaining shareholder, 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:

192013 E

Fairview Nursing Care Center, Inc.

APPROVAL CONTINGENT UPON:

1. Submission of a photocopy of the amended bylaws, acceptable to the Department. (CSL)
2. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



Project # 192014-E
Always There Family Home Health Services

Program: Certified Home Health Agency
Purpose: Establishment

County: Ulster
Acknowledged: July 19, 2019

Executive Summary

Description

The Dominican Sisters Family Health Services, Inc. d/b/a ArchCare at Home, a voluntary not for profit (NFP), Article 36 Certified Home Health Agency (CHHA) located at 115 East Stevens Avenue, Valhalla (Westchester County), requests approval to merge and consolidate Ulster Home Health Services, Inc. d/b/a Always There Family Home Health Services (Always There), a voluntary NFP, Article 36 CHHA located at 918 Ulster Avenue, Kingston (Ulster County), into its operation. ArchCare at Home is authorized to provide CHHA services in Bronx, Kings, Nassau, New York, Orange, Putnam, Queens, Richmond, Rockland, Suffolk, and Westchester counties and is certified to provide home health aide, medical social services, physical therapy, medical supplies equipment and appliances, nursing, nutritional, occupational therapy, physical therapy, and speech language pathology services. Always There is authorized to serve Ulster County and is licensed to provide the same CHHA services as ArchCare at Home. Upon Public Health and Health Planning Council (PHHPC) approval, Always There will close and ArchCare at Home will expand its geographic service area to include Ulster County. There will be no changes to the services provided by ArchCare at Home.

Catholic Health Care System d/b/a ArchCare, an NFP located in New York County, is the sole corporate member of The Dominican Sisters Family Health Services, Inc. The sole corporation member of ArchCare is Providence Health Services, an NFP corporation. On June 7, 2018, ArchCare became the sole corporate member of Always There. On November 28, 2018, the New York State Department of Health

approved a management agreement between Always There and ArchCare at Home (manager), which will terminate upon closing of this application.

BFA Attachment A shows the before and after ownership of the CHHA.

OPCHSM Recommendation
Contingent Approval

Need Summary

There will be no net impact to patient/resident services provided. Always There Family Home Health Services is certified to provide services in Ulster County. Upon approval of this merger, Always There will close, and Ulster County will be added to ArchCare at Home's operating certificate.

Program Summary

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

Financial Summary

There are no project costs associated with this application. The Catholic Health Care System and The Catholic Health Care Foundation of the Archdiocese of New York will provide the working capital via cash equity.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$47,012,814	\$48,536,978
Expenses	\$46,606,898	\$48,015,751
Net Income	\$405,916	\$521,227

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 building sub-lease agreement, acceptable to the Department of Health. (BFA)
2. Submission of an executed transfer agreement, acceptable to the Department of Health. (BFA)
3. Submission of a photocopy of an executed Resolution of the Board of Directors of Catholic Health Care System d/b/a ArchCare, acceptable to the Department. (CSL)
4. Submission of a photocopy of an executed Resolution of the Board of Directors of Providence Health Services (PHS), acceptable to the Department. (CSL)
5. Submission of a photocopy of the Certificate of Incorporation of PHS, 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 Certificate of Assumed Name, acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Proposal

The Dominican Sisters Family Health Service, Inc. d/b/a ArchCare at Home, a not-for-profit corporation, requests approval to acquire and merge the assets of a Ulster Home Health Services, Inc. d/b/a Always There Family Home Health Services (Always There), an existing Article 36 Certified Home Health Agency (CHHA) serving Ulster county.

ArchCare at Home, is an existing CHHA operating in Westchester, Bronx, Suffolk, Kings, New York, Queens, Richmond, Orange, Putnam, Rockland and Nassau Counties. The ArchCare at Home CHHA is parented by Catholic Health Care System d/b/a ArchCare, which is ultimately parented by Providence Health Services.

As part of project 181191, Catholic Health Care System d/b/a ArchCare was approved to become the sole corporate member of the Always There Family Home Health Services CHHA, with Providence Health Services becoming the ultimate parent corporation as of June 7, 2018. Additionally, as part of an approved management agreement, Dominican Sisters Family Health Service, Inc. has been managing the operations of Always There Family Home Health Services since November 28, 2018.

This project seeks approval of a transfer agreement wherein Always There Family Home Health Services agrees to transfer all of its assets to ArchCare at Home. Upon approval, Always There Family Home Health Services will close and ArchCare at Home will add Ulster County to its approved geographical service area.

Character and Competence Review

The Board of Directors of The Dominican Sisters Family Health Services d/b/a ArchCare at Home is comprised of the following individuals:

<p>Karen A. Gray HR Director, Christie's, Inc.</p>	<p>Joseph P. LaMorte Vicar General/Chancellor, Archdiocese of New York <u>Affiliations</u></p> <ul style="list-style-type: none"> • Carmel Richmond Healthcare & Rehabilitation Center (12/2018 – Present) • Ferncliff Nursing Home & Rehabilitation Center (12/2018 – Present)
<p>Thomas M. O'Brien Vice Chairman, Emigrant Bank President, Naples Commercial Finance <u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (2015-present) • Carmel Richmond Healthcare & Rehabilitation Center (2005-present) • Empire State Home Care Services, Inc. (2015-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2005-present) • Kateri Residence (2005-8/28/2013) • Mary Manning Walsh Home (2005-present) • St. Teresa's Nursing Home (1/1/2013-2/1/2013) • St. Vincent de Paul Residence (2005-present) • Terence Cardinal Cooke Health Care Center (2005-present) 	<p>Charles J. Fahey Retired - 2001 <u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare Advantage (2014-present) • ArchCare at Home (5/1/2014-present) • ArchCare Senior Life (2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (2006-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2006-present) • Kateri Residence (2006-8/28/2013) • Mary Manning Walsh Home (2006-present) • St. Teresa's Nursing Home (2006-2/1/2013) • St. Vincent de Paul Residence (2006-present) • Terence Cardinal Cooke Health Care Center (2006-present)

<p>John T. Dunlap, Esq. Partner, Dunnington, Bartholow & Miller LLP</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (5/1/2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (2006-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2006-present) • Kateri Residence (2006-8/28/2013) • Mary Manning Walsh Home (2006-present) • St. Teresa's Nursing Home (2006-2/1/2013) • St. Vincent de Paul Residence (2006-present) • Terence Cardinal Cooke Health Care Center (2006-present) 	<p>Eric P. Feldmann Retired – April 30, 2013</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • Carmel Richmond Healthcare & Rehabilitation Center (2005-present) • Ferncliff Nursing Home & Rehabilitation Center (2009-present) • Kateri Residence (2009-2013) • Mary Manning Walsh Home (2009-present) • St. Teresa's Nursing Home (2009-2/1/2013) • St. Vincent de Paul Residence (2009-present) • Terence Cardinal Cooke Health Care Center (2009-present)
<p>Rory Kelleher, JD Senior Counsel, Sidley Austin LLP</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (5/1/2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (1/1/2008-3/1/2012 & 1/1/2013-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (1/1/2008-3/1/2012 & 1/1/2013-present) • Kateri Residence (2005-3/1/2012 & 1/1/2013-8/28/2013) • Mary Manning Walsh Home (1/1/2008-3/1/2012 & 1/1/2013-present) • St. Teresa's Nursing Home (1/1/2008-3/1/2012 & 1/1/2013-2/1/2013) • St. Vincent de Paul Residence (1/1/2008-3/1/2012 & 1/1/2013-present) • Terence Cardinal Cooke Health Care Center (1/1/2008-3/1/2012 & 1/1/2013-present) 	<p>Jeffrey J. Hodgman Retired – August 19, 2005</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (11/2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (7/1/2016-present) • Empire State Home Care Services, Inc. (7/1/2016-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (7/1/2016-present) • Mary Manning Walsh Home (7/1/2016-present) • St. Vincent de Paul Residence (7/1/2016-present) • Terence Cardinal Cooke Health Care Center (7/1/2016-present)
<p>Thomas J. Fahey, Jr., MD Retired</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (5/1/2014-present) • Calvary Hospital (2000-present) • Carmel Richmond Healthcare & Rehabilitation Center (2009-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2009-present) • Kateri Residence (2009-8/28/2013) • Mary Manning Walsh Home (2009-present) • St. Teresa's Nursing Home (2009-2/1/2013) • St. Vincent de Paul Residence (2009-present) • Terence Cardinal Cooke Health Care Center (2009-present) 	<p>Tara Cortes, PhD, RN Executive Director/Professor, The Hartford Institute for Geriatric Nursing at NYU College of Nursing</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (2013-present) • Carmel Richmond Healthcare & Rehabilitation Center (2013-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2013-present) • Kateri Residence (2013-8/28/2013) • Mary Manning Walsh Home (2013-present) • St. Teresa's Nursing Home (2013-2/1/2013) • St. Vincent de Paul Residence (2013-present) • Terence Cardinal Cooke Health Care Center (2013-present)

<p>Francis J. Serbaroli, Esq., Chairman Partner, Greenberg Traurig, LLP</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare Advantage (1/2008-present) • ArchCare at Home (5/2014-present) • ArchCare Senior Life (11/2008-present) • Carmel Richmond Healthcare & Rehabilitation Center (2008-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (2008-present) • Kateri Residence (2008-8/28/2013) • Mary Manning Walsh Home (2008-present) • St. Teresa's Nursing Home (2008-2/1/2013) • St. Vincent de Paul Residence (2008-present) • Terence Cardinal Cooke Health Care Center (2008-present) 	<p>Kathryn K. Rooney, Esq. Attorney, Law Offices of Kathryn K. Rooney</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (5/1/2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (1/2001-present) • Empire State Home Care Services, Inc. (2014-10/4/2016) • Safe Harbor Healthcare Services (1988-present) • Kateri Residence (2005-8/28/2013) • Mary Manning Walsh Home (2005-present) • Richmond University Medical Center (1/2007-present) • St. Vincent de Paul Residence (2005-present) • Terence Cardinal Cooke Health Care Center (2005-present)
<p>Gerald T. Walsh Vicar, Archdiocese of New York</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (2013 – Present) • Carmel Richmond Healthcare & Rehabilitation Center (2013 – Present) • Ferncliff Nursing Home & Rehabilitation Center (2013-present) • Kateri Residence (2013 – 8/28/2013) • Mary Manning Walsh Home (2013-present) • St. Teresa's Nursing Home (2013 – 2/1/2013) • St. Vincent de Paul Residence (2013 – Present) • Terence Cardinal Cooke Health Care Center (2013 – Present) • Isabella Geriatric Center (7/1/1999 – Present) 	<p>Thomas E. Alberto Retired – October 31, 2013</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (1990-present) • Carmel Richmond Healthcare & Rehabilitation Center (2013-present) • Ferncliff Nursing Home & Rehabilitation Center (2013-present) • Kateri Residence (2013-8/28/2013) • Mary Manning Walsh Home (2013-present) • St. Teresa's Nursing Home (2008-2/1/2013) • St. Vincent de Paul Residence (2008-present) • Terence Cardinal Cooke Health Care Center (2008-present)
<p>George B. Irish Eastern Director, Hearst Foundations</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (3/8/2017-present) • Carmel Richmond Healthcare & Rehabilitation Center (3/8/2017-present) • Ferncliff Nursing Home & Rehabilitation Center (3/8/2017-present) • Mary Manning Walsh Home (3/8/2017-present) • St. Vincent de Paul Residence (3/8/2017-present) • Terence Cardinal Cooke Health Care Center (3/8/2017-present) 	<p>Clarion E. Johnson, MD (Maryland) Retired - March 31, 2013</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare at Home (7/1/2016-present) • Carmel Richmond Healthcare & Rehabilitation Center (7/1/2016-present) • Empire State Home Care Services, Inc. (7/1/2016-10/4/2016) • Ferncliff Nursing Home & Rehabilitation Center (7/1/2016-present) • Mary Manning Walsh Home (7/1/2016-present) • St. Vincent de Paul Residence (7/1/2016-present) • Terence Cardinal Cooke Health Care Center (7/1/2016-present)

<p>Gerald T. Sweeney Chief Information Officer, Healthfirst</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare Advantage (2012-present) • ArchCare at Home (5/1/2014-present) • ArchCare Senior Life (2012-present) • Carmel Richmond Healthcare & Rehabilitation Center (2012-present) • Ferncliff Nursing Home & Rehabilitation Center (2012-present) • Kateri Residence (2012-8/28/2013) • Mary Manning Walsh Home (2012-present) • St. Teresa's Nursing Home (2012-2/1/2013) • St. Vincent de Paul Residence (2012-present) • Terence Cardinal Cooke Health Care Center (2012-present) 	<p>Gennaro J. Vasile, PhD Retired</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • ArchCare Advantage (2014-present) • ArchCare Senior Life (2014-present) • Carmel Richmond Healthcare & Rehabilitation Center (1/1/2013-present) • Ferncliff Nursing Home & Rehabilitation Center (1/1/2013-present) • Kateri Residence (1/1/2013-8/28/2013) • Mary Manning Walsh Home (1/1/2013-present) • St. Teresa's Nursing Home (1/1/2013-2/1/2013) • St. Vincent de Paul Residence (1/1/2013-present) • Terence Cardinal Cooke Health Care Center (1/1/2013-present)
<p>Scott P. LaRue, RD President/CEO, ArchCare</p> <p><u>Affiliations</u></p> <ul style="list-style-type: none"> • Carmel Richmond Healthcare & Rehabilitation Center (03/2011 – Present) • Ferncliff Nursing Home & Rehabilitation Center (03/2011 – Present) • Kateri Residence (03/2011 – Present) • Mary Manning Walsh Home (03/2011 – Present) • St. Teresa's Nursing Home (03/2011 – 02/01/2013) • St. Vincent de Paul Residence (03/2011 – Present) • Terence Cardinal Cooke Health Care Center (03/2011 – Present) • ArchCare Senior Life (03/2011 – Present) • ArchCare Advantage (03/2011 – Present) • Calvary Hospital (03/2011 – Present) • ArchCare at Home (04/2016 – Present) 	

The Board of Directors of Catholic Health Care System d/b/a ArchCare is identical to the Board of The Dominican Sisters Family Health Services d/b/a ArchCare at Home, disclosed above.

The Board members of Catholic Health Care System d/b/a ArchCare have attested to being the subject of an investigation by either federal or state law enforcement agencies on issues related to Medicare or Medicaid fraud. In 2013, the U.S. Attorney's Office, District of Massachusetts, undertook an investigation of therapy provided in three of the nursing homes sponsored by Catholic Health Care System (CHCS) by a subcontractor, an affiliate of Kindred Healthcare, Inc. CHCS and its nursing homes were not the target of the investigation. The investigation focused on allegations that the three facilities submitted claims to Medicare that sought inflated amounts of reimbursement based on either the provision of unreasonable or unnecessary rehabilitation therapy. On February 24, 2014, CHCS entered into a settlement agreement regarding this investigation. On March 12, 2014, CHCS made a \$3.5 million payment to the U.S. Department of Justice in connection with this matter. There were no findings of False Claims Act violations, the Department of Justice noted CHCS's cooperation and the changes it made in reaching the resolution.

The Board of Trustees of Providence Health Services is comprised of the following individuals:

Timothy M. Dolan Archbishop, Archdiocese of New York
Gerald T. Walsh Disclosed Above
William Whiston CFO, Archdiocese of New York <u>Affiliation</u> <ul style="list-style-type: none"> • New York State Catholic Health Plan, Inc. (MLTCP)

The applicant has confirmed that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with the consultation of legal counsel, and it is concluded that proceeding with the proposal is appropriate.

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List. A search of the individual named above on the New York State Unified Court System revealed that the individual is currently registered and has no disciplinary actions taken against them. The Office of the Professions of the State Education Department, the New York State Physician Profile and the Office of Professional Medical Conduct, indicates no issues with the licensure of the health professionals associated with this application.

Facility Compliance/Enforcement

The compliance history of the following providers, parented by Catholic Health Care System d/b/a ArchCare, were reviewed as part of this application:

- Calvary Hospital
- Calvary Hospital CHHA
- Calvary Hospital Hospice Care
- Carmel Richmond Healthcare & Rehabilitation Center
- Ferncliff Nursing Home
- Empire State Home Care Services, Inc. (CHHA) (*Closed October 2016*)
- Mary Manning Walsh Home (RHCF)
- St. Vincent DePaul Residence (RHCF)
- St. Vincent DePaul Assisted Living Program
- Terence Cardinal Cooke Health Care Center (RHCF)
- ArchCare Senior Life (HMO)
- ArchCare Community Life (MLTCP)
- Dominican Sisters Family Health Service, Inc. d/b/a ArchCare at Home (CHHA)
- Family Home Health Care, Inc. (LHCSA)

The information provided by the Division of Hospitals and Diagnostic & Treatment Centers, the Division of Home and Community Based Services, the Office of Managed Care, the Bureau of Managed Care Certification and Surveillance, the Division of Adult Care Facilities and Assisted Living Surveillance, and the Bureau of Quality and Surveillance has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of patients and to prevent recurrent code violations.

CHHA Quality of Patient Care Star Ratings as of October 24, 2019	
New York Average: 3.5 out of 5 stars National Average: 3.5 out of 5 stars	
CHHA Name	Quality of Care Rating
Dominican Sisters Family Health Service, Inc. d/b/a ArchCare at Home	3.5 out of 5 stars
Ulster Home Health Services, Inc. d/b/a Always There Family Home Health Services	2.5 out of 5 stars
Calvary Hospital CHHA	Not Available

Conclusion

There will be no net impact to patient/resident services provided. 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

Transfer Agreement

The applicant has submitted a draft transfer agreement for the right, title and interest in the transferor's CHHA business property and materials. The terms of the agreement are summarized below.

Execution Date:	Proposed transfer agreement to be executed upon satisfaction of all closing conditions and deliverables of the transferee and transferor, completion of Department of Health closing conditions, and judicial approval of sale or dissolution upon closure.
Transferor:	Ulster Home Health Services Inc. d/b/a Always There Family Home Health Services (Always There)
Transferee:	The Dominican Sisters Family Health Services, Inc., d/b/a ArchCare at Home
Included Assets:	Land, building and equipment of \$101,977 net of additional accumulated depreciation at closing.
Liabilities Assumed:	Transferee shall not assume any liabilities or obligations of Transferor arising and to be performed before the closing date.
Purchase Price:	Not applicable - There is not acquisition cost or purchase agreement involved in the transfer agreement

The applicant 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. As of November 5, 2019, the facility had no outstanding Medicaid overpayment liabilities.

Lease Agreement

The applicant has submitted the master lease agreement for the Kingston site. The terms are summarized below:

Date:	March 27, 2009
Premises:	15,583 sq. ft. of usable and rentable space hereinafter referred to as the Office Space and in addition 577 sq. ft. of usable and rentable space hereinafter referred to as the Storage Space on south portion of 918 Ulster Avenue, Kingston, New York.
Landlord:	SMCBC, LLC
Tenant:	UMC Ulster Home Health Care, Inc. D/B/A Always There, Guarantor
Term:	20 Years commencing November 1, 2009 and ending October 31, 2029
Rental Payments:	Office and Adult Day Care Space as follows: Year 1-5: \$564,883.80 with \$9,414.73 paid monthly; Year 6-10: \$681,756.00 with \$11,362.60 paid monthly; Year 11-15: \$973,937.40 with \$16,232.29 paid monthly; Year 16-20: \$1,071,331.20 with \$17,855.52 paid monthly. Rent of Storage Space: Year 1-5: \$11,539.20 with \$193.32 paid monthly; Year 6-10: \$14,425.20 with \$240.42 paid monthly; Year 11-15: \$17,310.00 with \$288.50 paid monthly; Year 16-20: \$20,194.80 with \$336.58 paid monthly.
Provisions:	Plus 50% of Gas & Utilities, HVA repair and maintenance, and electrical service; and 28% of building operating expenses.

The applicant has provided an affidavit stating the landlord and tenant are not related entities and therefore the master lease is an arm's length agreement.

Sub-Lease Agreement

The applicant submitted a draft sub-lease for the site to be occupied. The terms are summarized below:

Premises:	15,583 rentable sq. ft. located at 918 Ulster Avenue, Kingston, New York, 12401
Sub-Lessor:	UMC Inc.
Sub-Lessee:	The Dominican Sisters Family Health Services Inc. dba Arch Care at Home
Term:	20 years commencing November 1, 2019 and ending October 31, 2029.
Sublease Annual Base Rent:	Office and Adult Day Care Space shall be as follows: Year 1-5: \$564,883.80 with \$9,414.73 paid monthly; Year 6-10: \$681,756.00 with \$11,362.60 paid monthly; Year 11-15: \$973,937.40 with \$16,232.29 paid monthly; Year 16-20: \$1,071,331.20 with \$17,855.52 paid monthly. Rent of Storage Space: Year 1-5: \$11,539.20 with \$193.32 paid monthly; Year 6-10: \$14,425.20 with \$240.42 paid monthly; Year 11-15: \$17,310.00 with \$288.50 paid monthly; Year 16-20; \$20,194.80 with \$336.58 paid monthly.
Provisions:	Provisions of Master Lease

The applicant has provided an affidavit stating there is a common affiliation between the sub-tenant and the sub-landlord, and therefore is a non-arm's length agreement.

Operating Budget

The applicant submitted their current year (2018) results (ArchCare at Home) and an operating budget, in 2019 dollars, for the first and third year of operations subsequent to the merger, summarized below:

<u>Revenues</u>	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
Medicaid FFS	\$281,681	\$437,773	\$446,528
Medicare FFS	10,852,816	20,322,600	20,729,052
Commercial FFS	1,233,267	1,062,618	1,083,870
Commercial MC	2,877,623	2,479,439	2,529,028
Private Pay	0	21,300	21,300
All Other	19,874,514	22,689,084	23,727,200
Total Revenues	\$35,119,901	\$47,012,814	\$48,536,978
<u>Expenses</u>			
Operating	\$36,861,419	\$45,473,764	\$46,884,201
Capital	<u>1,132,882</u>	<u>1,133,134</u>	<u>1,131,550</u>
Total Expenses	\$37,994,301	\$46,606,898	\$48,015,751
Net Income	(\$2,874,400)	\$405,916	\$521,227
Utilization (Visits)	215,230	293,516	307,029
HHA Hours	693,129	908,797	953,052

Utilization by payor source is as follows:

<u>Payor</u>	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
Medicaid FFS	0.39%	0.70%	0.69%
Medicare FFS	21.89%	32.53%	32.34%
Commercial FFS	3.89%	1.70%	1.69%
Commercial MC	9.08%	3.97%	3.94%
Private Pay	0.00%	0.03%	0.03%
All Other	<u>64.75%</u>	<u>61.07%</u>	<u>61.30%</u>
Total	100.00%	100.00%	100.00%

The current year revenue and expenses are based on the draft 2018 CHHA Cost Report, and include Metro NY, Hudson Valley, and Long Island Regions. ArchCare at Home closed its branch offices on Long Island during 2018. The first and third-year forecast includes Metro NY, Hudson Valley and Ulster County, and excludes the Long Island Region. The region changes result in a significant shift in budgeted revenues, expenses and census.

Medicare Fee for Service and Medicaid Fee for Service payor revenue and utilization are expected to increase in Year One and Year Three by the additional operations of ArchCare at Home. Total revenues are budgeted to increase 34% in Year One and 38% in Year Three of operations. Commercial Fee for Service and Managed Care payor revenue and utilization are budgeted to decline by 12% to 14% in the first and third year of operation. Reimbursement assumptions are based on Medicare rates held constant at the overall current rate by region and include a Case Mix Index of 1.02 and an average Low Utilization Payment Adjustment (LUPA) of 8.5%. The Medicare and Medicaid rates were reduced each year by the 2% mandatory sequestration factor. Total operating costs are budgeted to increase 23% in Year One and 26% in Year Three due to increases in supervisory salaries, transportation, purchased services, medical supplies, and other miscellaneous costs. Expenses are budgeted to decline in non-medical supplies, administrative management salaries, and general office costs.

Capability and Feasibility

There are no project costs, acquisition costs or purchase agreement associated with this application. Working capital requirements are estimated at \$1,670,242, which is equivalent of two months of incremental third year expenses. The Catholic Health Care System and The Catholic Health Care Foundation of the Archdiocese of New York will provide the working capital via cash equity. BFA Attachment F is the 2017 and 2018 certified financial statements of Catholic Health Care System, which indicates the availability of sufficient funds to meet the working capital requirement.

The submitted budget projects a positive net income position of \$405,898 and \$521,227 in the first and third year of operations, respectively. Revenues are based on current reimbursement methodologies for CHHA services. The budget appears reasonable.

BFA Attachment B is the 2018 and 2017 certified financial statements for Dominican Sisters Family Health Service, Inc. and Family Home Health Care, Inc., which indicate an average negative working capital position, an average negative net asset position, and an average operational loss. The reason for the negative positions are the following: ArchCare has purchased many financially distressed home care agencies requiring ArchCare capital to cover financial deficits; the expenses of implementing an electronic medical records system; moving the patient population to managed care; DSFHS experienced reductions in revenue due to utilization declines caused by the closing of branch offices and termination of contracts with managed care entities reimbursing below direct cost of services; and DSFHS professional fee expenses increased with the contracting of Black Tree Healthcare Consulting to improve the effectiveness of the billing and collection process, and the efficiency of the insurance eligibility and authorization processes. The entity implemented the following steps to improve operations: DSFHS increased efforts to consolidate Human Resources, Finance, Information Technology and leased space after ArchCare became the sole corporate member of DSFHS and DSFHS was awarded a \$6 million Statewide Health Care Facility Transformation Program II grant for debt relief including capital for long-term accounts payable, working capital and transformation expense.

BFA Attachment C is the internal financial statements Dominican Sisters Family Health Service, Inc. as of June 30, 2019, which indicate a negative working capital position, a negative net asset position and an operational loss. BFA Attachment D is the 2018 certified financial statements for UMC, d/b/a Always There and Subsidiaries, which indicate a negative working capital position, negative net asset position and a net loss. The operating loss was caused by staffing losses and census instability. BFA Attachment E is the internal financial statements for Ulster Home Health Services, Inc. as of June 30, 2019, which indicates a negative working capital position, negative net asset position and an operating loss. Operational losses in 2019 were caused by ongoing staffing issues and census instability.

Conclusion

Based on the preceding, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	Organizational Chart before and after implementation of the transfer agreement.
BFA Attachment B	2018 & 2017 Certified Financial Statement - Dominican Sisters Family Health Service, Inc. d/b/a ArchCare at Home and Family Home Health Care, Inc.
BFA Attachment C	Internal Financial Statement as of June 30, 2019 - Dominican Sisters Family Health Service, Inc.
BFA Attachment D	Certified Financial Statement as of December 31, 2018 – UMC, Inc. d/b/a Always There and Subsidiaries
BFA Attachment E	Internal Financial Statement of as of June 30, 2019 - Ulster Home Health Services. Inc.
BFA Attachment F	June 30, 2019 internal financial statements of Catholic Health Care System
BFA Attachment G	2018 Certified Financial Statements of Catholic Health Care System

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to merger and consolidate of Always There Family Home Health Services into The Dominican Sisters Family Health Services, Inc. d/b/a ArchCare at Home, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

192014 E

Always There Family Home Health Services

APPROVAL CONTINGENT UPON:

1. Submission of an executed building sub-lease agreement, acceptable to the Department of Health. (BFA)
2. Submission of an executed transfer agreement, acceptable to the Department of Health. (BFA)
3. Submission of a photocopy of an executed Resolution of the Board of Directors of Catholic Health Care System d/b/a ArchCare, acceptable to the Department. (CSL)
4. Submission of a photocopy of an executed Resolution of the Board of Directors of Providence Health Services (PHS), acceptable to the Department. (CSL)
5. Submission of a photocopy of the Certificate of Incorporation of PHS, 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 Certificate of Assumed Name, acceptable to the Department. (CSL)

APPROVAL CONDITIONED UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



Project # 192157-E
SLHS Massena, Inc. d/b/a Massena Hospital

Program: Hospital
Purpose: Establishment

County: St. Lawrence
Acknowledged: October 7, 2019

Executive Summary

Description

St. Lawrence Health System, Inc. (SLHS), a not-for-profit health care organization, requests approval to establish SLHS Massena, Inc., a New York not-for-profit corporation, as the new operator of Massena Memorial Hospital (MMH), a 25-bed, public municipal, Article 28 sole community hospital located at 1 Hospital Drive, Massena (St. Lawrence County), and to establish SLHS as the hospital's active parent and co-operator. The hospital's sponsorship will be converting to a 501(c)(3) governance structure. Upon approval by the Public Health and Health Planning Council (PHHPC), SLHS will change its name to Massena Hospital, Inc., and be known as Massena Hospital. Recently under CON 191208, the hospital decertified 25 beds and requested approval to operate as a Critical Access Hospital (CAH). Approval of CAH designation by the Centers for Medicare and Medicaid Services (CMS) is pending.

The proposed governance restructuring and affiliation with SLHS are part of an overall sustainability plan to preserve essential health care services in the Town of Massena and enable the hospital to become financially sustainable.

The parties to this Transaction are SLHS (Purchaser) and the Town of Massena and Massena Memorial Hospital (collectively Seller). The Seller and Purchaser executed a Management Agreement dated June 19, 2019, whereby the Purchaser is providing general management services to MMH. The Seller, Purchaser and NYSDOH are parties to a Supervisory Agreement effective June 19, 2019, whereby the NYSDOH provides oversight to the

arrangement. On July 30, 2019, the Seller and Purchaser executed an Asset Purchase Agreement (APA) that provided for the transfer of all the hospital's assets, including the real property, and the assignment and assumption of certain liabilities and obligations relating to MMH prior to Closing. The purchase consideration is \$8,000,000 and provides a commitment of capital and the funding of services including providing financial support for workforce liabilities.

SLHS has developed an overall Transformation Plan for the Hospital. The Plan is to transform the Hospital to a financially sustainable institution capable of preserving essential health care services in St. Lawrence County. The purpose of the Plan is to grow a coordinated, highly integrated system with the objectives of improving quality, increasing access and lowering the costs of health care in the communities served by SLHS and MH.

On July 31, 2019, the Town of Massena was awarded a \$20 million Statewide Health Care Facility Transformation Program Phase II grant. The purpose of the grant is to retire debt and support the conversion of MMH from a public hospital to a voluntary non-profit hospital affiliated with SLHS. The NYSDOH notified MMH that the grant is conditioned upon, among other things, the conversion of the hospital to a voluntary non-profit 501(c)(3) hospital corporation that is co established with SLHS pursuant to an APA agreement acceptable to the Department. SLHS is a not-for-profit 501(c)(3) organization that serves as the sole corporate member, active parent and co-

operator of Canton-Potsdam Hospital (CPH) and Gouverneur Hospital (GH), both located in St. Lawrence County.

OPCHSM Recommendation
Contingent Approval

Need Summary
There will be no change to beds or services as a result of this application.

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

There are no project costs associated with this project. The currently identified acquisition price is valued at approximately \$8,000,000 and includes assumption of liabilities, commitment of capital, and the funding of services including providing financial support for workforce liabilities.

<u>Budget</u>	<u>Current Year</u>
Revenues	\$51,460,734
Expenses	\$63,526,226
Net Income/(Loss)	(\$12,065,492)

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$53,427,636	\$54,627,693
Expenses	\$55,408,808	\$54,608,808
Net Income/(Loss)	(\$1,981,172)	\$18,985

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 photocopy of an amended and executed Certificate of Amendment to the Certificate of Incorporation of St. Lawrence Health System, Inc. (Health System), acceptable to the Department. [CSL]
2. Submission of a photocopy of the amended bylaws of the Health System, acceptable to the Department. [CSL]
3. Submission of a photocopy of an executed Resolution of the Board of Directors of the Health System, acceptable to the Department. [CSL]
4. Submission of a photocopy of an executed Resolution of the Town Council of the Town of Massena, acceptable to the Department. [CSL]
5. Submission of a photocopy of an amended and executed Certificate of Incorporation of SLHS Massena, Inc., acceptable to the Department. [CSL]
6. Submission of a photocopy of an amended and executed Restated Certificate of Incorporation of SLHS Massena, Inc., acceptable to the Department. [CSL]
7. Submission of a photocopy of the bylaws of Massena Hospital, Inc., acceptable to the Department.

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Background

MMH is currently certified for 25 beds and through project 191208 is seeking to become designated as a Critical Access Hospital (CAH). CMS approval of the CAH designation is pending. With the change in ownership, there are no additional projected changes in the services or beds. The approval of this project will allow St. Lawrence Health System to coordinate an integrated system to improve quality, access and decrease costs.

Character and Competence

The initial Board of Directors of SLHS Massena Inc. are:

Name	Title/Position
Edward Mucenski	Director
Mark Cornett	Director
Mark Brackett	Director
Michael Burgess	Director
Donald Dangremond	Director

The SLHS Massena, Inc Board of Directors subsequent to final PHHPC approval are:

Name	Title/Position
Bedros Bakirtzian, MD	Director
Michael Cook	Director
Real C. Coupal	Director
Susanne Day, MD	Director
Dawn Hewlett	Director
David LeClair, Jr.	Director
Lenore Levine	Director
G. Michael Maresca	Director
Paul B. Morrow	Director
Loretta Perez	Director

Mr. Bedros Bakirtzian, M.D. is an Orthopedic Surgeon who has been in private practice for 29 years. He received his medical degree from the University De Sherbrooke in Canada. He is board-certified in Orthopedic Surgery.

Mr. Mark Brackett is a retired pharmacist with over 45 years of practice at a local pharmacy. He was also the Vice President of Human Resources for the pharmacy.

Mr. Michael Burgess is the Vice President of Financial Planning and Treasury Services for a national provider of pharmaceutical and healthcare services company. He is a Secretary of the Board for the St. Lawrence Health System and Chair of the Board for Gouverneur Hospital.

Mr. Michael Cook is employed as the Director of Health Operations of the St. Regis Mohawk Health Services for over six years. He was previously employed as the Project Officer at a health services facility in Tennessee.

Mr. Mark Cornett is the Chief Operating Officer a biometrics company for seven years. He has a general management and business background. He was the previous Chief Operating Officer of a platform technology company for 12 years.

Mr. Real Coupal is the President and Owner of a Ford and Chevrolet Auto Dealerships for over 37 years. He oversees 75 employees for both corporations. He is the member of multiple boards. He is the real estate manager of 25 rental units.

Mr. Donald Dangremond is retired from Clarkson University where he spent over 44 years. He held numerous senior management and administrative roles including Director of Residence Life, Associate Dean of Students, Director of Alumni Relations, Executive Director of Alumni and Parent Relations, Associate Vice President and Vice President of University Relations, and most recently Senior Gift Planning Officer. He is a trustee on the board of Canton-Potsdam Hospital and the St. Lawrence Health System.

Susanne Daye, M.D. is a retired Physician. She retired in 2017 with over 12 years as a Radiologist at multiple facilities and a remote Radiologist with coverage at hospitals in multiple states. She graduated with her medical degree from Georgetown University. She completed her transitional internship at the Letterman Army Medical Center in California. She completed her Diagnostic Radiologic Residency at the Brooke Army Medical Center in Texas. She completed a Body Imaging Fellowship at the University of Texas Houston Medical School.

Ms. Dawn Hewlett is the Financial Controller of a Data Center for over one year. She is responsible for financial accounting and reporting. She oversees the management of 70 employees. She was previously the Director of Decision Support and Budgeting and the Interim Controller at the University of Vermont for three years. Her responsibilities included being the point of contact for network budget software implementation, providing leadership for the integration, operation, maintenance, and reporting capabilities of the network decision support and cost accounting system, working to improve decision making and organizational performance by collaborating with departments to review cost center reports and department specific performance analysis.

Mr. David LeClair, Jr. has been employed for over 20 years in Production at Alcoa, an aluminum manufacturer. He is also trained and qualified on parts of each job in management. He has sat on the Massena School Board. He was the local union President. Each of these various board experiences has given him experience from daily operations to fiscal responsibility.

Ms. Lenore Levine is a Registered Nurse with over 37 years of experience. She retired in 2017 with 21 years of service at Massena Memorial Hospital Ambulatory Surgical Services and Medical Imaging Services.

G. Michael Maresca, M.D. is a currently practicing Radiologist and CEO and Founder of a private radiology practice. He received his medical degree from the University of Maryland School of Medicine. He completed his Diagnostic Radiology residency from the State University of New York Health Science Center in Syracuse. He is board-certified in Radiology and Physician Special Purpose Exam. He provides professional radiology services to numerous facilities.

Paul B. Morrow is the owner of an international multi-medical manufacturing and distributing corporation. He has operated a large corporation for over 19 years. He was previously employed as a supervisor for General Motors. He taught as a substitute teacher in the Business Department at the local high school.

Mr. Edward Mucenski is the Officer/Director of the Certified Public Accounting firm he has been employed by for over 35 years. He is a trustee of Canton-Potsdam Hospital and of the St. Lawrence Health System. He was also a trustee of St. Joseph's Rehabilitation Center.

Ms. Loretta Perez is the Owner/Manager of a travel agency for over 38 years. She was previously a Teacher for middle and high school English and Math for 26 years. She participated as the Department Chairperson, Student Council, and Class Advisor. She has been a board member of the Massena Memorial Hospital board for six years. She has served as chair of the Medical Affairs, Executive Committee, chair of the Finance Committee, member of the Safety Building and Grounds, and member of the Audit and Compliance Committee. She currently chairs the Board of Managers.

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. Maresca disclosed that he was named in two open malpractice lawsuits. The first case alleged that a patient who presented with a head injury after a fall failed to properly diagnose hematoma and/or cystic hygromas that resulted in emergency brain surgery. The second case alleges a negligent read of appendicitis by Radiology. The patient received a laparoscopic appendectomy and expired. Both cases are pending.

The **St. Lawrence Health System Board**, comprised of 14 officers and directors, was subject to a Character and Competence review.

Name	Title/Position
Edward Mucenski	Chair
Mark Cornett	Vice Chair
Mark Brackett	Treasurer
Michael Burgess	Secretary
Florence Bero, MD	Director
Ronald Berry	Director
Donald Dangremond	Director
Brian Gardam	Director
Michael Griffin	Director
Stephen Knight	Director
Anne Richey	Director
James Theodore	Director
Michael Tulloch, MD	Director
David Acker	Chief Executive Officer

Dr. Florence Bero M.D. disclosed that being named in three malpractice cases, one that is opened and one that is closed. The closed malpractice case was filed on February 21, 2011 and alleged wrongful death, negligence, and improper care for an obstetrical patient who presented to the emergency department and became an inpatient. Dr. Bero was the covering physician during a portion of the patient's inpatient care. The case was settled and Dr. Bero was dropped from the case prior to the final settlement. On March 13, 2018 there was a stipulation of discontinuation for all the defendants. The second case was filed on behalf of the patient by his parents for prolonged resuscitation of a newborn, postpartum on August 4, 2014, and alleged failure to monitor labor and that the infant was hypoxic and cerebral palsy. The case remains ongoing. The third case was brought against the physician practice in April 2018. It was found that they had never provided care to this patient and they were dropped from the case in May 2018.

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.

The Department issued a Stipulation and Order (S&O) dated November 16, 2018 and fine to MMH \$6,000 based on an investigation into nursing failing to monitor telemetry patient alarms appropriately. The patients were not being monitored by nurses trained in cardiac monitoring and dysrhythmias.

Prevention Agenda

Massena Memorial Hospital submitted a joint planning document (CSP/CHIP) with St Lawrence Health System and the St. Lawrence Department of Health. This combined report identified two priorities

- Preventing chronic disease – Reducing obesity in children and adults with activities focused on increasing physical activity in schools and the community. They identified transportation as a disparity,

- Promoting mental health and preventing substance abuse, focusing on strengthening the drug task forces, and safe disposal of prescription drugs and sharps

The applicant specified the evidence-based interventions selected to address these priorities. The partners have engaged with diverse local organizational partners in Prevention Agenda efforts to plan and/or implement appropriate interventions and will continue to do in the new structure.

No financial data are available for Massena Memorial Hospital and their community benefit spending is not known. Massena Memorial Hospital is currently in a transition phase and in the process of being purchased by St. Lawrence Health System, as indicated in the application.

Conclusion

Approval will preserve hospital services for the Massena community. 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

Asset Purchase Agreement

The applicant has submitted an executed APA detailing the transfer of the hospital’s assets and liabilities from the Town of Massena and Massena Memorial Hospital to St. Lawrence Health System.

Date:	July 30, 2019
Seller:	Town of Massena and Massena Memorial Hospital
Purchaser:	St. Lawrence health System
Assets/Liabilities Acquired:	Seller’s rights and assets in the Facility and Business; Assets include: real property used in the operation of the Hospital (land, buildings, other improvements); tangible personal property (all inventory, supplies, all furniture, fixtures, and equipment); all books and records relating to the Hospital; patient medical records to the extent legally transferable; all cash, cash equivalents and securities held in accounts relating to the Hospital; accounts receivable and prepaid expenses; all rights and benefits under the assumed contracts, agreements, leases or instruments between Seller and any third party; and the name; Medicare and Medicaid provider numbers and all associated PINs related to physician employees and independent contractors, goodwill and intellectual property.
Excluded Assets:	MMH’s general ledgers, corporate charter, minute and stock record books, Tax ID number, income tax returns and corporate seals; membership interest of the Seller related to the business; all employee benefit plans; the excluded contracts; the asset described on the MMH balance sheet as line item “deferred outflows-pension;” all claims (and benefits arising therefrom) that relate to any liability other than the assumed liabilities; all rights (including tax and other refunds and claims thereto) relating to the excluded liabilities; all records relating to the excluded assets or excluded liabilities; all other records Seller is required under applicable law to maintain in their possession; all of the Seller’s rights under this agreement; all assets, whether real, personal, or mixed, tangible or intangible, owned or leased by the town and not held or used for the operation of the business or facility.
Acquisition Price:	Valued at \$8,000,000. Includes assumption of liabilities and commitment of capital, funding and services of \$8,000,000, which includes providing financial support for workforce liabilities.

The applicant has submitted an affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 28 of the Public

Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of the liability and responsibility. As of October 25, 2019, there are no outstanding Medicaid liabilities or assessments.

Operating Budget

The applicant has submitted an operating budget, in 2019 dollars, as summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Inpatient Revenues</u>			
Commercial - FFS	\$316,815	\$347,862	\$361,818
Commercial - MC	\$239,352	\$262,808	\$273,352
Medicaid - FFS	\$326,389	\$358,374	\$372,752
Medicaid - MC	\$2,353,485	\$2,584,116	\$2,687,793
Medicare - FFS	\$2,353,485	\$2,584,116	\$2,687,793
Medicare - MC	\$3,077,634	\$3,379,228	\$3,514,907
Private Pay	<u>\$384,704</u>	<u>\$422,403</u>	<u>\$439,352</u>
Total Inpt Revenues	\$9,051,864	\$9,938,907	\$10,337,767
<u>Outpatient Revenues</u>			
Commercial - FFS	\$7,685,667	\$7,916,756	\$8,088,234
Commercial - MC	\$3,742,102	\$3,854,618	\$3,938,110
Medicaid - FFS	\$1,044,834	\$1,076,249	\$1,099,561
Medicaid - MC	\$8,044,810	\$8,286,698	\$8,466,189
Medicare - FFS	\$9,625,040	\$9,914,443	\$10,129,190
Medicare - MC	\$3,663,262	\$3,773,407	\$3,855,140
Private Pay	<u>\$2,108,615</u>	<u>\$2,172,018</u>	<u>\$2,219,062</u>
Total Outpt Revenues	\$35,914,330	\$36,994,189	\$37,795,486
Other Oper Revenue	\$6,332,502	\$6,332,502	\$6,332,502
Non-Oper Revenue	<u>\$162,038</u>	<u>\$162,038</u>	<u>\$162,038</u>
Total Revenue	\$51,460,734	\$53,427,636	\$54,627,793
<u>Expenses</u>			
Operating	\$60,858,080	\$52,740,662	\$51,940,662
Capital	<u>\$2,668,146</u>	<u>\$2,668,146</u>	<u>\$2,668,146</u>
Total Expenses	\$63,526,226	\$55,408,808	\$54,608,808
Net Income/(Loss)	(\$12,065,492)	(\$1,981,172)	\$18,985
Total Discharges	1,436	1,295	1,277
Visits	83,245	81,580	82,413

Utilization by payor source for the the Current Year and Years One and Three is as follows:

<u>Payor</u>	<u>Inpatient %</u>	<u>Outpatient %</u>
Commercial - FFS	3.48%	21.40%
Commercial - MC	2.65%	10.42%
Medicaid - FFS	3.62%	2.91%
Medicaid - MC	25.98%	22.40%
Medicare - FFS	25.98%	26.80%
Medicare - MC	33.98%	10.20%
Private Pay	3.20%	4.17%
Charity Care	<u>1.11%</u>	<u>1.70%</u>
Total	100.00%	100.00%

There will be no changes in the daily operations of the hospital. The recent bed reduction to 25 certified beds will result in the following expense reductions: Salaries and Wages by \$3,000,000; Employee Benefits by \$800,000 in year one and \$1,600,000 in year three; Professional Fees by \$400,000; Medical/Surgical Supplies by \$500,000; and Purchased Services by \$2,917,418. Utilization is projected to decrease in Year One due to the current lack of community trust in the institution. The applicant expects utilization to improve by Year Three once community starts to gain trust in the hospital under SLHS's leadership. Revenue is based on CAH status achieved by the start of Year One.

Capability and Feasibility

There are no project costs or purchase price associated with this transaction. There will be no change in daily operations of the hospital, although the facility is projecting cost benefits from the changes in health insurance, retirement plans and interest expense.

BFA Attachment A is the 2016-2017 audited financial statements and the 2018 interim and as of June 30, 2019 internal financial summary of Massena Memorial Hospital (A Component Unit of the Town of Massena, New York). As shown, the facility had an average negative working capital position, an average positive net asset position, and achieved an average net loss of \$6,820,971 for the 2016-2017 period. For the period 2018 through June 30, 2019, the facility achieved an average net loss of \$6,714,919. The negative working capital position and negative net income are due to the overall changing health care market and the facility's overall small size and rural nature. With declining volumes and costs remaining stagnant, the facility has continued to lose money annually despite state support through the Interim Access Assurance Fund Program and Vital Access Provider Assurance Program funding and a \$5.8 million Essential Health Care Provider Program grant to retire debt.

BFA Attachment B is the 2017 and 2018 audited financial summary of St. Lawrence Health System. As shown, the System had a negative working capital position, a positive net asset position and achieved an average net income of \$9,649,537 for the period shown. The negative working capital position is due to a \$4.1 million increase in estimated third party settlements. The System places a significant amount of its cash in its Foundation and not in the current assets account and retains the majority of assets as long-term assets. As of December 31, 2018, the System had approximately \$88 million in total net assets and unrestricted cash and investments amounted to approximately \$60 million comprised of \$6.8 million from cash/cash equivalents, \$36.8 million from assets whose use is limited (Board Designated Only) and \$16.4 million from Canton-Potsdam Hospital Foundation, Inc., which is classified as cash and investments. The System's certified financial statements show income from operations of \$9.8 million and excess revenue over expenses of \$10.1 million in 2018. Also, the System experienced an increase in cash and cash equivalents of \$2.6 million in 2018 over 2017, indicating a strong health care system overall.

BFA Attachment C is the Massena Hospital Pro Forma Balance Sheet, which shows the facility will have an equity position of \$2,017,827 as of the first day of operation.

BFA Attachment D is the pre- and post-closing organization chart of the facility.

Conclusion

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

Attachments

BFA Attachment A	Financial Summary-Massena Memorial Hospital audited periods 2016-2017, and 2018 interim and as of June 30, 2019 internal financial summary.
BFA Attachment B	2017 and 2018 audited financial summary of St. Lawrence Health System
BFA Attachment C	Pro Forma Balance Sheet of Massena Hospital
BFA Attachment D	Pre and Post Closing Organization chart.

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 12th day of December 2019, 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 SLHS Massena, Inc. as the new operator of Massena Memorial Hospital and establish St. Lawrence Health System, Inc. as the co-operator/active-parent, 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:

192157 E

SLHS Massena, Inc. d/b/a Massena Hospital

APPROVAL CONTINGENT UPON:

1. Submission of a photocopy of an amended and executed Certificate of Amendment to the Certificate of Incorporation of St. Lawrence Health System, Inc. (Health System), acceptable to the Department. [CSL]
2. Submission of a photocopy of the amended bylaws of the Health System, acceptable to the Department. [CSL]
3. Submission of a photocopy of an executed Resolution of the Board of Directors of the Health System, acceptable to the Department. [CSL]
4. Submission of a photocopy of an executed Resolution of the Town Council of the Town of Massena, acceptable to the Department. [CSL]
5. Submission of a photocopy of an amended and executed Certificate of Incorporation of SLHS Massena, Inc., acceptable to the Department. [CSL]
6. Submission of a photocopy of an amended and executed Restated Certificate of Incorporation of SLHS Massena, Inc., acceptable to the Department. [CSL]
7. Submission of a photocopy of the bylaws of Massena Hospital, Inc., acceptable to the Department.

APPROVAL CONDITIONAL UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



Project # 191075-E
Excellent Home Care Services, LLC

Program: Certified Home Health Agency
Purpose: Establishment

County: Kings
Acknowledged: June 6, 2019

Executive Summary

Description

Excellent Home Care Services, LLC (Excellent), a New York limited liability company that operates an Article 36 Certified Home Health Agency (CHHA) located at 91-93 South Third Street, Brooklyn (Kings County), requests approval to transfer 100% membership interest in the CHHA. Per their establishment approval effective November 10, 2004, Excellent was certified as a Special Population CHHA with services limited to the Office for People with Developmental Disabilities population. The agency is authorized to serve Bronx, Kings, New York, Queens and Nassau Counties, and is licensed to provide Home Health Aide, Personal Care, Medical Social Services, Medical Supplies/Equipment and Appliances, Nursing, Nutritional, Occupational Therapy, Physical Therapy, Respiratory Therapy and Speech Language Pathology services. There will be no change in services or counties served as a result of this application.

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

Table with 2 columns: Member Name and Percentage. Rows include Current Members (Benjamin Landa 50%, Guttman Estate 50%) and Proposed Members (Excel Health, LLC 50%, Joseph Goldberger (100%) 50%, Superb Health LLC 50%, Samuel Rosenbaum (92%), Ryvkie Goldberger (8%)).

As shown, the current members of Excellent are Benjamin Landa (50%) and the Guttman Estate (50%). Mr. Jeno Guttman passed away in December 2007 and his membership interest rights passed to his wife, Ms. Szerena Guttman, who subsequently passed away in November 2012. As executor of Ms. Guttman's last will and testament, her daughter, Ms. Ryvkie Goldberger, is authorized to represent Ms. Guttman's interest in Excellent and to execute all legal documents to complete the sale of the Guttman's interest in the CHHA.

On July 21, 2017, Joseph and Ryvkie Goldberger entered into a Membership Interest Purchase Agreement (MIPA) with Benjamin Landa to purchase his 50% membership interest in Excellent for \$700,000. Subsequently, on August 29, 2019, Joseph and Ryvkie Goldberger executed an Assignment Agreement to assign this 50% membership interest to Excel Health LLC, whose sole member is Joseph Goldberger. On September 12, 2018, Superb Health LLC, an existing New York limited liability company, entered into a MIPA to purchase the Guttman Estate's 50% membership interest in Excellent for \$700,000. All transactions will be effectuated upon Public Health and Health Planning Council (PHHPC) final approval.

Concurrently under review is CON 121223 in which the CHHA seeks to convert the Special Population CHHA to a General Purpose CHHA.

OPCHSM Recommendation
Contingent Approval

Need Summary

There will be no Need recommendation of this project.

Program Summary

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

Financial Summary

There are no project costs associated with this application. The applicant will acquire 100% membership interest in the CHHA for a total purchase price of \$1,400,000 apportioned as follows: \$700,000 due from Joseph and Ryvkie Goldberger (paid and held in escrow until closing), and \$700,000 due from Superb Health LLC funded via a Promissory Note for a seven-year term (level debt payments) with interest at 6%. The projected budget is as follows:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$44,270,093	\$50,406,522
Expenses	<u>\$42,947,003</u>	<u>\$47,139,297</u>
Net Income	\$1,323,090	\$3,267,225

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 Promissory Note for the sale of the Guttman Estate's membership interest, acceptable to the Department of Health. [BFA]
2. Submission of an executed building lease agreement, acceptable to the Department of Health. [BFA]
3. Submission of documentation confirming repayment of the loan made to Benjamin Landa, acceptable to the Department of Health. [BFA]
4. Submission of documentation confirming repayment of the loan made to the Guttman Estate, acceptable to the Department of Health. [BFA]
5. Submission of documentation confirming repayment of the loan Joseph Goldberger made to Excellent Home Care Services, LLC, acceptable to the Department of Health. [BFA]
6. Submission of a photocopy of the applicant's amended and executed Operating Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the applicant's amended and executed Membership Interest Purchase Agreement for Benjamin Landa to Excel Health LLC, acceptable to the Department. [CSL]
8. Submission of a photocopy of the applicant's amended and executed Membership Interest Purchase Agreement for the Estate of Szerena Guttman to Superb Health LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the applicant's amended and executed Management Agreement, acceptable to the Department. [CSL]
10. Submission of a photocopy of an amended and executed Articles of Organization for Excel Health LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of an amended and executed Operating Agreement for Excel Health LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of an amended and executed Articles of Organization for Superb Health LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of an amended and executed Operating Agreement for Superb Health LLC, acceptable to the Department. [CSL]

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Program Analysis

Program Description

Excellent Home Care Services, LLC, a limited liability company, requests approval for a 100% change in members of Excellent Home Care Services, LLC, an existing Special Population CHHA serving the Office for People with Development Disabilities population in Bronx, Kings, New York, Queens and Nassau Counties. There will be no changes to the counties served or services provided as a result of this application. The applicant has entered into a management agreement with Excel Health, LLC, which was approved by the Department July 10, 2019.

Concurrently under review is CON 121223, where Excellent seeks approval to convert from a Special Population CHHA to a General Purpose CHHA.

The current and proposed membership of Excellent Home Care Services, LLC is as follows:

Name	Current	Proposed
Benjamin Landa	50%	0%
Guttman Estate	50%	0%
Excel Health, LLC	--	50%
<i>Joseph Goldberger (100%)</i>		
Superb Health, LLC	--	50%
<i>Samuel Rosenbaum (92%)</i>		
<i>Ryvkie Goldberger (8%)</i>		

Mr. Jeno Guttman passed away in December 2007. Upon his death, the rights to his membership interest in Excellent Home Care Services, LLC transferred to his wife, Szerena Guttman. Mrs. Guttman passed away in November 2012. The executor of Szerena Guttman's last will and testament is her daughter, Ryvkie Goldberger. As the executor, Ms. Goldberger is authorized to represent the Guttman's interested in Excellent Home Care Services, LLC and will execute all legal documents to support and complete sale of the CHHA.

Character and Competence Review

Joseph Goldberger

CEO, Excellent Home Care (CHHA)

Ryvkie Goldberger

Director of Human Resources, Excellent Home Care (CHHA)

President, Dependable Check Cashing

Affiliations

Brookhaven Rehabilitation & Health Care Center (RHCF)

Samuel Rosenbaum

Asset Manager, Tonelle Center LLC

Joseph Goldberger disclosed that there are pending lawsuits against a business in which he is a capital investor.

Ryvkie Goldberger disclosed that she is named as a defendant in an open lawsuit that alleges a nurse did not receive overtime pay.

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The Bureau of Quality and Surveillance has reviewed the compliance history of the above-mentioned Skilled Nursing Facilities and reports as follows:

- **Brookhaven Rehabilitation & Health Care Center** was fined \$12,000.00 pursuant to Stipulation and Order NH-17-033 for inspection findings during a complaint survey conducted on July 26, 2016.

The information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations

CHHA Quality of Patient Care Star Ratings as of March 7, 2019 New York Average: 3.5 out of 5 stars National Average: 3.5 out of 5 stars	
CHHA Name	Quality of Care Rating
Excellent Home Care Services, LLC	3 out of 5 stars

Conclusion

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a certified home health agency.

Financial Analysis

Membership Interest Purchase Agreements (MIPA) and Assignment Agreement
The applicant has submitted two executed MIPAs to acquire the 100% of the CHHA membership, to be effectuated upon PHHPC approval. The terms are summarized below:

MIPA #1

Date:	July 21, 2017
Purpose:	Purchase Seller's 50% membership interest in Excellent Home Care Services, LLC
Seller:	Benjamin Landa (50% member)
Buyers:	Joseph Goldberger and Ryvkie Goldberger
Assets Transferred:	Seller's right, title, and interest in the company; upon closing, the right to receive any and all distributions subsequent to the effective date, free and clear of all liens.
Purchase Price:	\$700,000
Payment of the Purchase Price:	Paid (held in escrow)

Assignment Agreement related to MIPA #1

Date:	August 29, 2019
Assignors:	Joseph Goldberger and Ryvkie Goldberger
Assignee:	Excel Health LLC
Assignment Price:	All rights, title, and interest as Purchasers under the MIPA with Benjamin Landa
Price:	\$0

MIPA #2

Date:	September 12, 2018
Purpose:	Purchase Seller's 50% membership interest in Excellent Home Care Services, LLC
Seller:	Estate of Szerena Guttman (50% member)
Buyer:	Superb Health LLC
Assets Transferred:	Seller's right, title, and interest in the company; upon closing, the right to receive any and all distributions subsequent to the effective date, free and clear of all liens.
Purchase Price:	\$700,000
Payment of the Purchase Price:	\$700,000 via Promissory Note

The purchase price for the Guttman Estate's membership interest will be paid via a Promissory Note at 6% interest for seven-year term, payable in equal monthly installments of \$10,225.99 per month over 84 months. BFA Attachment A is the proposed members' net worth statement, which indicates sufficient liquid resources. It is noted that liquid resources may not be available in proportion to the proposed ownership interest of Superb Health LLC. Ryvkie Goldberger provided an affidavit stating her willingness to contribute resources disproportionate to her membership interest in the entity.

Governmental Payor Liabilities

Medicaid

The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing Excellent of its liability and responsibility. As of September 10, 2019, the facility had \$1,365,022 in outstanding Medicaid liabilities pursuant to audits conducted by the New York State Office of Medicaid Inspector General (OMIG). The details and current Medicaid recoupment status of these audit is as follows:

- #11-6186: Covers Medicaid claims for dates of service (DOS) January 1, 2008 – December 31, 2010; final overpayment determination = \$404,561; Stipulation and Settlement fully executed July 16, 2019; repayment terms provide for a \$20,000 initial withhold with remaining to be recouped via withholds of \$15,000 per week against Medicaid payable claims plus interest accruing starting 90 days from execution date; balance due as of October 3, 2019 = \$268,162.73.
- #18-7945: Covers Medicaid claims for DOS April 1, 2016 – November 8, 2016; final overpayment issued = \$610,119.45; posted to eMedNY on July 15, 2019; recoupment at 50% due to lack of response from the provider/their legal representative; claimed legal representative was not copied on disposition; placed on hold pending provider's legal response due in early October.
- #19-3459: Covers Medicaid claims for DOS October 1, 2016 – June 24, 2017; final overpayment issued = \$426,739.94; posted to eMedNY on July 29, 2019; recoupment at 50% due to lack of response from the provider/their legal representative; provider requested reissue of drafts for their legal representative to review; placed on hold pending provider's legal response due in early October.

Medicare

The Centers for Medicare and Medicaid Services (CMS) performed an audit of the CHHA, which indicated a Medicare overpayment of \$1,201,733 for DOS January 1, 2011 – December 31, 2012 (APROV-CLA-935). Excellent reached a settlement agreement with CMS to pay back the amount via fixed monthly payments of \$38,565.32 (level debt payments of principal and interest at 9.625%) for a 36-month periods commencing September 1, 2018. The payments are to be collected automatically through payment withholds on the 1st of each month. The terms provide that should the facility default on any one payment, the agreement becomes null and void and the facility would be placed on a 100% withhold until the outstanding liability has been fully repaid. BFA Attachment G is the repayment schedule agreed to between the parties. The applicant provided an affidavit attesting that they are current with all payments with a balance due of \$774,957.67 as of October 1, 2019.

Rental Agreement

The existing lease was executed June 1, 2010. The lease term expired December 31, 2016. The applicant indicated that a month-to-month arrangement is currently in place.

Premises:	91-93 South Third Street, Brooklyn, NY 11211
Landlord:	Seymour Realty, LLC
Tenant:	Excellent Home Care Services, LLC
Term:	Month-to-Month
Rent:	\$399,964 per year (\$33,330.33 per month)
Provisions:	Maintenance, repairs, sanitation, taxes (40%), and utilities

Joseph Goldberger, CEO of Excellent, provided an affidavit attesting that Excellent continues to lease the space on a month-to-month basis pursuant to a verbal agreement with the landlord and is currently in negotiations for a long-term lease. The existing lease is an arm's-lengths agreement as there is no relationship between the landlord and tenant.

Interim Consulting Agreement

The applicant provided an executed Interim Consulting Agreement:

Effective Date	September 12, 2018
Consultant:	Excel Health, LLC
Facility:	Excellent Home Care Services, LLC
Services:	Assist with day-to-day operations including: ensuring appropriate patient care services are provided; review overall charge structure; personnel administration services; evaluate purchases and leases; oversee policies and procedures; maintain medical and clinical records; billing, collections, payment of accounts and indebtedness, maintaining financial records and deposit of funds on behalf of the managing members; quality control; and, development and implementation of complaint procedures.
Compensation:	\$33,333 monthly or \$400,000 annually.
Terms:	Term is within 30-days' notice or upon closing of the purchase agreement.

The agreement provides that the Licensed Operator retains "full authority and ultimate and control" of the Agency. Upon PHHPC approval, the interim consulting agreement will cease, and the management agreement will take effect.

Management Agreement

The applicant provided an executed Management Agreement, which has been reviewed and approved by the Department on July 10, 2019:

Date:	September 12, 2018
Consultant:	Excel Health, LLC
Facility:	Excellent Home Care Services, LLC
Manager Responsibilities:	Manage the day-to-day operations including: supervision, clerical and support services, monitor patient care, charges relating to business negotiations, rates and filing of cost reports, personnel administration related to pay wage and benefits, purchasing care policies and procedures, patient records management, quality control indicators, complaint procedures development, contract services, policy and procedure development, management reports, compliance reports, insurance, maintain licenses, permits, accreditation and provider numbers, maintenance of fiscal stability.
Compensation:	\$400,000 per year payable in 12 equal monthly installments
Terms:	3-year term on anniversary of the effective date.
Provisions:	Either party may terminate the agreement with cause with 30 days' notice. Either party may terminate with 90 days of written notice. The agreement shall terminate in the event a party terminates the Purchase Agreement in accordance with the provisions of the Purchase Agreement, effective upon the effective date of termination of the Purchase Agreement.

The management agreement mirrors the interim agreement for oversight of the day to day operations and is become effective upon PHHPC approval of this application.

Operating Budget

The applicant submitted their current year results (2018), and their projected first- and third-year operating budgets, in 2019 dollars as summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>	<u>Total</u>	<u>Total</u>	<u>Total</u>
Commercial-FFS	\$1,269,491	\$1,318,360	\$1,843,276
Medicare-MC	\$6,409,306	\$7,027,270	\$8,044,174
Medicaid-FFS	\$27,289,745	\$29,556,098	\$33,285,542
Medicaid-MC	<u>\$5,842,611</u>	<u>\$6,368,365</u>	<u>\$7,233,530</u>
Total Revenue	\$40,811,153	\$44,270,093	\$50,406,522
<u>Expenses</u>			
Operating	\$39,788,448	\$42,523,392	\$46,715,686
Capital	<u>\$423,611</u>	<u>\$423,611</u>	<u>\$423,611</u>
Total Expenses	\$40,212,059	\$42,947,003	\$47,139,297
Net Income	<u>\$599,094</u>	<u>\$1,323,090</u>	<u>\$3,267,225</u>
Total Visits *	70,573	83,133	103,804
Total Hours **	1,132,996	1,208,046	1,331,546

* Nursing, PT, OT, Speech Pathology, Medical Social Services

** Hours are for Home Health Aide

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

<u>Payor</u>	<u>Current Year</u>	<u>First Year</u>	<u>Third Year</u>
Commercial-FFS	6.97%	6.15%	5.22%
Medicare-MC	38.32%	35.59%	32.54%
Medicare-FFS	46.13%	48.51%	51.17%
Medicaid-MC	7.41%	8.46%	9.63%
Charity Care	1.17%	1.30%	1.44%
Total	100%	100%	100%

The following is noted with respect to the submitted budget:

- Revenues, expenses and utilization are based on historical experience. The projected Year One and Year Three increases reflect the expansion in utilization expected as if CON 121223 is approved to convert from a Special Population CHHA to a general purpose CHHA.
- Capital cost includes annual rent expense of \$399,964 (verified per the 2018 certified financial statements) that are expected to continue upon re-negotiation of the expired lease.
- According to the 2018 cost report, the average cost per hour is \$25.53 for Home Health Aide Hours. Medicare, Medicaid, and Commercial revenues are based on an episodic payment methodology. Projected Medicaid revenue is based on the 2018 CHHA Medicaid payment rate as proxy.
- Utilization is based on existing historical services and the current footprint it currently services using historical data and projections based on increased need as projected under companion CON 121223.
- The CHHA has an existing charity care policy which will continue to be utilized after the transfer of membership interest.

Capability and Feasibility:

There are no project costs associated with this application. The applicant will acquire 100% membership interest in the CHHA for a total purchase price of \$1,400,000. Joseph and Ryvkie Goldberger have paid \$700,000 (held in escrow until closing) for Benjamin Landa's membership interest. Payment was required 120 days after July 21, 2017, the effective date of the MIPA. The remaining \$700,000 is due from Superb Health LLC and will be funded via a Promissory Note for a seven-year term (equal monthly payments) with interest at 6%. On August 29, 2019, Joseph and Ryvkie Goldberger executed an Assignment Agreement to assign their 50% membership interest to Excel Health LLC, whose sole member is Joseph Goldberger. BFA Attachment A is the net worth statements of the proposed members, which indicates sufficient resources to meet the terms of the transactions.

The submitted budget projects gain of \$1,323,090 and \$3,267,225 in the first and third year, respectively. Revenues are based on the current reimbursement methodologies. The submitted budget is reasonable based on the current services and population expansion requested under CON 121223.

BFA Attachment C is the 2017 and 2018 certified financial statements of Excellent Home Care Services, LLC, which indicate the facility achieved positive net asset and working capital positions and generated positive net income for the periods shown. BFA Attachment D is their internal financial statement as of July 31, 2019, which shows a positive net asset position of \$4,610,328, a positive working capital position of \$8,450,819 and net income of \$3,099,393.

The working capital requirement is estimated at \$7,157,833 based on two months of first-year expenses to be funded via operations. BFA Attachment E is the Pro Forma Balance Sheet that suggests working capital resources of \$8,450,818. However, current assets include an amount "Due from Members" of \$6,469,283. Amounts "Due from Members" are also presented in prior year certified financial statements as a current asset (\$7,347,058 in 2017, \$7,883,469 in 2018). No details are provided in the Notes to the financial statements. The applicant indicated this receivable pertains to loans made to current members Benjamin Landa (\$5.71M) and the Guttman estate (\$761.3K) in 2010 (some in 2012 and 2013). The loans are non-interest-bearing demand loans that can be called in as needed. No determination has been made regarding when they will be paid off. Current assets also include "Other Current Assets" of \$1,647,971, which includes "other loans and exchanges" of \$1.51M directly related to the short-term loan listed under current liabilities. At the end of 2018, Excellent borrowed \$2.7M from Mr. Goldberger in a non-interest-bearing loan to ensure sufficient cash flow. Approximately \$1.2M has been used and the remaining \$1.51M is the current balance available from the loan. The remaining "Other Current Assets" consist of prepaid expenses (\$39,621.77) and loans made to multiple line-level employees (\$101,883.45) that are being repaid via monthly employee paycheck deductions. Lastly, "Other Current Liabilities" include short term notes (\$43.7K), accrued payroll (\$10.6K), deferred taxes (\$49.1K), and other accrues expenses (\$211.8K) incurred in the normal course of business payable this year when due. Given the above, the working capital resources available as of the first day of operations is assessed at \$1,117,692 based on cash plus cash accounts minus accounts payable. The various loans to the current members and from the proposed member to Excellent must be repaid in full by all respective parties prior to final approval of this application.

BFA Attachment F provides details related to three lawsuits against Excellent that remain pending final determination. The amounts identified as potential liabilities were disclosed by the applicant as a possible outcome of the litigation. Disclosure of the Medicare and Medicaid audit liabilities are also provided. BFA attachment G is the repayment schedule agreed to by Medicare to resolve the overpayment. The applicant remains current and has not defaulted on repayment.

Attachments

BFA Attachment A	Personal Net Worth Statement-Proposed Members of Excellent CHHA
BFA Attachment B	Organizational Chart
BFA Attachment C	2017 and 2018 Certified Financial Statements
BFA Attachment D	Internal Financial Statements (January 1, 2019 – May 31, 2019)
BFA Attachment E	Pro Forma Balance Sheet of Excellent
BFA Attachment F	Pending and Settled Lawsuits, Governmental Payor Liabilities
BFA Attachment G	Medicare – Repayment Schedule

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to transfer of 100% ownership interest of Excellent Home Care Services, LLC, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

191075 E

Excellent Home Care Services, LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed Promissory Note for the sale of the Guttman Estate's membership interest, acceptable to the Department of Health. [BFA]
2. Submission of an executed building lease agreement, acceptable to the Department of Health. [BFA]
3. Submission of documentation confirming repayment of the loan made to Benjamin Landa, acceptable to the Department of Health. [BFA]
4. Submission of documentation confirming repayment of the loan made to the Guttman Estate, acceptable to the Department of Health. [BFA]
5. Submission of documentation confirming repayment of the loan Joseph Goldberger made to Excellent Home Care Services, LLC, acceptable to the Department of Health. [BFA]
6. Submission of a photocopy of the applicant's amended and executed Operating Agreement, acceptable to the Department. [CSL]
7. Submission of a photocopy of the applicant's amended and executed Membership Interest Purchase Agreement for Benjamin Landa to Excel Health LLC, acceptable to the Department. [CSL]
8. Submission of a photocopy of the applicant's amended and executed Membership Interest Purchase Agreement for the Estate of Szerena Guttman to Superb Health LLC, acceptable to the Department. [CSL]
9. Submission of a photocopy of the applicant's amended and executed Management Agreement, acceptable to the Department. [CSL]
10. Submission of a photocopy of an amended and executed Articles of Organization for Excel Health LLC, acceptable to the Department. [CSL]
11. Submission of a photocopy of an amended and executed Operating Agreement for Excel Health LLC, acceptable to the Department. [CSL]
12. Submission of a photocopy of an amended and executed Articles of Organization for Superb Health LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of an amended and executed Operating Agreement for Superb Health LLC, acceptable to the Department. [CSL]

APPROVAL CONDITIONED UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



**Project # 192009-E
VNA of Staten Island**

Program: Certified Home Health Agency
Purpose: Establishment

County: Richmond
Acknowledged: August 2, 2019

Executive Summary

Description

Through approval of this application, Richmond Medical Center d/b/a/ Richmond University Medical Center (RUMC), a voluntary not-for-profit, Article 28 acute care hospital whose main campus is located at 355 Bard Avenue, Staten Island (Richmond County), will become the sole corporate member/parent and Bridge Regional Health System, Inc. will become the grandparent of VNA of Staten Island, an Article 36 Certified Home Health Agency (CHHA) operated by Visiting Nurse Association Health Care Services, Inc. (VNAHCS) whose office is located at 400 Lake Avenue on Staten Island. VNAHCS is a voluntary not-for-profit entity approved to provide CHHA, Long Term Home Health Care Program (LTHHCP), Early Intervention, Nursing Home Transition and Diversion Medicaid Waiver Program, and Traumatic Brain Injury Medicaid Waiver Program services. The sole member of VNAHCS is Visiting Nurse Association of Staten Island, Inc. (VNASI). VNASI is also the sole owner of Healthwatch-Lifeline, Inc. (HWL), a for-profit supplier of Personal Emergency Response Systems, and Visiting Nurse Plus, Inc. (VNP), a dormant not-for-profit entity that previously operated a Licensed Home Care Service Agency. Through this project, VNASI will merge into RUMC and all assets, including the CHHA's office site which is owned by VNASI, will become assets of RUMC.

The CHHA and LTHHCP are authorized to serve the residents of Richmond County. The CHHA is certified to provide nursing, physical, occupational and speech language pathology therapies, medical social services, medical supplies/equipment/appliances, nutritional services and home health aide services. Since

the LTHHCP does not currently see patients, the operating certificate will be surrendered upon implementation of this project. There will be no change in the authorized services or service area of the CHHA as a result of the proposed project. Upon approval by the Public Health and Health Planning Council (PHHPC), the assumed name of the CHHA will be changed to VNA of Staten Island: An Affiliate of Richmond University Medical Center.

Through approval of this application, VNASI will merge into RUMC. HWL, VNP, and VNAHCS will survive as separate legal entities under RUMC. The transition of the other VNAHCS programs and HWL to RUMC do not require submission of a CON application. RUMC will work with the Department to transition those services/programs to the Medical Center through separate processes. Upon completion of the merger, VNASI will cease to exist.

Ownership of the CHHA before and after the requested change is as follows:

<u>Current</u>	
Operator:	Visiting Nurse Association Health Care Services, Inc.
Parent:	Visiting Nurse Association of Staten Island, Inc.

<u>Proposed</u>	
Operator:	Visiting Nurse Association Health Care Services, Inc.
Parent:	Richmond University Medical Center
Grandparent:	Bridge Regional Health System, Inc.

BFA Attachment A presents an organizational chart pre- and post-transition to RUMC.

OPCHSM Recommendation
Contingent Approval

Need Summary
This project will have no impact on the counties served or services provided by the CHHA.

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

Financial Summary

There are no project costs or purchase price associated with this application.

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$10,770,000	\$12,062,000
Expenses	<u>\$10,592,755</u>	<u>\$11,627,455</u>
Net Income	\$177,245	\$434,545

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 merger agreement between Visiting Nurse Association of Staten Island, Inc. and Richmond Medical Center d/b/a Richmond University Medical Center (surviving entity), acceptable to the Department of Health. (BFA)
2. Submission of a photocopy of an executed Resolution of the Board of Directors of Bridge Regional System, Inc., acceptable to the Department. (CSL)
3. Submission of a photocopy of an executed Resolution of the Board of Directors of Richmond Medical Center, acceptable to the Department. (CSL)
4. Submission of a photocopy of an executed Resolution of the Board of Directors of Visiting Nurse Association Health Care Services, Inc., acceptable to the Department. (CSL)
5. Submission of a photocopy of an executed Resolution of the Board of Directors of Visiting Nurse Association of Staten Island, Inc., acceptable to the Department. (CSL)

Approval conditional upon:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

Council Action Date

December 12, 2019

Need and Program Analysis

Proposal

Richmond Medical Center d/b/a Richmond University Medical Center (“RUMC”), a not-for-profit corporation operating an Article 28 hospital, seeks approval for a change in controlling persons of Visiting Nurse Association Health Care Services, Inc. (VNAHCS) d/b/a VNA of Staten Island Certified Home Health Agency (CHHA) under Article 36 of the Public Health Law.

VNAHCS, which serves Richmond county, has been experiencing financial difficulties for the past several years. In 2016, the CHHA experienced a net operating loss of \$1,480,145.00 and in 2017 the loss was even greater at \$2,576,801. Richmond University Medical Center has had a strong, collaborative working relationship with VNAHCS in the form of referrals to the agency. Due to this close collaboration, Richmond University Medical Center understands the importance of continuing the provision of CHHA services and is proposing this change in ownership in response to the unstable financial situation of VNAHCS

Richmond Medical Center d/b/a Richmond University Medical Center is currently parented by Bridge Regional Health System, Inc. Upon approval of this project RUMC will become a parent entity of Visiting Nurse Association Health Care Services, Inc. with Bridge Regional Health System, Inc. becoming the grandparent of the CHHA.

Visiting Nurse Association Health Care Services, Inc. also operates a Long Term Home Health Care Program (LTHHCP). The LTHHCP does not currently have a patient load and the operating certificate for the program will be surrendered upon implementation of this project.

This project will have no impact on the counties served or services provided by the CHHA. The applicant proposes to change the assumed name of the CHHA. Upon approval, the full legal name of the CHHA will be Visiting Nurse Association Health Care Services, Inc. d/b/a VNA of Staten Island: An Affiliate of Richmond University Medical Center.

Character and Competence Review

The Board of Directors of Bridge Regional Health System, Inc. and Richmond University Medical Center are identical and as follows:

<p>Tony Baker, Sr. Pastor, St. Philips Baptist Church <u>Affiliation</u> Richmond University Medical Center</p>	<p>Alan S. Bernikow Retired <u>Affiliation</u> Richmond University Medical Center</p>
<p>Pietro Carpenito, MD Executive Vice President, RUMC <u>Affiliation</u> Richmond University Medical Center</p>	<p>Katherine Connors, PT Physical Therapist Consultant <u>Affiliations</u> Richmond University Medical Center Carmel Richmond Nursing Home (RHCF)</p>
<p>Thomas DelMastro CEO, Staten Island Marine Development, LLC <u>Affiliation</u> Richmond University Medical Center</p>	<p>Sara Gardner Executive Director, FPHNYC <u>Affiliation</u> Richmond University Medical Center</p>
<p>Gina Gutzeit Senior Managing Director, FTI Consulting, Inc. <u>Affiliation</u> Richmond University Medical Center</p>	<p>Timothy C. Harrison Manager, TCH Realty & Development Co., LLC <u>Affiliation</u> Richmond University Medical Center</p>

<p>Steven M. Klein President & CEO, Northfield Bank <u>Affiliations</u> Richmond University Medical Center CentraState Medical Center (NJ)</p>	<p>Marianne La Barbera, MD Medical Doctor, Amboy Medical <u>Affiliation</u> Richmond University Medical Center</p>
<p>Daniel J. Messina, NHA (NJ) President, CEO, Richmond University Medical Center <u>Affiliation</u> Richmond University Medical Center</p>	<p>James Molinaro Lobbyist, Pitta Bishop & Del Giorno <u>Affiliation</u> Richmond University Medical Center</p>
<p>Jill O'Donnell-Tormey CEO, Director of Scientific Affairs, Cancer Research Institute <u>Affiliation</u> Richmond University Medical Center</p>	<p>Pankaj Patel, MD Consultant, Richmond University Medical Center <u>Affiliation</u> Richmond University Medical Center</p>
<p>Catherine Paulo, Esq. Owner, Paulo Financial Advisors, LLC Attorney, Catherine M. Paulo, Esq. <u>Affiliation</u> Richmond University Medical Center</p>	<p>Ronald A. Purpora President, R.A. Purpora Consulting <u>Affiliation</u> Richmond University Medical Center Staten Island Heart Institute</p>
<p>Dennis W. Quirk President, NYS Court Officers Union <u>Affiliation</u> Richmond University Medical Center</p>	<p>John C. Santora Vice Chairman, President of New York Region, Cushman & Wakefield <u>Affiliation</u> Richmond University Medical Center</p>
<p>John V. Scalia, Sr., Funeral Director Owner, John Vincent Scalia Home for Funerals, Inc. <u>Affiliation</u> Richmond University Medical Center</p>	<p>Samala Swamy, MD Physician, Self-Employed <u>Affiliation</u> Richmond University Medical Center</p>
<p>John G. Tapinis President, John Tapinis & Associates Ltd. <u>Affiliation</u> Richmond University Medical Center</p>	<p>Kathryn K. Rooney, Esq. Attorney, Law Officers of Kathryn K. Rooney <u>Affiliations</u> Richmond University Medical Center Carmel Richmond Nursing Home (RHCF) Kateri Residence (RHCF) The Mary Manning Walsh Nursing Home Company, Inc. (RHCF) St. Vincent de Paul Residence (RHCF) Terence Cardinal Cooke Health Care Center (RHCF) Homemakers of Staten Island (LHCSA) ArchCare at Home (CHHA) Ferncliff in Rhinebeck (RHCF) ArchCare Senior Life (LHCSA)</p>

Pankaj Patel was named as a defendant in a malpractice suit in the 1980s against the staff of the Psychiatry Inpatient Unit at Bayley Seton Hospital. The case was resolved in favor of the hospital and staff.

Marianne La Barbera disclosed an alleged negligent medical treatment claim. The complaint was filed November 9, 2012 and the case was settled November 8, 2013.

The applicant has confirmed that the proposed financial/referral structure has been assessed in light of anti-kickback and self-referral laws, with the consultation of legal counsel, and it is concluded that proceeding with the proposal is appropriate.

A search of the individual named above on the New York State Unified Court System revealed that the individual is currently registered and has no disciplinary actions taken against them.

The Office of the Professions of the State Education Department, the New York State Physician Profile and the Office of Professional Medical Conduct indicate no issues with the licensure of the health professionals associated with this application.

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The information provided by the Division of Home and Community Based Services, the Bureau of Quality and Surveillance, and the Division of Hospitals and Diagnostic & Treatment Centers has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

CHHA Quality of Patient Care Star Ratings as of October 10, 2019	
New York Average: 3.5 out of 5 stars National Average: 3.5 out of 5 stars	
CHHA Name	Quality of Care Rating
Visiting Nurse Association Health Care Services, Inc. d/b/a VNA of Staten Island	4 out of 5 stars

Conclusion

The establishment of new controlling persons will not result in any changes to the county being served or to the services provided. Review of the personal qualifying information indicates that the applicant has the required character and competence to operate a certified home health agency.

<h2>Financial Analysis</h2>

Agreement and Plan of Merger

The applicant submitted a Draft Agreement and Plan of Merger, summarized below:

Purpose:	This sole Staten Island CHHA has been experiencing financial difficulties for several years. Operations are unsustainable and a new parent is needed to allow the CHHA to continue operating. RUMC was chosen due to their strong working relationship with VNAHCS and their strong financial standing.
Merging Entities:	Visiting Nurse Association of Staten Island, Inc.
Survivor Entity:	Richmond University Medical Center
Assets Acquired:	All Assets associated with the operations of the CHHA
Assumed Liabilities:	All debts, liabilities and duties of the Merging entities
Purchase Price:	\$0

The Merger Agreement provides the RUMC will assume all debts and liabilities; hence, any Medicaid overpayment liabilities would transfer to the survivor entity. The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/or surcharges, assessments or fees due from the transferor pursuant to Article 36 of the Public Health Law with respect to the period of time prior to the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of October 25, 2019, the CHHA had no outstanding Medicaid overpayment liabilities.

Management Agreement

On July 10, 2019, RUMC executed an Interim Consulting Agreement (ICA) with VNAHCS to assist with the day-to-day operations of the CHHA, pending Department approval of a concurrently executed Management Agreement (MA) between the parties. The MA was approved by the Department on September 10, 2019, and the ICA was effectively terminated. The MA will cease upon PHHPC approval of this application.

Operating Budget

The applicant submitted their current year (2018) results and an operating budget, in 2019 dollars, for the first year and third year of operations, summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>			
Medicaid	\$1,639,519	\$2,000,000	\$2,241,000
Medicare	\$4,344,735	\$5,306,000	\$5,941,000
Commercial	\$2,853,133	\$3,457,000	\$3,872,000
Private Pay	\$6,480	\$7,000	\$8,000
All Other-CTI	<u>\$438,545</u>	<u>\$0</u>	<u>\$0</u>
Total Revenues	\$9,282,412	\$10,770,000	\$12,062,000
<u>Expenses</u>			
Operating	\$9,923,102	\$10,298,755	\$11,333,455
Capital	<u>\$231,452</u>	<u>\$294,000</u>	<u>\$294,000</u>
Total Expenses	\$10,154,554	\$10,592,755	\$11,627,455
Net Income	<u>(\$872,142)</u>	<u>\$177,245</u>	<u>\$434,545</u>
Utilization (Visits)	61,920	69,343	77,668
HHA Hours	39,986	44,780	50,150

Care Transitions Intervention (CTI) is a Delivery System Reform Incentive Payment Program (DSRIP) program addressing Staten Island Performing Provider System's (PPS) Project 2.b.iv goal of reducing 30-day hospital admissions. Unless a federal extension is granted, DSRIP is scheduled to end March 31, 2020. VNAHCS has kept the CTI program in its operating budget projections and is working with the Staten Island PPS to secure continued funding should DSRIP sunset. If CTI funding is not renewed, the applicant will assess options for continuing the program in a financially sustainable manner. The current CTI operating budget, and projected year one and year three budgets should the program be continued, is as follows:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
CTI Revenue	\$438,545	\$438,545	\$438,545
Operating Expenses	<u>\$438,545</u>	<u>\$438,545</u>	<u>\$438,545</u>
Total Income	\$0	\$0	\$0

Visit utilization by payor for the current, first and third years (all identical) is as follows:

<u>Payor</u>	<u>%</u>
Medicaid	16.86%
Medicare	36.48%
Commercial	46.59%
Charity Care	.02%
Private Pay	<u>.05%</u>
Total	100.00%

Hour utilization (Home Health Aide) by payor for the current, first and third years (all identical) is as follows:

<u>Payor</u>	<u>%</u>
Medicaid	3.55%
Medicare	53.10%
Commercial	43.35%
Total	100.00%

The following is noted with respect to the submitted budget:

- Revenue, expense and utilization assumptions are based on the historical experience of the CHHA, with increases projected as a result of the merger.
- Utilization is based on the current year with a 6% annual increase due to a closer relationship with RUMC and a physical presence in the hospital.
- Revenues are based on the increased utilization, projected increases in contracted reimbursement rates and increased efficiencies primarily due to investment and improvements in technology.
- Technology Improvements include:
 - New electronic platform for Clinical Patient Management (Netsmart);
 - New iPad/iPhone for improved efficiency in “Point of Service” data collection for field Clinicians;
 - New and more efficient phone system for improved communication;
 - New electronic fax system to support improved communication from physicians’ offices and other referral sources; and
 - Implementation of a new automated Patient Revenue Management System.
- The facility incorporated a 4% to 4.5% increase in payment rates for Year One for commercial, Medicare and Medicaid payors, and a slight decrease in the private pay rate based on operational efficiencies due to upgraded technology and standard rate progression from year to year. As a conservative estimate, the rates for Year Three remain static.
- Expenses are based on the increase in utilization, the reorganization of CHHA staffing and the effect of merging the operations with RUMC.

Capability and Feasibility

There are no project costs or purchase prices associated with this application. There is no working capital need associated with this application, as all the operations are going concerns that have been in operation for many years. Any future working capital needs will be provided by the survivor entity, RUMC, which has significant positive working capital of \$46,206,589 as of December 31, 2018.

The submitted budget projects a positive net income of \$177,245 and \$434,545 in the first and third year of operations, respectively. Revenues are based on current reimbursement methodologies with a slight increase in the per visit rate. The budget appears reasonable.

BFA Attachment B is the 2017-2018 certified financial statements of Visiting Nurse Association of Staten Island, Inc. and Subsidiaries. As shown, the entity had average positive working capital and net asset positions and an average operating loss before other changes of \$2,224,807 for the 2017-2018 period. The losses were due to the movement of approximately 300 patients from the LTHHCP service line to Managed Care. Since VNASI/VNAHCS did not have access to many managed care contracts, the shift resulted in a rapid decline in daily patient census and patient revenue. The losses were primarily due to the inability of the organization to quickly reduce fixed costs at the same rate as the rapid reduction in revenue. There was gradual improvement in 2018 which is expected to continue into 2019-2020. To improve operations the facility is working to reduce operational fixed costs, implement improvements in technology, negotiate new Managed Care contracts with new payors to broaden their referral base, and collaborating with Richmond University Medical Center

BFA Attachment C is the 2017 and 2018 certified financial statements of Visiting Nurse Association of Staten Island, Inc. and Subsidiaries broken out by entity. As shown, Visiting Nurse Association of Staten Island, Inc. had average positive working capital and net asset positions and an average operating loss before other changes of \$166,556 for the 2017-2018 period. As of June 30, 2019, the CHHA had positive working capital and net asset positions and an operating loss of \$22,643.

BFA Attachment D is the internal financial statements for Visiting Nurse Association Health Care Services, Inc as of June 30, 2019.

BFA Attachment E is the 2017-2018 certified and internal financial statements for Richmond University Medical Center as of June 30, 2019. As shown, the entity had average positive working capital position and net asset positions, and an average operating loss of \$2,336,387 for the 2017-2018 period. As of June 30, 2019, the entity had positive working capital and net asset positions and a net loss of \$4,245,196. The loss was due to the timing of the ramp-up of new service lines and ambulatory locations in which the Medical Center has invested. RUMC has implemented numerous Management Action Plans over the past several years to mitigate operating losses of the Medical Center.

Conclusion

Based on the preceding, the applicant demonstrated the capability to proceed in a financially feasible manner.

Attachments

- BFA Attachment A Pre and Post Closing Organization Chart
- BFA Attachment B Visiting Nurse Association of Staten Island, Inc. and subsidiaries 2017-2018 Certified and 1/1/2019-6/30/2019 Internal Financial Statement.
- BFA Attachment C Visiting Nurse Association of Staten Island, Inc. 2017-2018 Certified and 1/1/2019-6/30/2019 Internal Financial Statement.
- BFA Attachment D Visiting Nurse Association Health Care Services, Inc. 1/1/2019-6/30/2019 Internal Financial Statement
- BFA Attachment E Richmond University Medical Center 2017-2018 Certified and 1/1/2019-6/30/2019 Internal Financial Statement

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to establish Richmond University Medical Center as the parent of the certified home health agency currently operated by Visiting Nurse Association Health Care Services, Inc. and establish Bridge Regional Health System as the grandparent, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

192009 E

VNA of Staten Island

APPROVAL CONTINGENT UPON:

1. Submission of an executed merger agreement between Visiting Nurse Association of Staten Island, Inc. and Richmond Medical Center d/b/a Richmond University Medical Center (surviving entity), acceptable to the Department of Health. (BFA)
2. Submission of a photocopy of an executed Resolution of the Board of Directors of Bridge Regional System, Inc., acceptable to the Department. (CSL)
3. Submission of a photocopy of an executed Resolution of the Board of Directors of Richmond Medical Center, acceptable to the Department. (CSL)
4. Submission of a photocopy of an executed Resolution of the Board of Directors of Visiting Nurse Association Health Care Services, Inc., acceptable to the Department. (CSL)
5. Submission of a photocopy of an executed Resolution of the Board of Directors of Visiting Nurse Association of Staten Island, Inc., acceptable to the Department. (CSL)

APPROVAL CONDITIONED UPON:

1. The project must be completed within one year from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]

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



Project # 191101-E

Underwood Gardens Homecare, LLC
d/b/a Underwood Manor LHCSA

Program: LHCSA
Purpose: Establishment

County: Cattaraugus
Acknowledged: March 7, 2019

Executive Summary

Proposal

Underwood Gardens Homecare, LLC d/b/a Underwood Manor LHCSA, a limited liability company, requests approval for a change in ownership of Ronald R. Johnson d/b/a Underwood Manor, a sole proprietorship LHCSA. This LHCSA is associated with the Assisted Living Program known as Underwood Manor. The LHCSA and the ALP will have identical ownership. The applicant will be restricted to serving the residents of Cattaraugus County from an office located at 4460 Union Hill Road, RD#1, Hinsdale, New York 14743.

The applicant will provide the following health care services:

- Nursing
- Home Health Aide
- Personal Care

Recommendations

Office of Primary Care and Health Systems Management

Approval, contingent upon:

1. The submission of documentation to verify the approval of ACF Application 3133OFD2. [CHA]
2. The submission of an executed copy of the purchase and sale agreement, acceptable to the Department. [CSL]

Approval, conditional upon:

1. The Agency is restricted to serving the residents of the associated Assisted Living Program. [CHA]

Council Action Date
December 12, 2019

Review

Character and Competence

The membership of Underwood Gardens Homecare, LLC d/b/a Underwood Manor LHCSA comprises the following individuals:

Ronald R. Johnson – 51%

President/Chief Executive Officer, Human Services Management Inc.

Affiliations

Ronald R. Johnson d/b/a Underwood Manor (LHCSA)

Johnson Adult Homes - Forestville (Adult Home, 1962-2014)

Underwood Manor (Adult Home, 1990-present)

Eili Kaganoff, PhD, LNHA, LCSW - 49%

Managing Member, Underwood Gardens Management, LLC

The Office of the Professions of the State Education Department indicates no issues with the license of the health care professional associated with this application.

The Bureau of Professional Credentialing has indicated that Eili Kaganoff, NHA license 05520, holds an NHA license in good standing and the Board of Examiners of Nursing Home Administrators has never taken disciplinary action against this individual or his license.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A seven-year review of the operations of the affiliated facilities/agencies was performed as a part of this review.

Underwood Manor (Adult Home) was fined \$1,300 pursuant to a Stipulation and Order, dated March 22, 2016, for surveillance findings on November 28, 2014 and June 22, 2015. Deficiencies were found under 18 NYCRR 487 Social Services.

The Information provided by the Division of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety and welfare of residents and to prevent recurrent code violations.

Conclusion

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following application for licensure to convert the operator of a licensed home care services agency exclusively serving the residents of an assisted living program located at 4460 Union Hill Road, Hinsdale from a sole proprietorship to a limited liability company, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

191101 E

FACILITY:

Underwood Gardens Homecare, LLC
d/b/a Underwood
Manor LHCSA

APPROVAL CONTINGENT UPON:

1. The submission of documentation to verify the approval of ACF Application 3133OFD2. [CHA]
2. The submission of an executed copy of the purchase and sale agreement, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON

1. The Agency is restricted to serving the residents of the associated Assisted Living Program. [CHA]

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



Project # 192006-E

Marchand Home Care at Sharon Springs

Program: LHCSA

County: Schoharie

Purpose: Establishment

Acknowledged: August 1, 2019

Executive Summary

Proposal

Marchand Home Care at Sharon Springs LLC d/b/a Marchand Home Care at Sharon Springs, a limited liability company, requests approval for a change in ownership of Marchand Manor, LLC d/b/a Marchand Manor, a licensed home care services agency under Article 36 of the Public Health Law. This LHCSA will be associated with the Assisted Living Program to be known as Marchand Manor. The LHCSA and the ALP will have identical ownership. The applicant will be restricted to serving the residents of Marchand Manor (ALP) in Schoharie County from an office located at 121 Main Street, Route 10, Sharon Springs, New York 13459.

The applicant proposes to provide the following health care services:

- Nursing
- Home Health Aide
- Personal Care

Recommendations

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of documentation of approval of ACF Application 190003, acceptable to the Department. [CHA]

Approval conditional upon:

1. The agency will be restricted to serving the residents of the Assisted Living Program known as Marchand Manor. [CHA]

Council Action Date

December 12, 2019

Review

Character and Competence

The membership of Marchand Home Care at Sharon Springs LLC includes the following individuals:

Michael Zyskind, LNHA (NJ & NY) - 50%
Administrator, Fishkill Center for Rehabilitation and Nursing

Eili Kaganoff, PhD, LNHA (NY & OH), LCSW - 50%
Managing Member, Underwood Gardens Management, LLC
Regional Administrator, Embassy Healthcare

The Office of the Professions of the State Education Department indicates no issues with the license of the health care professional associated with this application.

The Bureau of Professional Credentialing has indicated that Eili Kaganoff, NHA license #05520, holds an NHA license in good standing and the Board of Examiners of Nursing Home Administrators has never taken disciplinary action against this individual or his license.

The Ohio Department of Aging has indicated that Eili Kaganoff, LNHA license #7259, holds an LNHA license in good standing and the Board of Executives of Long-Term Services & Supports has never taken disciplinary action against this individual or his license.

The Bureau of Professional Credentialing has indicated that Michael Zyskind, NHA license #05800, holds an NHA license in good standing and the Board of Examiners of Nursing Home Administrators has never taken disciplinary action against this individual or his license.

The New Jersey Department of Health has indicated that Michael Zyskind holds LNHA license #3237 and is in good standing.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

A seven-year review of the operations of Marchand Manor (LHCSA) indicates no enforcements for the review period.

Conclusion

Review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 12th day of December 2019, having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following application to Establish Marchand Home Care at Sharon Springs LLC as the new operator of the LHCSA serving the residents of the ALP currently known as Marchand Manor in Sharon Springs, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY:

192006 E

Marchand Home Care at Sharon Springs

APPROVAL CONTINGENT UPON:

1. Submission of documentation of approval of ACF Application 190003, acceptable to the Department. [CHA]

APPROVAL CONDITIONAL UPON

1. The agency will be restricted to serving the residents of the Assisted Living Program known as Marchand Manor. [CHA]

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