

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

ANNUAL MEETING

AGENDA

February 10, 2022

*Immediately following the Committee on Codes, Regulations and Legislation Meeting
(Codes scheduled to begin at 10:15 a.m.)*

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

I. INTRODUCTION OF OBSERVERS

Jeffrey Kraut, Chair

II. ELECTION OF OFFICERS

A. Election of Vice Chairperson

B. Announce Committee Chairpersons and Vice Chairpersons

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

III. APPROVAL OF MINUTES

December 9, 2021 Meeting Minutes

January 11, 2022 Special PHHPC Meeting Minutes

IV. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

A. Report of the Department of Health

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

B. Report of the Office of Public Health

Ursula Bauer, PhD, MPH, Deputy Commissioner, Office of Public Health

V. REGULATION

Report of the Committee on Codes, Regulations and Legislation

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

For Emergency Adoption

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

20-07 Amendment of Section 2.60 of Title 10 NYCRR & Repeal of Subpart 66-3 of Title 10 NYCRR (Face Coverings for COVID-19 Prevention)

21-15 Addition of Sections 2.9 and 2.62 to Title 10 NYCRR (COVID-19 Reporting and Testing)

For Adoption

21-19 Amendment of Sections 600.1 and 600.2 of Title 10 NYCRR (Article 28 Nursing Homes; Establishment; Notice and Character and Competence Requirements)

VI. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

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

A. APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Acute Care Services - Construction

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	212135 C	University Hospital SUNY Health Science Center (Onondaga County)	Contingent Approval

Hospice Services - Construction

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	212149 C	Hospice of Jefferson County/Palliative Care of Jefferson County (Jefferson County)	Contingent Approval

CATEGORY 2: Applications Recommended for Approval with the Following:

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

CON Applications

Acute Care Services - Construction

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	212113 C	North Shore University Hospital (Nassau County) Mr. Kraut – Recusal Dr. Strange – Recusal	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

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

NO APPLICATIONS

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>E.P.R.C. Recommendation</u>
1.	201004 B	Pelham Parkway SC, LLC d/b/a Pelham Parkway Surgery Center (Bronx County)	Contingent Approval

Diagnostic and Treatment Centers – Establish/Construct

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	192211 B	Beach Channel D&TC, LLC d/b/a Beach Channel Diagnostic and Treatment Center (Queens County)	Contingent Approval
2.	211085 B	KD Hudson Ventures, LLC d/b/a Avalon Medical Group (Orange County)	Contingent Approval

Dialysis Centers – Establish/Construct

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	211201 E	MVNY Partners I, LLC d/b/a U.S. Renal Care Faxton Dialysis (Oneida County)	Contingent Approval
2.	211202 B	MVNY Partners II, LLC d/b/a U.S. Renal Care St. Luke’s Home Dialysis (Oneida County)	Contingent Approval
3.	211203 B	MVNY Partners III, LLC d/b/a U.S. Renal Care Masonic Care Community Dialysis (Oneida County)	Contingent Approval
4.	211204 B	MVNY Partners IV, LLC d/b/a U.S. Renal Care Rome Dialysis (Oneida County)	Contingent Approval

5.	211205 B	MVNY Partners V, LLC d/b/a U.S. Renal Care Herkimer Dialysis (Herkimer County)	Contingent Approval
6.	211206 B	MVNY Partners VI, LLC d/b/a U.S. Renal Care Hamilton Dialysis (Madison County)	Contingent Approval
7.	211207 B	MVNY Partners VII, LLC d/b/a U.S. Renal Care Oneida Dialysis (Madison County)	Contingent Approval

Certified Home Health Agencies – Establish/Construct

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	202185 E	Wellbound II LLC (Westchester County)	Contingent Approval

CATEGORY 2: Applications Recommended for Approval with the Following:

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

CON Applications

Ambulatory Surgery Centers – Establish/Construct

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	202057 B	Premier SC, LLC t/b/k/a Premier Ambulatory Surgery Center of New York, LLC (Queens County) Dr. Lim – Interest/Abstaining	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

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

CON Applications

Diagnostic and Treatment Centers – Establish/Construct

	<u>Number</u>	<u>Applicant/Facility</u>	<u>E.P.R.C. Recommendation</u>
1.	211151 B	W Medical, LLC d/b/a W Health Center (Kings County) Dr. Gutierrez – Opposed at EPRC	Contingent Approval

2. 211226 E Perry Avenue Family Medical, Inc. Contingent Approval
(Bronx County)
Dr. Bennett – Abstained at EPRC

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

VII. NEXT MEETING

March 24, 2022, Albany
Tuesday, April 5, 2022, Albany

VIII. ADJOURNMENT

State of New York
Public Health and Health Planning Council

Minutes
December 9, 2021

The meeting of the Public Health and Health Planning Council was held on Thursday, December 9, 2021 at the Empire State Plaza, Concourse Level, Meeting Room 6, Albany, New York and Zoom. Chairman Jeffrey Kraut presided.

COUNCIL MEMBERS PRESENT

Dr. Howard Berliner – Zoom	Ms. Ann Monroe – Zoom
Dr. Jo Boufford - Zoom	Dr. Mario Ortiz – Zoom
Dr. Angel Gutiérrez – Zoom	Ms. Ellen Rautenberg - Zoom
Mr. Thomas Holt – Albany	Mr. Peter Robinson – Albany
Dr. Gary Kalkut – Zoom	Dr. John Ruge - Albany
Mr. Jeffrey Kraut – Zoom	Dr. Theodore Strange – Zoom
Mr. Scott LaRue – Zoom	Mr. Hugh Thomas - Albany
Mr. Harvey Lawrence - Zoom	Dr. Anderson Torres - Zoom
Dr. Roxanne Lewin - Zoom	Dr. Kevin Watkins – Zoom
Dr. Sabina Lim – Zoom	Dr. Patsy Yang – Zoom

DEPARTMENT OF HEALTH STAFF PRESENT

Dr. Ursula Bauer – Albany	Ms. Kathy Marks – Albany
Mr. Mark Furnish – Albany	Mr. Nicholas Mestoik - Albany
Ms. Shelly Glock – Albany	Ms. Marthe Ngwashi - Albany
Mr. Brian Gallagher - Zoom	Ms. Lauren Oricioli – Zoom
Mr. Michael Heeran – Albany	Mr. Jason Riegert - Albany
Mr. Adam Herbst – Zoom	Ms. Laura Santilli
Dr Eugene Heslin – Albany	Ms. Lisa Thomson - Albany
Mr. Jonathan Karmel – Albany	Ms. Jennifer Treacy - Albany
Ms. Colleen Leonard- Albany	Ms. Kristine Wheeler - Zoom
Ms. Karen Madden – Zoom	

INTRODUCTION

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

RESOLUTION OF APPRECIATION FOR COMMISSIONER ZUCKER

Mr. Kraut extended his appreciation for Dr. Zucker who served as Commissioner for the past sever years and gave some highlights of his achievements. On behalf of the Council a Resolution of Appreciation for Dr. Zucker was signed by Mr. Kraut and Dr. Boufford.

APPROVAL OF THE MEETING MINUTES OF OCTOBER 7, 2021, OCTOBER 26, 2021 AND NOVEMBER 18, 2021

Mr. Kraut asked for a motion to approve the October 7, 2021 Minutes of the Public Health and Health Planning Council meeting. Dr. Gutiérrez motioned for approval. Dr. Yang seconded the motion. The minutes were unanimously adopted. Please refer to page 3 of the attached transcript.

Mr. Kraut asked for a motion to approve the October 26, 2021 Minutes of the Special Public Health and Health Planning Council meeting. Dr. Ortiz motioned for approval. Dr. Yang seconded the motion. The minutes were unanimously adopted. Please refer to page 3 of the attached transcript.

Mr. Kraut asked for a motion to approve the November 18, 2021 Minutes of the Special Public Health and Health Planning Council meeting. Dr. Gutiérrez motioned for approval. Dr. Watkins seconded the motion. The minutes were unanimously adopted. Please refer to page 3 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Public Health

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

Dr. Bauer introduced herself to the Council and gave an overview of her career in public health. She noted the Office Public Health's role is to develop, deploy and evaluate public health programs drawing on the best available data science and practice to foster innovation in public health, science and practice based on emerging evidence and through basic and applied research and to strive to ensure public health interventions reach deeply, widely and equitably throughout the state and across communities in collaboration, of course, with our stakeholders and partners. Dr. Bauer stated that nearly everyone at the Department, including herself have been or is contributing to the COVID-19 pandemic response. In the nearly two years that we have been fighting the pandemic with all hands on deck several public health crises have emerged or accelerated. The opioid crisis has gotten worse. Congenital syphilis has re-emerged. Sexually transmitted infections are increasing. Progress toward ending the HIV AIDS epidemic appears to be stalling. Vaccine hesitancy has become a public health threat. Climate change has exacerbated public health issues from algal blooms to legionellosis to zoonotic infections. Dr. Bauer stated that each of these issues is a top concern for the Office of Public Health and each requires financial and staff resources, leadership, attention and political will to address.

Dr. Bauer announced that there is now a new Governor, new Commissioner acting, new Office of Public Health Director, a new OPH Deputy Director who started in November and a new Deputy Director for the Wadsworth Center who started that morning. The Department just closed the application period for the Wadsworth Center Director position and look forward to interviewing candidates. The Office is working hard to fill key positions throughout the Office of

Public Health. The Department is also eager to see the Wadsworth Center Life Sciences building come to fruition. The Wadsworth Center is our premier public health laboratory with programs currently dispersed across five facilities, facilities on five campuses throughout the Capital District, with over 700 employees. Efforts to bring these dispersed labs and programs together began in early 2018, when the total appropriation to build a new facility reached 750 million. The Department then paused due to the pandemic and are now in the process of getting back on track with that work.

Dr. Bauer noted that local health departments are critical allies. The Department cannot accomplish our public health mission without their dedication, collaboration, expertise and boots on the ground. The Department is eager to find better ways to support our local health departments in meeting their increasing demands beyond the current pandemic, including issues like elevated blood lead levels, opioid related overdoses and deaths, enforcing community sanitation regulations and responding to drinking water quality concerns. Dr. Bauer stated that these were a couple of examples of urgent needs we think we can make progress on in 2022. Other early wins we can put on the list are leading the nation on PFAS compounds and publishing all maximum contaminant level public testing data on the Department's website, deploying federal and state resources for lead service line replacement and establishing state infrastructure and state funding for pandemic and health emergency response.

Dr. Bauer concluded her report thanking the members for the opportunity to introduce herself and looks forward to working with the Council. To view the complete report and Members comments and questions, please see pages 4 and 5 of the 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

21-08 Amendment of Section 756.3 and Repeal of Section 756.4 of Title 10 NYCRR (Abortion Services)

Dr. Gutiérrez began his report by introducing Amendment of Section 756.3 and Repeal of Section 756.4 of Title 10 NYCRR (Abortion Services) and motioned for adoption. Dr. Yang seconded the motion. The motion carried with Mr. LaRue's abstention. Please see page 6 of the attached transcript.

20-25 Amendment of Section 405.34(g) of Title 10 NYCRR (Stroke Services)

Dr. Gutiérrez began his report by introducing 20-25 Amendment of Section 405.34(g) of Title 10 NYCRR (Stroke Services) and motioned for adoption. Dr. Yang seconded the motion. Please see pages 6 and 7 of the attached transcript.

19-33 Amendment of Subpart 5-1 of Title 10 NYCRR (Public Water Systems)

Dr. Gutiérrez began his report by introducing Amendment of Subpart 5-1 of Title 10 NYCRR (Public Water Systems) and motioned for adoption. Dr. Yang seconded the motion. Please see page 7 of the attached transcript.

Dr. Gutiérrez concluded his report

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

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

Report of the Committee on Establishment and Project Review

Peter Robinson, Chair, Establishment and Project Review Committee

B. APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

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

CON Applications

Diagnostic and Treatment Centers Surgery Centers – Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
201273 B	CFR Advance Services, LLC d/b/a Village Med & Rehabilitation (Queens County)	Contingent Approval
211132 B	Arena Care LLC (Suffolk County)	Contingent Approval
211270 B	Samaritan Daytop Health, Inc. (Bronx County)	Contingent Approval
212015 B	RiverSpring Project Corp. t/b/k/a RiverSpring DTC Corp. (Kings County)	Contingent Approval
212032 B	Emes Vision Center LLC (Kings County)	Contingent Approval

Certificates

Certificate of Amendment of the Certificate of Incorporation

Applicant

Hudson River Healthcare, Inc.

Council Action

Approval

Certificate of Dissolution

Applicant

Buena Vida Corporation

Council Action

Approval

Mr. Robison calls applications, 201273, 211132, 211270, 212015, 212032, Hudson River Healthcare, Inc. and Buena Vida Corporation and motioned for approval. Dr. Kalkut seconded the motion. The motion to approve carried. Please see pages 7 and 8 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 -Establish/Construct

Number

Applicant/Facility

Council Action

212009 E

Long Island Community Hospital
and Hospice
(Suffolk County)
Dr. Kalkut – Recusal

Contingent Approval

Mr. Robison calls application 212009 and notes for the record that Dr. Kalkut had declared a conflict and has left the meeting. Mr. Robinson motions for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried with Dr. Kalkut’s recusal. Dr. Kalkut returns to the meeting site. Please see page 9 of the transcript.

Diagnostic and Treatment Centers -Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
211262 E	Montefiore Westchester Community Corp. t/b/k/a Montefiore Einstein Advanced Care (Westchester County) Ms. Soto – Recusal (not present at meeting)	Contingent Approval

Mr. Robison introduces application 211262 and notes for the record that Ms. Soto had declared a conflict but was not present at the meeting. Mr. Robinson motions for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried. Please see page 10 of the transcript.

Certified Home Health Agency -Establish/Construct

<u>Number</u>	<u>Applicant/Facility</u>	<u>Council Action</u>
211107 E	Northern Lights Home Health Care (St. Lawrence County) Mr. Thomas – Recusal	Approval

Mr. Robison introduces application 211107 and notes for the record that Mr. Thomas had declared a conflict and has exited the meeting room. Mr. Robinson motions for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried with Mr. Thomas’ recusal. Mr. Thomas returns to the meeting room. Please see pages 10 and 11 of the transcript.

211169 E	OGL Holdings, LLC d/b/a Mount Sinai at Home (Nassau County) Dr. Lim - Recusal	Contingent Approval
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Mr. Robison introduces application 211169 and notes for the record that Dr. Lim had declared a conflict and has exited the meeting. Mr. Robinson motions for approval, Dr. Gutiérrez seconded the motion. The motion to approve carried with Dr. Lim’s’ recusal. Dr. Lim returns to the meeting. Please see page 11 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

Mr. Robinson concluded his report.

ADJOURNMENT:

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

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
DECEMBER 9, 2021
CONCOURSE MEETING ROOM 6, ALBANY AND ZOOM

Mr. Kraut I'm Jeffrey Kraut. I'm Chair of the committee. I'd like to welcome members, department staff, participants and observers. Today's meeting, we are going to hear a report from Dr. Ursula Bauer from the Office of Public Health that will be followed by a report by Dr. Gutierrez presenting regulations for adoption and then under a project review recommendations and establishment actions, Mr. Robinson. At the outset of the Codes committee, Dr. Gutierrez provided the guidelines for a successful meeting. I hope everybody remembers them and will continue to follow them. Under the agenda that we are going to take today, we've particularly for the Establishment and Project Review Committee, we've established the agenda based on the topics and categories that captures our roles and responsibilities, and we're batching certificate of need applications. I'd ask all the members to take the time to review those batched applications that Mr. Robinson is going to be presenting. If you have any issue with how we've batched them or would like to have an applicant removed, please feel free to do so. Originally, Dr. Bassett, our a newly appointed Commissioner of Health was going to be able to meet with us. Unfortunately, she sends her regrets. She's unable to participate in today's meeting due to her attending an event with the Governor. However, she did indicate that she certainly is planning to join us at the next full council meeting in February, and we hope that comes to pass. You may have an opportunity to welcome the Commissioner in other venues, hope you do so, and we're certainly looking forward to working with her on all the issues that we have worked on and need to address in the upcoming months and year. I also want to take this time and extend our appreciation to Dr. Zucker, who served as Commissioner of Health for the past seven years and was a member of this council. And throughout his time in New York, he faced many challenges. Dr. Zucker, along with his team was tremendously diligent during those times and as we know, under very, very challenging circumstances. And on behalf of the council, Dr. Boufford and myself have signed a resolution of appreciation for Dr. Zucker. I just want to share with you the highlights of that resolution, how Dr. Zucker has diligently served the residents of the State of New York since his tenure, which began in 2014, and he's diligently also supported the activities of this council in carrying out our mandate to protect and improve the health of all New Yorkers. The partnership that he developed with us, I think we certainly move closer to that shared goal of making New Yorkers among the healthiest people in the nation that has been validated by many surveys and rankings. And I think Dr. Zucker, to his credit was one of the driving forces to make that happen. He led the initiative for the Prevention Agenda to improve the health and well-being of all of New Yorkers. He was the principal public health expert in addressing COVID-19 pandemic response. We know he was guided by the science and tried to make decisions based on the best information available at that time. He implemented emergency regulations for the protection against COVID-19, prohibited the sale of electric electronic liquids with flavors, warning signage against the dangers of vaping and illegal e-cigarettes and e-liquid products. He authorized the State Sanitary Code regulations to ensure safe drinking standards, improve access to breast cancer screening, implemented requirements for children's camps, expanded the list of prohibited synthetic cannabinoids and was instrumental in supporting the development of the One Brooklyn Health System to improve the health care outcomes attain financial stability and sustainability I should say for the three safety net hospitals in Central Brooklyn that comprise One Brooklyn Health. He facilitated and led the response to the measles

outbreak and was instrumental in advocating and improving maternal health outcomes with a wide range of initiatives.

Dr. Gutierrez Mr. Gallagher, if you could mute yourself, please.

Dr. Gutierrez And he improved the maternal health outcomes in a wide range of activities and partnerships. On behalf of the members, we want to express to Dr. Zucker our affection, respect and admiration for his leadership, his commitment, his dedication and his professionalism has helped to make New York State and the Department of Health a national leader in health care in a symbol of excellence. And of course, on behalf of the council, the pleasure, we enjoyed working with him, an innovative, discerning and courageous leader who consulted with us and developed policies and programs with members of the council and just keeping in mind what we were all here to do. I think all of us appreciated his philosophy, his openness and his style. He had a vision, and he certainly pursued it with great vigor. I just want to thank everybody. I want to thank him in particular for the work he's done. I'm grateful that we've had the opportunity to serve with him. I hope each and every one of you share your sentiments when you do see him.

Mr. Kraut And if anybody would like to add anything, I'll just open it up before I move on to the next item.

Mr. Kraut Dr. Boufford

Dr. Boufford Thanks, Jeff.

Dr. Boufford I just want to to highlight in the presentation you just made all of the things that were going on in the department because of the staff's commitment and Howard's leadership other than COVID. This is really having been in public service and large organization that's really the challenge of leadership is to keep the trains running on time when these emergencies just really push for distraction at every moment, really for political reasons and other reasons, really, you know, obviously fundamental and profound public health reasons because of the scope of this pandemic. I think Howard should be congratulated and I'm glad you acknowledged all of the other sort of amazing public health progress that was made under his leadership. I just also wanted to share. He was kind enough to meet with our inaugural class at the School of Public Health a couple of weeks ago really after his stepping down had been announced relative to the new Governor's appointment of Dr. Bassett, who we I agree with you. We are just delighted is joining us. He was unbelievably gracious and I think very open with the students about. We often forget this. I think about the real political challenges of being a public health professional at state level and at city level. I just want to echo his commitment to having evidence based interventions and the challenges of a very, very challenging environment in which to work. So thanks Howard. Personally for me and I think our students in the next generation of public health professionals have a lot to learn about this balancing act that is public health leadership.

Dr. Boufford Thank you.

Mr. Kraut Thank you so much, Dr. Boufford.

Mr. Kraut Mr. La Rue.

Mr. La Rue Thank you, Mr. Kraut.

Mr. La Rue Scott La Rue, member the council. I just want to also thank Dr. Zucker. He always recognized and appreciated the role and the service of faith based and mission driven organizations and community organizations across the state and always ensured that they had a seat at the table and we'll always be appreciative for all the support that he gave us.

Mr. La Rue So, thank you, Dr. Zucker.

Mr. Kraut Thank you, guys. Thank you.

Mr. Kraut I'd now like to turn to adoption of the minutes.

Mr. Kraut May I have a motion for the adoption of the October 7, 2021 minutes of the Public Health and Health Planning Council?

Mr. Kraut I have a motion, Gutierrez.

Mr. Kraut I have a second.

Mr. Kraut All those in agreement, say aye or indicate, aye.

Mr. Kraut Thank you.

Mr. Kraut That's approved.

Mr. Kraut May I have a motion for the adoption of the October 26th, 2021, Public Health and Health Planning Council minutes?

Mr. Kraut I have a motion, Dr. Ortiz.

Mr. Kraut Second.

Mr. Kraut All those in favor indicate by raising your hand or saying, aye.

Mr. Kraut Thank you.

Mr. Kraut And then lastly, may I have a motion for adoption of the November 18th, 2021, Public Health and Health Planning Council minutes?

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

Mr. Kraut A second by Dr. Watkins.

Mr. Kraut Thank you very much.

Mr. Kraut All those approved say aye or raise your hand.

Mr. Kraut Thank you very much.

Mr. Kraut I now want to turn it over to Dr. Bauer, who is our newly appointed leader to serve the department as Deputy Commissioner in the Office of Public Health, who will give us a report on the activities of our office. I wish her a warm welcome for joining us.

Mr. Kraut Dr. Bauer.

Dr. Bauer Thank you.

Dr. Bauer Good morning, everyone. I'll just reiterate, Dr. Bassett does send her regrets and looks forward to meeting with you at the next meeting and working with you. Thank you for the opportunity to introduce myself to you today. I'm Ursula Bauer, Deputy Commissioner for Public Health and director of the Office of Public Health. I joined the department in August of this year and previously had worked at the department from 2001 to 2009. In 2010, I left to become the Director of the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention, a job I held for 8 and a half years. From there, I joined the Office of the Surgeon General at the U.S. Department of Health and Human Services as a Senior Advisor for Community Health and economic prosperity. I served in that role for 3 years. I'm a Chronic Disease Epidemiologist by training. I earned a Ph.D. in Epidemiology from Yale University, a Master of public health degree from Columbia University and a Master of Arts degree in Political Science from Rutgers. I also served in the Epidemic Intelligence Service, which is a two year training program at the CDC. I've worked as a Chronic Disease Epidemiologist in three state health departments; Louisiana, Florida and New York State. I'm delighted to be part of the New York State Department of Health team. As many of you already know, the Office of Public Health is one of about a dozen offices within the department. The office, OPH includes the AIDS Institute, the Center for Community Health, the Center for Environmental Health, the Office of Health Emergency Preparedness, the Office of Public Health Practice and the Wadsworth Center and Laboratories. The Office of Public Health Practice spearheads the prevention agenda for the department, and that's an initiative I know the council has a keen interest in. The Office of Public Health is home to a variety of public health functions focused on communicable and chronic diseases, maternal child and family health, nutrition, environmental health, injury prevention and more. It's a vast and deep portfolio and I have so much to learn about our work. It's difficult to capture the work of OPH in concise language that really reflects the richness and variety of the portfolio. From my perspective, OPH's role is to develop, deploy and evaluate public health programs drawing on the best available data science and practice to foster innovation in public health, science and practice based on emerging evidence and through basic and applied research and to strive to ensure public health interventions reach deeply, widely and equitably throughout the state and across communities in collaboration, of course, with our stakeholders and partners. Nearly everyone at the department, including myself, has been or is contributing to the COVID-19 pandemic response. In the nearly two years that we've been fighting the pandemic with all hands on deck several public health crises have emerged or accelerated. The opioid crisis has gotten worse. Congenital syphilis has re-emerged. Sexually transmitted infections are increasing. Progress toward ending the HIV AIDS epidemic appears to be stalling. Vaccine hesitancy has become a public health threat. Climate change has exacerbated public health issues from algal blooms to legionellosis to zoonotic infections. Each of these issues is a top concern for the Office of Public Health. Each requires financial and staff resources, leadership, attention and political will to address. We have a new Governor, as you know, a new Commissioner acting, a new Office of Public Health Director, a new OPH Deputy Director who started last month and a new Deputy Director for the Wadsworth Center who started this morning. We just closed the application period for the Wadsworth Center Director position and look

forward to interviewing candidates. We are working hard to fill key positions throughout the Office of Public Health. In this context, we do see some opportunities for advancing some early wins, if you will, if we can garner the attention and resources needed for immediate action. We're eager to see the Wadsworth Center Life Sciences building come to fruition. As you know, the Wadsworth Center is our premier public health laboratory. There is a library there too, yes, that's right. The programs are currently dispersed across five facilities, facilities on five campuses throughout the Capitol district, with over 700 employees. Several of those facilities are in poor condition, and that does hamper employee safety, retention and recruitment and threatens quality, efficiency and work productivity. Efforts to bring these dispersed labs and programs together began in earnest in 2018, when the total appropriation to build a new facility reached 750 million. We then paused due to the the pandemic and are now in the process of getting back on track with that work. Local health departments are critical allies. We cannot accomplish our public health mission without their dedication, collaboration, expertise and boots on the ground. We're eager to find better ways to support our local health departments in meeting their increasing demands beyond the current pandemic, including issues like elevated blood lead levels, opioid related overdoses and deaths, enforcing community sanitation regulations and responding to drinking water quality concerns. These are a couple of examples of urgent needs we think we can make progress on in 2022. Other early wins we can put on the list are leading the nation on PFAS compounds and publishing all maximum contaminant level public testing data on our DOH website, deploying federal and state resources for lead service line replacement and establishing state infrastructure and state funding for pandemic and health emergency response. Again, I thank you for the opportunity to introduce myself to you this morning, and I look forward to working with you.

Dr. Bauer Thank you.

Mr. Kraut Dr. Bauer, thank you so much for the introduction. On behalf of the council, we're ecstatic that you've chosen to join and lead this role and we really look forward to working with you. As you know we'd like to spend more time working on the public health portion of health planning. I know our Committee Chair, Dr. Boufford, our Planning Chair a lot of agenda items we'd like to help support in the state. We welcome you.

Mr. Kraut Dr. Boufford.

Dr. Boufford Thanks Jeff.

Dr. Boufford I just want to welcome Dr. Bauer to indicate to colleagues that she and I have already had very productive conversations. I think she's excited. To me, I was really excited. She was incredibly knowledgeable about the prevention agenda given all the other things that she outlined that she's taking responsibility for. I know she will be very supportive as we reactivate the Public Health Committee of this council and hopefully the Ad Hoc Committee on Leadership for Public Health of the Council in the New Year. I think one of the really rewarding things in discussions that I've had with her and also continue to have with colleagues in the department is that the local health directors are still very much maintaining their local leadership on the prevention agenda, reporting in their information in the face of all of the pressures they're under with COVID. We're looking forward to engaging local health directors as well as our primary care colleagues in future plans for the department in the waiver that's still pending, as well as building back better and fairer after the epidemic and then in moving the prevention agenda and the Public Health Committee's interest in the context of the prevention agenda, which was developed initially and then interrupted by the pandemic in March of 2020, which we really kind of suspended

our formal activities. So with Dr. Bauer's presence, we're looking forward to working with her and reactivating our public health side of the council's work. So, thank you and welcome, Dr. Bauer.

Mr. Kraut Thanks so much, Dr. Boufford.

Mr. Kraut I'm now going to introduce Dr. Gutierrez to give a report on the Codes, Regulations and Legislation Committee. There are three items for us to discuss and adopt.

Mr. Kraut Dr. Gutierrez.

Dr. Gutierrez Thank you very much.

Dr. Gutierrez Good morning again, everybody. My name is Dr. Gutierrez. I am the Chair of the Committee of Codes, Regulation and Legislation. We met earlier this morning and we adopted or, we propose, have a proposal for the adoption of three amendments. The first one is 21-08 amendment to Section 756.3, repeal of Sections 756.4 of Title 10 NYCRR, abortion services. Ms. Carroll from the department is present should there be any questions from the members of the council.

Dr. Gutierrez At this point, I move to accept these regulations.

Mr. Kraut I have a motion from Dr. Gutierrez.

Mr. Kraut Do I have a second?

Mr. Kraut Are there any questions from the council?

Mr. Kraut Hearing, I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut All those against?

Mr. Kraut All those abstaining?

Mr. Kraut I have been abstention from Mr. La Rue.

Mr. Kraut The motion carries.

Mr. Kraut Thank you.

Mr. Kraut The second motion for adoption in stroke services 20-25, amendment of Section 405.34 G of Title 10 NYCRR stroke services. Lauren from the department is present should there be any questions of the members.

Dr. Gutierrez I so move to accept this regulation now.

Mr. Kraut I have a motion from Dr. Gutierrez.

Mr. Kraut May I have a second?

Mr. Kraut Thank you.

Mr. Kraut Are there any questions for the department?

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Dr. Gutierrez Last for adoption is a 19-3 amendment Subpart - 1 of Title 10 NYCRR Public Water Systems. Christine Wheeler from the department is present should there be any questions from the members.

Dr. Gutierrez I move to accept this regulation or to adopt rather this regulation.

Mr. Kraut I have a motion from Dr. Gutierrez.

Mr. Kraut I have a second.

Mr. Kraut Any question to the department?

Mr. Kraut Hearing none, all those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstention?

Mr. Kraut That motion carries as well.

Dr. Gutierrez This concludes my report.

Mr. Kraut Thank you very much, Dr. Gutierrez and members of the committee. You've been a little busy these last couple of months, and I suspect you will continue to be.

Mr. Kraut I now want to hand it over to Mr. Robinson, who will give us a report of the recommendations of Project Review and Establishment Committee.

Mr. Kraut Mr. Robinson.

Mr. Robinson Thank you, Mr. Kraut.

Mr. Robinson Just to remind members of the council about the batching that we are doing as my glasses fog up with the mask and everything. If there are any applications that you'd like to have considered separately, please indicate so now. Otherwise, I will proceed with the batching as we've structured it.

Mr. Kraut Okay.

Mr. Robinson Very good.

Mr. Robinson Application 201273B CFR Advanced Services LLC doing business as Village Med and Rehabilitation in Queens County to establish and construct a new diagnostic and treatment center to be located at 61-33 Woodhaven Boulevard in Rego Park. The department and the committee recommend approval with conditions and contingencies. Application 211132B Arena Care LLC in Suffolk County to establish and construct a diagnostic and treatment center to be located at 8 Maple Avenue in Bayshore to provide primary and specialty medical care, behavioral health, occupational therapy, physical therapy and speech language pathology services. Here again, the department and the committee recommend approval with conditions and contingencies. Application 211270B, Samaritan Day Top Health Inc in Bronx County. This is to establish and construct a diagnostic and treatment center to be located at 362 East 148 Street in the Bronx and Certified Medical Services and Primary Care. The Department and the committee recommend approval with conditions and contingencies. Application 212015B, River Spring Project Corp, also known as River Spring, DTC Corp in Kings county to establish and construct a diagnostic and treatment center to be located at 673 Livonia Avenue, Brooklyn, and an extension clinic to be located at 63 Marcus Garvey Boulevard in Brooklyn to serve the Pace program of Elder Serv Health Inc. The Department and the committee recommend approval with conditions and contingencies. Application 212032B, EMES Vision Center LLC in Kings County to establish and construct a diagnostic and treatment center to be located at 5202 5204 16th Avenue in Brooklyn to provide ophthalmology and optometry services. Again, the Department recommends approval with conditions and contingencies. Also, certificates of amendment for the Certificate of Incorporation of Hudson River Health Care Inc of a name change and a certificate of dissolution.

Mr. Robinson I make a motion for that batch.

Mr. Kraut Thank you, Mr. Robinson.

Mr. Kraut I have a second by Dr. Kalkut.

Mr. Kraut Are there any questions on any one of those applications?

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

Mr. Kraut All those in favor, aye.

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries

Mr. Robinson Thank you.

Mr. Robinson You are going to be recusing yourself and Dr. Boufford, you are going to take this application. I think.

Mr. Robinson This is application 212009E, Long Island Community Hospital and Hospice.

Dr. Kalkut Mr. Robinson, excuse me for interrupting. I'm also recusing.

Mr. Kraut I'm not recusing.

Mr. Robinson I apologize.

Mr. Robinson Thank you.

Mr. Robinson I misread the K's in my report here. You are correct. Mr. Kraut is not recusing. Dr. Kalkut is.

Mr. Robinson Thank you for that clarification.

Mr. Robinson Again, this is an application 212009E, Long Island Community Hospital and Hospice in Suffolk County to establish NYU Langone Health System as the active parent and cooperator of Long Island Community Hospital and Long Island Community Hospital Hospice, and change the corporate name of the operator. The department and the committee recommend approval with the condition and contingencies.

Mr. Robinson I so move.

Mr. Kraut I have a motion by Mr. Robinson.

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

Mr. Kraut Any questions?

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstention?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson This application includes a conflict and refusal by Ms. Soto, who I believe is not present at the meeting today, but just wanted to acknowledge her recusal.

Mr. Robinson Application 211262E, Westchester Community Corp doing businesses as Einstein advanced care in Westchester County, and this is to establishment Westchester Community Corp as the operator of the facility, located at f555 Paxton Road in Elmsford, that is currently operating as an extension clinic of Burke Rehabilitation Hospital and certify other medical specialties. The department and the committee recommend approval with conditions and contingencies.

Mr. Robinson I so move.

Mr. Kraut I have a motion by Mr. Robinson.

Mr. Kraut I have a second, Dr. Gutierrez.

Mr. Kraut Any questions?

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstention?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson I will note this application includes a conflict in recusal by Mr. Thomas, who has left the room.

Mr. Robinson This is application 211107E, Northern Lights Home Health Care in St. Lawrence County to transfer a 25 percent interest from one withdrawing member to the remaining members evenly. The department and the committee recommend approval with a condition.

Mr. Robinson I so move.

Mr. Kraut I have a motion.

Mr. Kraut I have a second, Dr. Gutierrez.

Mr. Kraut Any questions on this application?

Mr. Kraut All those in favor?

Mr. Kraut Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson The final application is a conflict and recusal by Dr. Lim, who has left her Zoom desk.

Mr. Robinson Application 211169E, OGL Holdings LLC, doing business as Mt. Sinai At Home in Nassau County to establish OGL Holdings LLC as the new operator of an existing certified home health agency located at 1,000 South Oyster Bay Road in Hicksville on Long Island. The department recommends approval with a condition and contingencies, as does the committee.

Mr. Robinson I so move.

Mr. Kraut I have a motion.

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

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson One additional item to mention that is not an application. During the course of the committee meetings, we noted the growing number of applications that are converting private practices to Article 28 diagnostic and treatment centres. Recognize that that sort of trend is happening on a transactional basis. Believe that it is appropriate for the department to consider this more from a strategic standpoint in terms of what the policy directions for this ought to be. And obviously, both the committee and the full council would very much like to engage in that conversation with you. Just wanted to make note of that and have it ticked on our agenda as a follow up item.

Mr. Robinson With that, I conclude the report of the establishment and Project Review Committee.

Mr. Kraut Thank you so much, Mr. Robinson.

Mr. Kraut The public portion of the Public Health and Health Planning Council is now going to be adjourned.

Mr. Kraut The next committee day that we have scheduled this January 27th and the full council is going to convene on the 10th. It is highly likely as we've been doing these last couple of months because of issues as public health concerns and emergencies that we may have to meet on an emergency basis prior to these dates as soon as we have confirmation to consider regulations or other matters. As soon as we do have confirmation of that, you'll be notified and we hope that everybody will make the effort as you have diligently done so this last year to help move things along on this kind of urgent basis. I want to end by just thanking everybody. It's been a tough, tough year. It's been a tough trying two years. We've had more meetings in this year than I think we've ever had in our history, and we've been able to diligently. I use that term a lot today, but we've really a committed bunch of people. You're all volunteers. You have a lot of demands on your time. I know the department, the State of New York, we're all grateful for all the efforts everybody has been made to keep things moving forward and to address the urgency of keeping New Yorkers as safe as possible and as healthy. And with that, you know, I just appreciate it and I want to wish everyone a joyous and a meaningful holiday. I hope the new year is going to be filled with health and happiness, not only for each of you and your families, but for all New Yorkers. We continue to do our work. I hope that those words have meaning throughout the year. Thank you so much again for your commitment to our cause here. And I want to thank the Department of Health staff similarly. You guys have been under tremendous almost 24 hours a day working on issues, and we were not at the tail end of this. We just have to adjust as circumstances dictate. Want to thank the department for the support it's given to council for this past year and for all the work you do and you do not get thanked enough for that work. We are grateful for our partnership and we want all New Yorkers to know how valued your efforts and your commitment is to the State of New York and thank the department and the leadership for all of that they've done this past year.

Mr. Kraut So with that, I'll have a motion to adjourn.

Mr. La Rue I did, Mr. Kraut.

Mr. La Rue I don't want to be a downer after those very nice comments and holiday greetings, but I know that the public comment period is continuing right now on the safe staffing legislation, and the department is working on promulgating these regulations. They go into effect on January 1st with or without these regulations. I just want to continue to voice my concern about the inability in this extraordinarily difficult staffing crisis for operators to meet this new requirement with the best of expectations and efforts to do so, and that there are penalties that can be implemented retrospectively in April for not meeting these. There is not a resolution to this. It's a matter of great concern for those of us who are operating nursing homes and already modulating admissions and taking beds off line in order to adjust to staffing levels. I know there is potentially a window in that legislation about a crisis or a set of circumstances under which these penalties can be waived, and I certainly hope everybody is taking this into consideration. We've got to, unfortunately, a well-intended piece of legislation that I'm not sure who is going to be able to meet on January 1st.

Mr. Kraut Thanks, Mr. La Rue.

Mr. Kraut I know, you know, I'm not going to ask the department necessarily to respond. I think we're all aware of the efforts the Governor has made to try to supplement some of the staffing Upstate with the use of the National Guard. I know the concerns Mr. La Rue has voiced have been heard and resonated up in Albany. I certainly believe that when we

do have a chance to reconvene after the new year, you'll have better answers to some of the questions.

Mr. Kraut Anybody else would like to make kind of a year end statement or any other issue?

Mr. Kraut Open it up for discussion.

Mr. Kraut Okay.

Mr. Kraut Well, again, thank you so much. Thank everybody and be well, be safe. Take care.

Mr. Kraut Bye bye.

Mr. Kraut We are adjourned.

State of New York
Special Public Health and Health Planning Council

Minutes
January 11, 2022

The meeting of the Public Health and Health Planning Council was held on Thursday, January 11, 2022 at the Empire State Plaza, Concourse Level, Meeting Room 6, Albany and via Zoom. Chairman Jeffrey Kraut presided.

COUNCIL MEMBERS PRESENT

Dr. Howard Berliner – Zoom	Dr. Mario Ortiz – Zoom
Dr. Jo Boufford - Zoom	Mr. Peter Robinson – Zoom
Dr. Angel Gutiérrez – Zoom	Dr. John Ruge - Zoom
Mr. Thomas Holt – Zoom	Ms. Nilda Soto – Zoom
Mr. Jeffrey Kraut – Zoom	Dr. Theodore Strange – Zoom
Mr. Scott LaRue – Zoom	Mr. Hugh Thomas - Zoom
Mr. Harvey Lawrence - Zoom	Dr. Anderson Torres - Zoom
Dr. Roxanne Lewin - Zoom	Dr. Kevin Watkins – Zoom
Dr. Sabina Lim – Zoom	Dr. Patsy Yang – Zoom
Ms. Ann Monroe – Zoom	

DEPARTMENT OF HEALTH STAFF PRESENT

Mr. Mark Furnish – Albany	Ms. Kathy Marks – Zoom
Mr. Michael Heeran – Albany	Mr. Nicholas Mestoik - Albany
Mr. Adam Herbst - Zoom	Ms. Marthe Ngwashi - Albany
Dr Eugene Heslin – Zoom	Mr. Jason Riegert – Zoom
Mr. Jonathan Karmel - Albany	Ms. Stephani Schulman - Zoom
Ms. Colleen Leonard- Albany	Mr. Michael Stelluti - Albany
Ms. Emily Lutterloh - Albany	Ms. Lisa Thomson - Albany
Ms. Karen Madden - Zoom	Ms. Jennifer Treacy - Albany

INTRODUCTION

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

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

20-22 Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements)

Dr. Gutiérrez introduced for emergency adoption the proposed Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements). Dr. Gutiérrez motioned for approval. Dr. Torres seconded the motion. The motion for emergency adoption carried. Please see page 1 of the attached transcript to view the members questions and comments.

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

Dr. Gutiérrez introduced for emergency adoption the proposed Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel). Dr. Gutiérrez motioned for approval. Dr. Yang seconded the motion. The motion for emergency adoption carried. Please see page 2 of the attached transcript to view the members questions and comments.

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

Dr. Gutiérrez introduced for emergency adoption the proposed 24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR, Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination System). Dr. Gutiérrez motioned for approval. Dr. Berliner seconded the motion. Dr. Boufford stated for the record that the Council has been raising systematically is that most of these regulations and access questions and ways of dealing with COVID response more effectively have applied only to hospitals in need. She noted that the Council has asked several times for clarification around why and how they might be extended to long term care facilities, as well as primary care and local health departments. The motion for emergency adoption carried. Please see pages 2 through 4 of the attached transcript to view the members questions and comments.

21-14 Addition of Section 2.61 to Title 10 NYCRR, Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities)

Dr. Gutiérrez introduced for emergency adoption the Addition of Section 2.61 to Title 10 NYCRR, Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities). Dr. Gutiérrez motioned for approval. Dr. Yang seconded the motion. The motion for emergency adoption carried with Dr. Watkins abstaining. Please see

pages 4 and 5 of the attached transcript to view the members questions and comments.

ADJOURNMENT:

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

NEW YORK STATE DEPARTMENT OF HEALTH
SPECIAL PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
JANUARY 11, 2022
CONCOURSE MEETING ROOM 6, ALBANY AND ZOOM

Mr. Kraut I'm Jeffrey Kraut. I have the privilege to call to order a special meeting of the Public Health and Health Planning Council. Going welcome members, participants and observers on January 11th, 2022. We have one item today for our meeting. Dr. Gutierrez will present regulations for emergency adoption. Before I turn to Dr. Gutierrez, I just want to acknowledge for your information. We've received several comments concerning nursing home visitation protocols and COVID testing for visitors. None of those emergency regulations proposed for adoption today concern the nursing home visitation or COVID testing for visitors.

Mr. Kraut I'll now turn to Dr. Gutierrez, who will give a report on the Codes, Regulation and Legislation Committee.

Mr. Kraut Dr. Gutierrez.

Dr. Gutierrez Thank you very much.

Dr. Gutierrez Good afternoon. At today's meeting of the Committee on Codes, Regulation and Legislation, the committee review and voted to recommend adoption of the following four regulation proposals for approval before the full Council. For Emergency Adoption was hospital and nursing home Personal Protective Equipment Requirements. Mark Furnish and Jonathan Karmel from the department are present should there be any questions from the members.

Dr. Gutierrez I move to accept this regulation.

Mr. Kraut I have a motion from Dr. Gutierrez.

Mr. Kraut May I have a second?

Mr. Kraut I have a second by Dr. Torres.

Mr. Kraut Any questions from the committee?

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut All those opposed?

Mr. Kraut Any abstentions?

Mr. Kraut The motion carries.

Dr. Gutierrez For Emergency Adoption also is COVID-19 vaccination of nursing home on adult care facility residents and personnel. Again, Jonathan Karmel and Dr. Emily Lutterloh from the Department are present should there be any questions from the members.

Dr. Gutierrez I move to accept this regulation.

Mr. Kraut I have a motion. I have a motion from Dr. Gutierrez.

Mr. Kraut I have a second by Dr. Yang.

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

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Abstentions?

Mr. Kraut The motion carries

Dr. Gutierrez Third for Emergency adoption as the Surge and Flex Health Coordination System. Mark Furnish and Jonathan Karmel from the department are present should there be any questions.

Dr. Gutierrez I move to accept this regulation.

Mr. Kraut I have a motion from Dr. Gutierrez.

Mr. Kraut A second by Dr. Berliner.

Mr. Kraut Are there any questions? Comments?

Mr. Kraut Ms. Monroe.

Ms. Monroe My question is still outstanding about who this covers, that doesn't cover. I would expect an answer that won't affect my vote, but I will want an answer why a significant amount of residential services for older people are not covered.

Mr. Kraut On the surge and flex regulation?

Ms. Monroe That's the one we're on, right?

Mr. Kraut Yes, that's correct. I'm just clarifying.

Ms. Monroe Yes.

Mr. Furnish And just for the record, this, you know, this deals with hospitals and not I think you said. You're very hard to hear today, but I think you said assisted living facilities. Is that correct?

Ms. Monroe Yes.

Mr. Kraut Is that correct? Does this apply to assisted living, the surge and flex?

NYSDOH Albany No.

Mr. Kraut Is it specific to hospitals? It does not apply to assisted living facilities.

Ms. Monroe That's correct. That was my question as to why not?

Mr. Kraut Okay.

Mr. Furnis We can get an answer as to why that's not included as a package, but this deals with just hospital, this regulation and it's the same regulation we've passed two times already. It just deals with hospitals surge and flex.

Mr. Kraut Yeah.

Mr. Kraut Somebody should go on mute. We're hearing your private conversation on the phone and your New Year plans.

Mr. Furnish Plus, I'd like to see the letter. I'd like to see the letter because I'm going. I haven't read the letter and I'd like to see the exact question, but I think that's the answer.

Mr. Kraut Colleen will send you the letter.

Ms. Monroe Are nursing homes covered by this surge and flex regulation?

Mr. Furnish Its hospitals, general hospitals Article 28.

Ms. Monroe Well, then my question is broader, and we could talk back to it at another time.

Mr. Kraut Okay.

Mr. Kraut Dr. Boufford.

Dr. Boufford Yeah, I'd just like to extend Ann's question. I think the question we've been raising systematically is that most of these regulations and access questions and ways of dealing with COVID response more effectively have applied only to hospitals in need. We have asked several times for clarification around why and how they might be extended to long term care facilities, as well as primary care and local health departments.

Dr. Boufford Thank you.

Mr. Kraut Okay.

Mr. Kraut Any other questions? Comments?

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

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Kraut Dr. Gutierrez, you're on mute.

Mr. Kraut Thank you.

Dr. Gutierrez Last for Emergency Adoption is COVID-19 transmission by covered entities. Jonathan Karmel and Dr. Emily Lutterloh from the department are present should there be any questions from the members.

Dr. Gutierrez I move to accept this regulation.

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

Mr. Kraut A second by Dr. Yang.

Mr. Kraut I would say that since this has engendered quite a bit of comments, any additional comments that we have from the council, I will put in a letter to the department, so there's a record of the concerns that we've raised, but I think just for the benefit, it would be helpful for anybody else to add those comments or to reiterate them.

Mr. Kraut Mr. Holt.

Mr. Holt Thanks.

Mr. Holt Member of the council. As was discussed in committee meeting, a lot of concern remains around implementation and just want to reiterate those points made and encourage the Health Department or request the Health Department work with the provider community on the implementation of this actual regulation.

Mr. Holt Thank you.

Mr. Kraut Thanks, Mr. Holt.

Mr. Kraut Mr. Thomas.

Mr. Thomas Thank you, Jeff.

Mr. Thomas Just again, to reiterate the comments I made during the committee meeting. We support the vaccine mandate that was adopted in the Fall. Not a question of supporting the science. We're beyond that conversation, but the implementation of this mandate, the booster change at this time will have very dramatic, could have very dramatic effects on the ground and very, very strenuous situations across our state, but in particular in our region, possibly driving staff out at the wrong time. And therefore, I would urge the Department of Health to take that into consideration in the balancing act that they

have been describing today as you decide to implement or how to implement what is a very complex situation from a care perspective, HR perspective and governance perspective.

Mr. Thomas Thank you.

Mr. Kraut Any other comments?

Mr. Kraut Hearing, I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut I'm sorry, Dr. Berliner, you voted aye. I'm sorry. You voted yes.

Mr. Kraut Okay.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut I see an abstention from Dr Watkins.

Mr. Kraut The motion passes.

Mr. Kraut I want to thank the committee. I want to thank the department for helping us sort through some of this issue. I would also thank the public who we received over 200 emails of letters from professional associations and we heard testimony here today. I want to thank you all.

Mr. Kraut I'll have a motion to adjourn.

Mr. Kraut The motion to adjourn, Dr. Strange.

Mr. Kraut A second by Dr. Berliner.

Mr. Kraut We are adjourned and we reconvene a little later next month for the next regular meeting of the council.

Mr. Kraut Thank you very much for your time.

Mr. Kraut Thank you for the day.

SUMMARY OF EXPRESS TERMS

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

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

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

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

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

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

* * *

- (h) Contact shall mean any person known to have been sufficiently associated with a case or suspected case that, based on the best available evidence of transmissibility, such person has had the opportunity to contract a particular disease or condition.

- (i) Isolation shall mean the physical separation and confinement of an individual or group of individuals who are infected or reasonably determined by the State Commissioner of Health or local health authority to be infected with a highly contagious disease or organism, for such time as will prevent or limit the transmission of the reportable disease or organism to non-isolated individuals, in the clinical judgment of the State Commissioner of Health, or of the local health authority and consistent with any direction that the State Commissioner of Health may issue.

- (j) Quarantine shall mean the physical separation and confinement of an individual or groups of individuals who are reasonably determined by the State Commissioner of Health or local health authority to have been exposed to a highly contagious communicable disease, but who do not show signs or symptoms of such disease, for such time as will prevent transmission of the disease, in the clinical judgment of the State Commissioner of Health, or of the local

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

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

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

- (1) Verify the existence of a disease or condition;
- (2) Ascertain the source of the disease-causing agent or condition;
- (3) Identify unreported cases;
- (4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;
- (6) Examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

- (7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

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

(d) Commissioner authority to lead investigation and response activities.

(1) The State Commissioner of Health may elect to lead investigation and response activities

where:

(i) Residents of multiple jurisdictions within the State are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(ii) Residents in a jurisdiction or jurisdictions within the State and in another state or states are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(iii) An outbreak of an unusual disease or a reportable disease or condition involves a single jurisdiction with the high potential for statewide impact.

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

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

(a) Duty to issue isolation and quarantine orders

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

(b) Any isolation or quarantine order shall specify:

- (1) The basis for the order;
- (2) The location where the person shall remain in isolation or quarantine, unless travel is authorized by the State or local health authority, such as for medical care;
- (3) The duration of the order;
- (4) Instructions for traveling to the isolation or quarantine location, if appropriate;
- (5) Instructions for maintaining appropriate distance and taking such other actions as to prevent transmission to other persons living or working at the isolation or quarantine location, consistent with any direction that the State Commissioner of Health may issue;
- (6) If the location of isolation or quarantine is not in a general hospital, instructions for contacting the State and/or local health authority to report the subject person's health condition, consistent with any direction that the State Commissioner of Health may issue;
- (7) If the location of isolation or quarantine is a multiple dwelling structure, that the person shall remain in their specific dwelling and in no instance come within 6 feet of any other person, and consistent with any direction that the State Commissioner of Health may issue;
- (8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;
- (9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;

- (10) Notification of the right to request that the public health authority issuing the order inform a reasonable number of persons of the conditions of the isolation or quarantine order;
- (11) A statement that the person has the right to seek judicial review of the order;
- (12) A statement that the person has the right to legal counsel, and that if the person is unable to afford legal counsel, counsel will be appointed upon request.

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

- (1) monitor such person to ensure compliance with the order and determine whether such person requires a higher level of medical care;
- (2) whenever appropriate, coordinate with local law enforcement to ensure that such person comply with the order; and
- (3) the extent such items and services are not available to such person, provide or arrange for the provision of appropriate supports, supplies and services, including, but not limited to: food, laundry, medical care, and medications.

(d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the

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

(e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.

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

(g) Duty of attending physician

(1) Every attending physician shall immediately, upon discovering a case or suspected case of a highly contagious reportable communicable disease, cause the patient to be appropriately isolated and contact the State Department of Health and the local health authority where the patient is isolated and, if different, the local health authority where the patient resides.

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

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

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

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

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

* * *

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

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

(12) whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, such

syndromic surveillance data as the commissioner deems appropriate, which the hospital shall submit in the manner and form determined by the commissioner; and

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

* * *

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

Section 58-1.14 Reporting of certain communicable diseases.

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

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

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

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

* * *

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

(g) Whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, the

commissioner may direct general hospitals, as defined in Article 28 of the public health law, and consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA), to accept patients pursuant to such procedures and conditions as the commissioner may determine appropriate.

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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

The statutory authority for the proposed amendments to section 405.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 2803 of the PHL, which authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

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

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

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

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had

existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, two years after the first cases were identified in the United States, Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Since late November 2021, cases have risen more than 40-fold, and over 98 percent of the sequenced recent positives in New York State were the Omicron variant.

In light of this situation, these regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

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

Part 2 Amendments:

- Relocate and update definitions, and add new definitions
- Repeal and replace current section 2.6, related to investigations, to make existing clarify local health department authority.
 - Sets forth specific actions that local health departments must take to investigate a case, suspect case, outbreak, or unusual disease.
 - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.

- While the Department works collaboratively with local health departments on a variety of public health issues, including disease control, this regulation clarifies the authority for the Commissioner to lead disease investigation activities under certain circumstances (i.e., where there is potential for statewide impact, multiple jurisdictions impacted, or impact on one or more New York State jurisdictions and another state or states), while working collaboratively with impacted local health departments. In all other situations, local health departments retain the primary authority and responsibility to control communicable disease within their respective jurisdictions, with the Department providing assistance as needed.

(i) Codifies in regulation the requirement that local health departments send reports the Department during an outbreak.

- New section 2.13 added to clarify isolation and quarantine procedures.
 - Clarify that the State Department of Health has the authority to issue isolation and quarantine orders, as do local departments of health.
 - Clarifies locations where isolation or quarantine may be appropriate.
 - Sets forth requirements for the content of isolation and quarantine orders.
 - Specifies other procedures that apply when a person is isolated or quarantined.
 - Explicitly states that violation of an order constitutes grounds for civil and/or criminal penalties
 - Relocates and updates existing regulatory requirements that require the attending physician to report cases and suspected cases to the local health

authority, and to requires physicians to provide instructions concerning how to protect others.

Part 58 Amendments

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

Part 405 Amendments

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

COSTS:

Costs to Regulated Parties:

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

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

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

Costs to Local and State Governments:

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

beyond what local health departments would incur in the absence of these regulations. Further, making explicit the Department's authority to lead investigation activities will result in increased coordination of resources, likely resulting in a cost-savings for State and local governments.

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

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rulemaking for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have a population of less than 200,000 based upon 2020

United States Census data:

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

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

Census estimated county populations for 2010:

Albany County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

Reporting, Recordkeeping, and Other Compliance Requirements; and Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19. New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak.

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. The substantial majority of sequenced positive cases in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

Based on the foregoing, the Department has determined that these regulations, while applicable to several diseases, are necessary to promulgate on an emergency basis to control the spread of COVID-19 in New York State. Accordingly, current circumstances necessitate immediate action, and pursuant to the State Administrative Procedure Act Section 206(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by repealing Subpart 66-3 and repealing and replacing Section 2.60, to be effective upon filing with the Secretary of State, to read as follows:

Subpart 66-3 is hereby repealed.

Section 2.60 is repealed and replaced to read as follows:

2.60. Face Coverings for COVID-19 Prevention

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

(b) Businesses must provide, at their expense, face-coverings for their employees required to wear a mask or face-covering pursuant to subdivision (a) of this section.

(c) large-scale indoor event venues with more than five thousand attendees shall require patrons to wear face coverings consistent with subdivision (a) of this section; may require all patrons to wear a face covering irrespective of vaccination status; and may deny admittance to any person who fails to comply. This regulation shall be applied in a manner consistent with the federal American with Disabilities Act, New York State or New York City Human Rights Law, and any other applicable provision of law.

(d) No business owner shall deny employment or services to or discriminate against any person on the basis that such person elects to wear a face-covering that is designed to inhibit the transmission of COVID-19, but that is not designed to otherwise obscure the identity of the individual.

(e) For purposes of this section face-coverings shall include, but are not limited to, cloth masks, surgical masks, and N-95 respirators that are worn to completely cover a person's nose and mouth.

(f) Penalties and enforcement.

(i) A violation of any provision of this Section is subject to all civil and criminal penalties as provided for by law. Individuals or entities that violate this Section are subject to a maximum fine of \$1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the Section shall constitute a separate violation under this Section.

(ii) All local health officers shall take such steps as may be necessary to enforce the provisions of this Section accordance with the Public Health Law and this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health (“Department”) to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults, those who have serious underlying medical health conditions and those who are unvaccinated.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are currently over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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

COSTS:

Costs to Regulated Parties:

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

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

Costs to Local and State Governments:

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

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

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

Duplication:

There is no duplication of federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County		

Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

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

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

Compliance Costs:

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

COVID-19 within the state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are currently over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is adding new sections 2.9 and 2.62, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.9 is added to read as follows:

2.9. COVID-19 Reporting in Schools. In addition to all other reporting requirements in this Part, every kindergarten, elementary, intermediate, or secondary school as well as any pre-kindergarten programs and school districts, as identified by the Department, shall report to the Department of Health, on a daily basis, in a form and manner to be determined by the Commissioner, all COVID-19 testing, positive test results reported in any manner to the school, and related information among students, teaching staff, and any other employees or volunteers. Such daily report shall include any other data elements as the Commissioner determines to be appropriate to track outbreaks of COVID-19 within such schools and school districts.

Section 2.62 is added to read as follows:

2.62. COVID-19 Testing Requirements.

(a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, the Commissioner may require routine COVID-19 testing in certain settings, which may include schools, homeless shelters, correctional facilities, nursing homes, and health care settings, and

which may distinguish between individuals who have received full vaccination against COVID-19 and those who have not. Such testing determination may also include alternatives to testing as well as prevention protocols pending test results based on symptoms and/or exposure in certain settings.

(1) Entities subject to routine COVID-19 testing pursuant to a Commissioner's determination may accept documentation demonstrating full vaccination in lieu of imposing such testing requirements, if permitted in a Commissioner's determination. "Full vaccination", for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of full vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system;

(iii) Excelsior Pass; or

(iv) any other documentation determined acceptable by the Department.

(2) Entities subject to a Commissioner's determination pursuant to this section shall document testing or vaccination in appropriate records in accordance with applicable

privacy laws and submit data and information related thereto to the Department in a manner and format set forth in such determination.

(3) The Commissioner shall issue findings regarding the necessity of testing requirements at the time such requirements are announced.

(b) Enforcement and Penalties

(1) All local health officers shall take such steps as may be necessary to assist with the enforcement of the provisions of this section in accordance with the Public Health Law and this Title.

(2) A violation of any provision of this section is subject to all civil and criminal penalties as provided for by law. Entities that violate this section are subject to a maximum fine of \$1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the section shall constitute a separate violation under this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new section 2.9 and 2.60 is sections 201, 206, and 225 of the Public Health Law (PHL). Subdivision (c) of section 201 of the PHL requires the Department to supervise the reporting and control of disease. Subdivision (d) of section 206 of the PHL requires the Commissioner to investigate the causes of diseases and epidemics. Section 225 of the Public Health Law (PHL) authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health (“Department”) to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are substantially similar to a common cold to severe pneumonia requiring medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults, those who have serious underlying medical conditions and those who are unvaccinated.

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

In response to this significant public health threat, the Department of Health seeks to empower the Commissioner through this emergency regulation to issue determinations requiring the immediate implementation of heightened COVID-19 testing protocols for population segments that may be at increased risk of transmission due, in part, to their employment or residential circumstances. Regular COVID-19 testing enables the immediate identification of COVID-19-positive individuals, even if they are not symptomatic, so that they can isolate and prevent further transmission. Additionally, the reporting of positive COVID-19 test results to public health authorities facilitates the rapid initiation of contact tracing to ensure close contacts are quarantined, tested, and isolated as needed.

These regulations also permit the Department to require reporting of testing and positive reports among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and positive reports in schools, given the number of students that are currently unvaccinated. Children ages 5 through 11 years old were only recently authorized by the U.S. Food and Drug Administration (FDA) to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

COSTS:

Costs to Regulated Parties:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of approximately 251 million dollars. These amounts are believed to be sufficient to offset any

costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and positive reports for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Costs to Local and State Governments:

Costs to local health departments and the Department are expected to be minimal and related to monitoring compliance with these regulations, which can be incorporated into existing reporting and oversight activities and resources.

Paperwork:

This measure will require documentation related to the testing requirement, as well as documentation to opt-out of testing by providing documentation of full vaccination against COVID-19 in appropriate records. No additional paperwork requirements are anticipated for the school reporting requirement, which is expected to take the form of electronic submission to the Department.

Local Government Mandates:

These regulations impose an obligation on schools and school districts to report COVID-19 testing and positive report data for students, teaching staff, and any other employees or volunteers. Local government may also be impacted if subject to a Commissioner's testing determination.

Duplication:

There is no duplication of federal law.

Alternatives:

The alternative to the school reporting requirement would be to not require COVID-19 related reporting for schools and school districts. A lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing. In addition, the Department would lose the ability to communicate with the community about COVID transmission patterns at the individual school level.

The alternative to permitting the Commissioner to issue determinations to require testing in certain settings would limit the ability for the Department to monitor trends related to COVID-19 transmission in more vulnerable populations, making it more difficult to work with partners to implement prevention strategies. Regular testing also helps to isolate infected individuals more quickly, as well as identify any contacts that need to be quarantined to prevent additional spread of COVID-19.

Federal Standards:

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

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address the COVID-19 pandemic, small businesses and local governments have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Given the testing and reporting mechanisms that have already been established in many settings, it is not anticipated that this regulation will have a significant impact on or cost to these entities. With regard to the school COVID-19 reporting requirement, this regulation will apply to private schools, including parochial schools, some of which may be small businesses, as well as public schools operated by local governments.

Compliance Requirements:

These regulations provide that testing may be required under certain circumstances, and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner's testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. These regulations also set forth specific COVID-19 testing and positive report reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

Professional Services:

As testing is a requirement of this regulation, the types of professional services that will be needed to comply with this rule include diagnostic and screening testing services offered by clinical laboratories that hold the appropriate New York State approval to carry out testing. Because there will be flexibility in the types of tests that can be used to operationalize testing, the types of clinical laboratories that can be used for testing will depend on the type of testing being performed. If a laboratory-based nucleic acid amplification tests (e.g., PCR) will be used to meet the testing requirement, testing will need to be performed off-site by a fully permitted clinical laboratory. In this scenario, individuals are sent to a partner for testing, or an arrangement can be made to conduct sample collection on-site for testing off-site at the clinical laboratory. If rapid waived tests will be used to meet the testing requirement, testing can be performed by a Limited Service Laboratory (LSL). Due to the lower requirements that need to be met for waived testing, an LSL can be established for on-site testing of individuals (e.g., performing testing on-site at a school).

Compliance Costs:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of

approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and diagnoses for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Any adverse impacts related to school reporting requirements are expected to be minimal, as it carries forward reporting requirements that schools were required to implement last year. The Department, however, will work with schools to ensure they are aware of the new regulations and have the information necessary to comply.

With regard to minimizing adverse impacts related to the Commissioner's authority to issue test-related determinations, many settings have been increasingly implementing COVID-19 prevention strategies, with testing being one such example. Specifically, schools became

familiar with COVID-19 testing last year when the Department provided no cost antigen test cards as part of the microcluster testing initiative. Some schools have already implemented regular pooled surveillance testing to give communities confidence in the safety of their schools. Where the Commissioner issues a testing-related determination, the Department will work with the entities subject to such determination to provide the guidance necessary to comply.

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

Allegany County	Greene County	Schoharie County
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Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County		

Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

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

These regulations provide that testing may be required under certain circumstances and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner’s testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. Lastly, these regulations also set forth specific COVID-19 testing and positive test reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

Compliance Costs:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and diagnoses for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Any adverse impacts related to school reporting requirements are expected to be minimal, as it carries forward reporting requirements that schools were required to implement last year. The Department, however, will work with schools to ensure they are aware of the new regulations and have the information necessary to comply.

With regard to minimizing adverse impacts related to the Commissioner's authority to issue test-related determinations, many settings have been increasingly implementing COVID-19 prevention strategies, with testing being one such example. Specifically, schools became familiar with COVID-19 testing last year when the Department provided no cost antigen test cards as part of the microcluster testing initiative. Some schools have already implemented regular pooled surveillance testing to give communities confidence in the safety of their schools. Where the Commissioner issues a testing-related determination, the Department will work with the entities subject to such determination to provide the guidance necessary to comply.

Rural Area Participation:

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

JOB IMPACT STATEMENT

A Job Impact Statement is not being submitted with this rule because it is evident from the subject matter of the rule that it will have no impact on jobs and employment opportunities. The primary purposes of this rule is to carry forward COVID-19 related reporting and to permit the Commissioner to impose COVID-19 testing requirements in certain settings based on specified criteria.

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are substantially similar to a common cold to severe pneumonia requiring medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. The substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

In response to this significant public health threat, the Department of Health seeks to empower the Commissioner through this emergency regulation to issue determinations requiring the immediate implementation of heightened COVID-19 testing protocols for population segments that may be at increased risk of transmission due, in part, to their employment or residential circumstances. Regular COVID-19 testing enables the immediate identification of COVID-19-positive individuals, even if they are not symptomatic, so that they can isolate and prevent further transmission. Additionally, the reporting of positive COVID-19 test results to public health authorities facilitates the rapid initiation of contact tracing to ensure close contacts are quarantined, tested, and isolated as needed.

These regulations also permit the Department to require reporting of testing and diagnoses among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and diagnoses in schools, given the number of students that are currently unvaccinated. Children ages 5 through 11 years old only recently were authorized by the FDA to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 NYCRR Sections 600.1 and 600.2.

Subdivision (d) is added to section 600.1 to articulate notice requirements for nursing home establishment applications, as required by new *Subdivision 2-b* of Article 2801-a of the Public Health Law. The State Long-Term Care Ombudsman and residents, staff, and other parties affiliated with an existing nursing home, will be notified once a nursing home establishment application has been acknowledged by the Department and also, when a nursing home establishment application is placed on the Establishment and Project Review Committee agenda of the Public Health and Health Planning Council, for consideration.

Paragraph (2) of subdivision (b) of section 600.2 is amended to make the “character, competence, and standing in the community” review standard comparable for all applicants; and to include a limited liability company as an acceptable legal entity applicant, whose members are subject to the “character, competence, and standing in the community” review.

Paragraph (4) of subdivision (b) of section 600.2 is amended to include additional titles of applicant individuals, it removes a reference to outdated reporting requirements that no longer appear in statute, it clarifies establishment application review criteria, and defines the terms ‘recurrent’ and ‘prompt correction’ related to violations at article 28 facilities.

Paragraph (5) is added to subdivision (b) of section 600.2 to incorporate additional information the Public Health and Health Planning Council is required to consider when making a determination about a “consistently high level of care” rendered at a nursing home. This required information is found in the new *Subdivision 3-b* of Article 2801-a of the Public Health Law. In addition, the proposed regulation clearly sets forth five (5) occurrences that automatically render a determination that a consistently high level of care is not found, including determining the percentage of nursing homes in an applicant individual’s portfolio with a CMS star rating of two stars or less. And finally, it also includes the amendments made to paragraph (4) of subdivision (b) of section 600.2, which applies to all article 28 facilities, generally.

Altogether, the proposed regulation in paragraph (5) of subdivision (b) of section 600.2 responds to legislative actions and recommendations and sets forth uniform, transparent, and outcome-based standards to determine when a “consistently high level of care” has been delivered by applicant operators in the nursing homes that they own or have owned over the last seven years.

Together the proposed regulations in Sections 600.1 and 600.2 of Title 10 NYCRR, strengthen the establishment application review process for all article 28 facilities, generally and nursing homes, specifically. They also provide the transparency and clarity necessary to determine when a nursing home establishment application (includes changes of ownership and transfers of ownership applications) will be considered by the Establishment and Project Review Committee of the Public Health and Health Planning Council.

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, Sections 600.1 and 600.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

New subdivision (d) is added to section 600.1 to read as follows:

(d) Notice about an application for establishment shall be administered in the following manner:

(1) Long-term care ombudsman (LTCO)

(i) Once an application for establishment of a nursing home has been acknowledged by the Department, the Department shall notify the office of the LTCO of such application for establishment, by regular mail or email, within thirty days of acknowledgement of an application for establishment.

(ii) Once an application for establishment of a nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, the Department shall notify the office of the LTCO by regular mail or email.

(2) Residents, staff, and others

(i) Once an application for establishment of an existing nursing home has been acknowledged by the Department, the current operator of the facility and the applicant, shall notify the residents and their designated

representatives and the staff, including their union representatives, if applicable, of such application for establishment. Notification shall be completed by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives, within thirty days of the Department's acknowledgement of an application for establishment.

(a) The notification shall include the pending change of ownership, as well as the legal entity and individual name(s) of the proposed buyer; the application number; instruction on how to submit comments about the application; and a link for the general public to view the application using the New York State Electronic Certificate-of-Need (NYSE-CON) system where applications are submitted.

(ii) Once an application for establishment of an existing nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, within twenty-four (24) hours, the current operator of the facility and the applicant shall notify the residents and their designated representatives and the staff, including their union representatives, if applicable by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives.

(a) The notification shall include the date, location(s), and time of the meeting of the committee designated by the public health and health planning council.

Paragraph (2) of subdivision (b) of section 600.2 is amended to read as follows:

(2) (i) If a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(ii) if a proprietary business, that the owner, or all the partners, if a partnership, are persons of good moral character [who are competent] with the experience, competence and standing as to give reasonable assurance of their ability to operate the business so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(iii) if a business corporation, that the members of the board of directors, the officers and the stockholders of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(iv) if a limited liability company, that the members, managers, and officers of the company, are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the company so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

Paragraph (4) of subdivision (b) of section 600.2 is amended to read as follows:

(4) that, with respect to an applicant who is already or within the past 10 years, [has] been an incorporator, director, sponsor, stockholder, member, controlling person, principal stockholder, principal member, or operator of any facility as specified in paragraph (b) of subdivision (3) of *section 2801-a of the Public Health Law*, a substantially consistent high level of care has been rendered in each such facility [with which] the applicant is or has been affiliated [during the past 10 years or during the period of affiliation, as appropriate]. [In reaching this determination, the Public Health Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter, periodic medical review/independent professional review (PMR/IPR) findings, routine and patient abuse complaint investigation results, and other available information. The Public Health Council's determination that a substantially consistent high level of care has been rendered shall be made after reviewing the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility

operation, and the remedial action, if any, taken after the violation was discovered.]

(i) In reaching this determination, the Public Health and Health Planning Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results; and other available information.

(ii) The Public Health and Health Planning Council's determination that a substantially consistent high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered.

(a) In [reviewing] evaluating the gravity of the violation, the Public Health and Health Planning Council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In [reviewing] evaluating the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, the Public Health and Health Planning Council shall consider whether a reasonably prudent individual of the

applicant/operator should have been aware of the conditions which resulted in the violation and was notified about the conditions which resulted in the violation and whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In [reviewing] evaluating any remedial action taken, the Public Health and Health Planning Council shall consider whether the applicant/operator investigated the circumstances surrounding the violation, and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(iii) When violations were found which either threatened to directly affect patient/resident health, safety or welfare, or resulted in direct, significant harm to the health, safety or welfare of patients/residents, there shall not be a determination of a substantially consistent high level of care if the violations [reoccurred] were recurrent or were not promptly corrected.

(a) A violation is recurrent if it has the same root cause as a violation previously cited within the last ten (10) years.

(b) A violation is not promptly corrected if a plan of correction has not been submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

New Paragraph (5) of subdivision (b) of section 600.2 is added to read as follows:

(5) that, with respect to an application to incorporate or establish a nursing home, an applicant who is already or within the past 7 years, been an incorporator, director, sponsor, stockholder, or member, has held a controlling interest or has been a controlling person, principal stockholder or principal member, or operator of a nursing home as specified in paragraph (b) of subdivision (3-b) of *section 2801-a of the Public Health Law*, has demonstrated satisfactory character, competence and standing in the community and a consistently high level of care has been rendered in each such nursing home that the applicant is or has been affiliated.

(i) In reaching this determination, the Public Health and Health Planning Council shall consider, at a minimum, the following:

(a) findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results;

(b) any instance of a facility affiliated with the applicant/operator earning a two-star rating or less by the federal centers for Medicare and Medicaid Services (CMS) (or a comparable rating under a successor CMS rating system); provided that a further consideration and mitigating factor in determining whether such star rating reflects a consistently high level of care is where an

applicant's ownership interest in the star rated facility commenced within the prior five years;

(c) any instance where there have been violations of the state or federal nursing home code, or other applicable rules and regulations, that threatened to directly affect the health, safety or welfare of any patient or resident, including but not limited to a finding of immediate jeopardy, or actual harm, and were recurrent or were not promptly corrected, including but not limited to repeat deficiencies for the same or similar violations over a three year period or during the entire duration of ownership if less than three years, or any facility which has been in receivership;

(d) any instance where a facility has closed or has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(e) any instance where a health care related facility, agency, or program was the subject of a decertification action or licensure revocation;

(f) any involuntary termination from the Medicare or Medicaid program; and

(g) any instance of a nursing home being designated a Special Focus Facility or Special Focus Facility Candidate.

The applicant shall be provided with the opportunity to submit an explanation and other supporting documentation regarding any of the

aforementioned occurrences which shall be considered by the Public Health and Health Planning Council prior to reaching a determination.

(ii) The Public Health and Health Planning Council's determination that a consistently high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: (i) the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered and (ii) the percentage of nursing homes in a portfolio with a two-star or less rating.

(a) In evaluating the gravity of the violation, the Public Health and Health Planning Council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In evaluating the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, the Public Health and Health Planning Council shall consider whether a reasonably prudent individual of the applicant/operator should have been aware of the conditions which resulted in the violation and whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In evaluating any remedial action taken, the Public Health and Health Planning Council shall consider whether the

applicant/operator investigated the circumstances surrounding the violation, and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(d) In evaluating instances of a facility affiliated with the applicant/operator earning a two-star or less rating, the Public Health and Health Planning Council shall determine the percentage of nursing homes in the portfolio, that each individual of the applicant/operator has held an ownership interest for forty-eight (48) months or more and has earned a CMS star rating of two-stars or less.

(iii) When any of the following has occurred in the prior five years, there shall not be a determination of a consistently high level of care:

(a) Closure of a facility or a facility has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(b) A health care related facility, agency, or program was the subject of a decertification action or licensure revocation.

(c) Involuntary termination of a health care related facility, agency, or program from the Medicare or Medicaid program.

(d) Violations found, which either threatened to directly affect patient/resident health, safety or welfare, or resulted in direct, significant harm to the health, safety or welfare of

patients/residents, and were recurrent or were not promptly corrected.

(1) A violation is recurrent if it has the same root cause as a violation previously cited within the last seven (7) years.

(2) A violation is not promptly corrected if a plan of correction has not been submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

(iv) When any individual of the applicant/operator has greater than 40% of the nursing homes in their portfolio with a CMS star rating of two stars or less and has held an ownership interest in such nursing home for forty-eight (48) months or more, there shall not be a determination of a consistently high level of care; unless the portfolio contains fewer than five (5) facilities, then the Public Health and Health Planning Council shall make a determination on a case-by-case basis, using the criteria set forth in subparagraph (ii) of this paragraph.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, including the establishment or incorporation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 2801-a is to provide a deliberate and reasonable application process for the establishment or incorporation of health care facilities in New York. The purpose of the establishment application process is to codify an application review process that includes an assessment of character and competence, quality of care metrics, financial feasibility, and other relevant factors, for the benefit of those who seek health care services at State-regulated facilities.

Needs and Benefits:

Rulemaking was necessitated by revisions to Public Health Law section 2801-a via Chapter 102 and 141 of the Laws of 2021. Regulations are being amended to codify the procedure for the notification to the Long-term care ombudsman (LTCO), Residents, staff, and others of an application for the establishment of a nursing home operator. Notification will occur when an application has been received and acknowledged by the State Department of Health (Department) and again when the application has been

scheduled for consideration by a committee designated by the Public Health and Health Planning Council. Notification to those who may be impacted by a nursing home establishment application will allow a chance for public comment to be submitted for consideration by the Public Health and Health Planning Council (PHHPC) before PHHPC acts upon the application. Regulations are being amended to add language for limited liability corporations for character and competence, consistent with other business types. Regulations are being amended for character and competence to require PHHPC to consider, in some cases, specified information and evaluate the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered before determining that a substantially consistent or a consistently high level of care has been rendered. New language has been added to codify standards of review for nursing home character and competence, using certain quality of care metrics when evaluating and making a determination that a consistently high level of care has or has not been rendered. The changes reflect the intent of the law to provide increased transparency to those with an interest in the establishment of a nursing home operator and to codify the metrics used for evaluating character and competency of proposed operators.

Costs:

Costs to Regulated Parties:

Nominal costs may be incurred by nursing home providers to adhere to the notification requirements when the establishment of a new operator is proposed. This

cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for those to be notified. Labor, legal and consulting costs may be incurred by applicants who have previously filed an establishment application which is pending PHHPC consideration, should they feel the need to revise their application based on the rule changes.

Costs to State Government and the Department of Health:

The Office of the State Long-Term Care Ombudsman will incur costs related to the labor involved in reviewing notices filed on nursing home establishment applications and, thereafter, submitting a recommendation about the application to the Department. The Department will incur additional staff time required to re-review pending establishment applications and revise materials previously prepared during the review of such applications. Costs to the Department for notification requirements will be absorbed into current costs.

Costs to Local Governments:

There should be no local government costs unless a County operated facility is the subject of a new operator nursing home establishment application. Should this occur the County would incur the costs associated with the current operator outlined in the Cost to the Regulated Parties Section.

Local Government Mandates:

There are no local mandates in the amended regulations. However, County operated nursing homes will be required to meet the notification requirements under the amended regulations.

Paperwork:

Under the amended regulations, the current facility and the applicant for establishment will be required to prepare written notification to residents, staff and other impacted parties after a nursing home establishment application has been acknowledged by the Department. Distribution lists for notifications will be required. All other requirements are consistent with the paperwork currently required during the establishment application process.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The Department considered current standards used in character and competence review and alternative metrics, ratings, and data available. The Department also considered the impact of the use of absolute thresholds to be achieved for determining that a consistently high level of care has been rendered. The Department found that currently published ratings, such as the CMS Star rating system, take into account many of the alternative factors and data being considered. To avoid duplication and promote

transparency, the Department incorporated the CMS Star Ratings, surveillance findings and enforcements that are available to the public via the NYS Nursing Home Page of the Department's website, and CMS special focus facility designations available to the public – all information and data familiar to the health care industry, in general, and the nursing home industry, specifically, to make a determination about a consistently high level of care at facilities. This combination of information incorporates a cross section of factors relevant to assessing quality of care at nursing homes. The Department also included additional factors to supplement information that may not be apparent in the main evaluation criteria such as length of time a facility was owned, the overall number of facilities owned, revocation of a license, involuntary closure of a facility, and if severe deficiencies were recurrent or were not promptly corrected.

The amended regulations reflect a regulatory framework to evaluate the general quality of care rendered by a proposed operator historically and incentivizes improvement in quality as a condition to acquiring additional facilities in New York State.

Federal Standards:

The amended regulations do not exceed any minimum standards of the federal government.

Compliance Schedule:

The amended regulations will take effect upon a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments and small businesses will not be affected by this rule, unless they operate a nursing home and, in such cases, will be impacted by the new, statutory notification requirements defined in Section 600.1. The current number of local governments and identified-small businesses (employ less than 100 staff) that operate a nursing home are seventy-nine (79). The Department does not anticipate an increase in nursing home establishment applications by such applicants as a result of the proposed regulations.

Compliance Requirements:

Regulated parties are expected to be in compliance with the amended regulations upon adoption. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for individuals to be notified.

Economic and Technological Feasibility:

The Department has considered feasibility and the amended regulations are economically and technically feasible.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since the new requirements are statutory and apply to all nursing home establishment applicants, however, an effort was made to broaden the method used for notice distribution.

Small Business and Local Government Participations:

Organizations who represent the affected parties will have several opportunities for participation. There are several opportunities to provide public comment, both written and orally, at the Public Health and Health Planning Council (PHHPC). Initially, the regulations will be presented twice in a public PHHPC meeting; first, for discussion and second, for final adoption. In both instances, the public, including any affected party,

is invited to provide comments during the PHHPC Committee on Codes, Regulations and Legislation meeting.

Second, the affected parties have the opportunity via the 60-day State Register process to provide comments and suggestions to the regulation. If substantial and material changes are made as a result of the public comments, the amended regulation will be subject to an additional 45-day comment period.

Finally, before going to PHHPC, a call was held with industry representatives highlighting the proposed regulation and to answer any questions industry representatives had regarding the regulation and the process of regulation adoption.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<http://quickfacts.census.gov>).

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

The following eleven counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Monroe	Orange
Broome	Niagara	Saratoga
Dutchess	Oneida	Suffolk
Erie	Onondaga	

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

Nursing home operators and applicants for establishment of new operators are expected to be in compliance with the amended regulations upon adoption. There are several licensed nursing homes in rural areas. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council. There are no new reporting requirements, but record keeping will be required by nursing home operators and applicants for establishment of a new operator to ensure notification to required parties. No additional professional staff are expected to be needed as a result of the amended regulations.

Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment.

Minimizing Adverse Impact:

The amended regulations do not create any adverse effect on regulated parties.

Rural Area Impact:

Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

**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.

Further, the new notification requirements in Section 600.1 will only impact an employer over a limited period and can be performed by existing staff resources. The amended regulations for Section 600.2 should not cause a change to the workload of applicants for establishment of new nursing home operators and will not increase nor decrease jobs and employment opportunities.



Project # 212135-C
University Hospital SUNY Health Science Center

Program: Hospital
Purpose: Construction

County: Onondaga
Acknowledged: October 19, 2021

Executive Summary

Description

University Hospital SUNY Health Science Center d/b/a Upstate University Hospital (Upstate), a 438-bed hospital at 750 East Adams Street, Syracuse (Onondaga County), requests approval to create a new division of Upstate to provide inpatient behavioral health services to adolescents and children. The new division will be at 620 Madison Avenue, Syracuse, and will be named "Upstate Hospital at Hutchings". The applicant requests certification of 29 inpatient psychiatric beds, which includes an 18-bed inpatient adolescent behavioral health unit serving individuals age 12 to 17, and an 11-bed dual-diagnosis inpatient unit to meet the needs of children age 5 to 17 with a developmental disability and a psychiatric condition.

As part of this proposal, Richard H. Hutchings Psychiatric Center (Hutchings) will close its Children and Adolescent Inpatient Service Units (a total of 30 beds), and Upstate will take professional jurisdiction of Building 7 at Hutchings to operate the proposed new division. Renovations will be performed to bring the space into compliance with Article 28 standards.

This application has been developed with the cooperation and support of the New York State Office of Mental Health (OMH) and the New York State Office for People With Developmental Disabilities (OPWDD) to address major shortages in behavioral health services for children and adolescents in the Central New York (CNY) region and to address a need for an inpatient program specifically designed for children with dual diagnoses and co-morbid

destructive behavior. There is currently no inpatient program in New York that is specifically designed to address the clinical needs of children with dual diagnoses and co-morbid destructive behavior. Families seeking this specialized inpatient care currently need to go to out-of-state facilities.

The concurrent OMH application is tentatively scheduled for the February 16, 2022 Behavioral Health Service Advisory Council.

OPCHSM Recommendation

Contingent Approval

Need Summary

The new Upstate Hospital at Hutchings will allow children and adolescents, including those who are dually diagnosed, to receive appropriate levels of inpatient mental health care closer to home.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary

The total project cost of \$3,086,375 will be met with equity from accumulated funds. The projected incremental budget is as follows:

Table with 3 columns: Incremental Budget, Year One, Year Three. Rows include Revenues, Expenses, and Net Income.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health (Department). 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 documentation of approval from the Office of Mental Health, acceptable to the Department. [PMU]

Approval conditional upon:

1. This project must be completed by **August 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **July 1, 2022**, and construction must be completed by **May 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The 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 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

February 10, 2022

Need and Program Analysis

Background

This application has been developed in conjunction with the NYS Office of Mental Health (OMH) and the NYS Office for People with Developmental Disabilities (OPWDD) to address major shortages in behavioral health services for children and adolescents in the Central New York Region and to address a need for an inpatient program specifically designed for children with dual diagnoses (i.e., developmental disability and psychiatric condition) and co-morbid destructive behavior. The new division will be located on the campus of the Richard H. Hutchings Psychiatric Center (Hutchings). Hutchings, operated by OMH, is a comprehensive, community-based mental health facility providing an integrated network of inpatient and outpatient services for children and adults residing in the Central New York region. The 12-building campus is adjacent to Upstate SUNY Medical University.

Upstate is currently certified for 438 beds, including 32 psychiatric beds. Upon approval, the new division will have 29 inpatient psychiatric beds, for a total of 61 psychiatric beds across the two campuses. As mentioned previously, the new division will have two units, an 18-bed inpatient adolescent behavioral health unit serving individuals age 12 to 17, and an 11-bed dual-diagnosis inpatient unit to meet the needs of children age 5 to 17 with a developmental disability and a psychiatric condition.

Analysis

The following factors were considered by Upstate and their partners in the assessment of the need for the proposed pediatric inpatient psychiatric beds under the auspices of Upstate:

- The demographics within the geographic service area.
- The lack of mental health services within the geographic area for children and adolescents.
- The need for improved accessibility to mental health care for underserved pediatric residents of the geographic region with acute mental health conditions.
- The proposed closure of the Hutchings children and adolescent units, which was announced by OMH in 2013 as part of a larger reconfiguration of the New York State mental health system.
- The importance of ensuring that children and adolescents who need inpatient mental health services receive them in a timely manner in a dually-certified Article 31 and Article 28 facility with strong surveillance and quality controls.
- The importance of providing comprehensive health care services at Upstate.

The primary services area (PSA) is Upstate's 17-county geographic region, which includes Broome, Cayuga, Chenango, Cortland, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, St. Lawrence, Tioga, Tompkins, Otsego, Seneca, and Chemung Counties. It is expected that families from across New York will seek out the specialized services proposed in this CON, as implementation of this project will result in the only inpatient unit addressing the clinical needs of children with dual diagnoses and co-morbid destructive behavior in the state.

Need for Inpatient Psychiatric Services for Children and Adolescents

As indicated in the table below, there are currently only 44 approved and operational inpatient psychiatric beds for children and adolescents in the primary service area:

Facility Name	Type of Facility	Number of Beds	Note(s)
University Hospital SUNY	Article 28	8	Adolescent Unit
Cayuga Medical Center at Ithaca	Article 28	6	Adolescent Unit
Richard H. Hutchings Psychiatric Ctr	Article 31	30	Child & Adolescent Units
Total		44	

Another 12 child and adolescent inpatient psychiatric beds are projected to become operational in mid-2022 at Claxton-Hepburn Medical Center in Ogdensburg (St. Lawrence County), which received contingent approval from the Public Health and Health Planning Council at its December 9, 2020 meeting to create a 12-bed inpatient psychiatric unit to serve children and adolescents (CON 202029).

This proposal, which adds 29 certified beds to Upstate and decertifies 30 certified beds from Hutchings, and the approved Claxton-Hepburn Medical Center 12-bed unit will result in a total of 55 inpatient psychiatric beds for children and adolescents in the CNY Region.

Facility Name	Current # of Beds	Change in Beds	Future # of Beds
University Hospital SUNY	8	+29	37
Cayuga Medical Center at Ithaca	6	0	6
Richard H. Hutchings Psychiatric Center	30	-30	0
Claxton-Hepburn Medical Center	0	+12	12
Total	44	+11	55

Up until 2004, there was a total of 100 inpatient psychiatric beds for children and adolescents in CNY. In 2004, a private 64-bed inpatient psychiatric treatment center for children and adolescents in Syracuse operated by Four Winds closed, reducing inpatient children and adolescent psychiatric bed availability in CNY to 36 beds. In fact, the Richard H. Hutchings Psychiatric Center was the only inpatient facility in Syracuse to provide inpatient children and adolescent services until early 2020 when Upstate opened an 8-bed adolescent unit.

However, as indicated in the 2017 Final Report on the Youth Mental Health Task Force, issued by a task force created in 2015 by Congressman John Katko (NY-24) and Assemblyman William B. Magnarelli (AD 129) to examine the mental health system for youth in CNY, Hutchings lacked contracts with major insurance carriers and many private health insurance companies would not pay for treatment at Hutchings, resulting in families sending children to facilities in Buffalo and Saratoga in New York and out-of-state to other facilities for services that would be covered by health insurance.

In 2016, 240 children and adolescents in need of psychiatric hospitalization came to Upstate. Of these, almost half (111) had be sent out of Onondaga County to find an available bed. Moreover, children and adolescents can be held for days in Comprehensive Psychiatric Emergency Programs (CPEPs), emergency departments, or in pediatric inpatient beds while waiting for an inpatient psychiatric bed to become available somewhere in State or out-of-state.

In 2013, OMH announced plans to close the Hutchings children and adolescent units as part of a larger reconfiguration of the OMH Statewide mental health system. The loss of the 30 inpatient beds at Hutchings, without creating additional capacity elsewhere in the region, would result in a shortage of inpatient beds for mentally ill children and adolescents in CNY, affecting an estimated 1,000 patients with many of them having to be transported to other parts of the state, making uninterrupted care more difficult.

Through this proposal, Upstate seeks to preserve and enhance access to child and adolescent inpatient psychiatric beds that will help to address an identified shortage of inpatient mental health services for children and adolescents in the geographic region served by Upstate. In addition, as a regulated Article 28 entity, Upstate has a quality assurance improvement program in place with strong surveillance and quality controls to ensure that the children and adolescents who need inpatient psychiatric care will receive them in a timely manner.

Capacity and Utilization of Inpatient Child and Adolescent Psychiatric Beds

As indicated in the table below, 12 of the 17 counties within Upstate’s geographic region had a higher average daily census (ADC) rate per 100,000 children/adolescents during 2017-2018 (latest data available) compared to the Statewide rate.

Child Total Psychiatric Inpatient Bed Capacity by Provider County and ADC by Patient County of Residence				
Region/County	Total Inpatient Capacity¹	Total Bed Capacity per 100,000	Total Inpatient ADC^{2,3}	Total ADC per 100,000
Statewide	1,606	38.2	1,343.9	32.0
Central New York	183	44.2	172.5	41.7
Broome	14	34.9	14.1	35.2
Cayuga	42	270.7	6.5	42.0
Chenango	18	180.9	6.7	67.0
Cortland	0	0.0	6.8	65.8
Herkimer	0	0.0	2.9	21.9
Jefferson	0	0.0	12.7	46.3
Lewis	0	0.0	1.6	26.9
Madison	0	0.0	4.5	30.0
Oneida	46	92.3	15.5	31.0
Onondaga	23	22.4	33.1	32.3
Oswego	0	0.0	13.0	50.2
Otsego	0	0.0	4.0	35.8
St. Lawrence	28	115.9	17.1	70.9
Western New York	258	41.8	229.0	37.1
Chemung	13	70.2	8.2	44.3
Seneca	0	0.0	1.4	20.5
Tioga	0	0.0	3.6	34.7
Tompkins	6	30.1	6.8	34.0

Source: *County Capacity and Utilization Data Book, Calendar Years 2017-2018*, New York State Office of Mental Health

1. Includes General Hospital (Article 28), Private Psychiatric Hospital (Article 31), State Psychiatric Centers' Budgeted Capacity for the county of the providers and Residential Treatment Facility (RTF) children beds for the county of the providers.
2. Average Daily Census (ADC) covers General, Private Psychiatric, State Psychiatric Hospital and RTF.
3. ADC is shown for county of residence.

Within Upstate’s geographic region, nine counties (Cortland, Herkimer, Jefferson, Lewis, Madison, Oswego, Otsego, Seneca and Tioga) do not have any inpatient capacity for child and adolescent psychiatric services, three counties (Broome, Onondaga and Tompkins) have an ADC over their total inpatient capacity (as defined in the OMH table above) and five counties (Cayuga, Chenango, Oneida, St. Lawrence and Chemung) have a lower ADC than their total inpatient capacity. Overall, the ADC for CNY is 94.3% of the total inpatient capacity and the total ADC for Western New York is 88.8% of the total inpatient capacity, indicating a need to preserve the number of inpatient psychiatric beds for children and adolescents in Upstate’s geographic region.

Central New York Region Mental Health Profile

The following tables show information on the number of pediatric and adolescent Medicaid individuals who reside in the CNY region who received services in a mental health program (i.e., emergency room, inpatient program) between 2014 and 2019, compared to Statewide.

Emergency Department Services Over Time – Psychiatric Services (includes CPEP)							
Number of Pediatric and Adolescent Medicaid Individuals Served							
Region	2014	2015	2016	2017	2018	2019	CAGR 2014-2019
Statewide	28,206	29,939	31,647	34,029	34,947	34,544	3.44%
Central NY	3,599	3,940	4,417	4,355	4,526	4,688	4.50%

Source: NYS OMH Medicaid Population Characteristics and Service Utilization Trends, New York State Office of Mental Health

As demonstrated in the above table, the number of children/adolescent Medicaid enrollees Statewide seen in the emergency department (ED) increased between 2015 and 2018, with a slight decrease in 2019. As noted in the table above, the compound annual growth rate (CAGR) of the CNY ED utilization was 4.5%, which is higher than the Statewide CAGR rate of 3.44% for the same time period.

Inpatient Services Over Time – Psychiatric Inpatient							
Number of Pediatric and Adolescent Medicaid Individuals Served							
Region	2014	2015	2016	2017	2018	2019	CAGR 2014-2019
Statewide	11,850	12,240	12,009	12,283	11,558	11,322	-0.76%
Central NY	1,009	1,161	1,246	1,304	1,286	1,276	3.99%

Source: NYS OMH Medicaid Population Characteristics and Service Utilization Trends, New York State Office of Mental Health

As demonstrated in the above table, the number of children/adolescent Medicaid enrollees Statewide who were admitted to an inpatient psychiatric program increased from 11,850 in 2014 to 12,283 in 2017, an increase of 3%. Since 2017, the number of children/adolescents admitted for inpatient services has been declining, resulting in a 4.5% decrease overall between 2014 and 2019 or a negative CAGR of -0.76%. The number of children/adolescent Medicaid enrollees residing in CNY who were admitted to an inpatient program increased from 1,009 in 2014 to 1,304 in 2017, an increase of 29%. Since 2017, the number of children/adolescents admitted for inpatient services has been relatively flat, resulting in a 26.5% increase overall between 2014 and 2019 or a CAGR of 3.99%.

The increases in ED utilization and inpatient utilization of psychiatric services for children/ adolescents in the CNY region support the need for the children/adolescent inpatient psychiatric beds being requested by Upstate.

Need for Inpatient Program Specifically Designed for Children with Dual Diagnoses

As part of Upstate’s proposal, the Hospital will create an 11-bed dual-diagnosis inpatient unit to meet the needs of children age 5 to 17 with a developmental disability and psychiatric condition. There is currently no inpatient program in New York that is specifically designed to address the clinical needs of children with dual diagnoses and co-morbid destructive behavior. There are only nine specialized inpatient psychiatric programs (units) in the United States for children with autism and developmental disorders (see table below). There are only regional, short-term admission placements such as comprehensive psychiatric emergency programs (CPEPs), which are ineffective in meeting the needs of this population. Therefore, patients needing these specialized services must seek out-of-state placements, travelling anywhere from five to 11 hours by car to seek these specialized services. Such distances make it difficult and sometimes impossible for parents to visit, provide the needed family support and participate in the treatment process. Additionally, there is typically a wait for a placement to become available in one of these nine specialized programs and patients remain in CPEP placement for days, instead of hours, or have to be admitted to acute inpatient beds while they await placement. This delays treatment when a patient is in crisis.

Specialized Inpatient Psychiatric Programs for Children with Autism and Developmental Disorders

Facility Name	City/State	# of Inpatient Units	Miles from Syracuse	Hours from Syracuse
Streamwood Behavioral Healthcare	Streamwood, IL	1	713.4	11
Spring Harbor Hospital	Westbrook, ME	1	410.2	6
Seacoast Mental Health Center	Portsmouth, NH	2	360.1	5.5
Bradley Hospital	East Providence, RI	2	308.7	5
Kennedy Krieger Institute	Baltimore, MD	2	332.4	5
UPMC Western Psychiatric Hospital	Pittsburgh, PA	1	361.0	5.5

Source: Siegel M, Doyle K, Chemelski B, Payne D, Ellsworth B, Harmon J, Robbins D, Milligan B, Lubetsky M.

Specialized inpatient psychiatry units for children with autism and developmental disorders: a United States survey. *J Autism Dev Disord.* 2012 Sep;42 (9):1863-9.

Per the applicant, New York State historically places approximately 400 children in out-of-state psychiatric inpatient facilities per year. The vast majority of these placements (90.1%) are for children and adolescents who present with the problems that will be targeted in Upstate's specialized inpatient unit. As there are presently no programs to provide this level of care in New York State, this equates to approximately 360 children per year who are placed at an out-of-state facility for inpatient psychiatric or residential services.

Continuum of Care

The CNY region is in need of an expanded continuum of care for children and adolescent behavioral health services in order to allow youth to receive appropriate levels of care in their own communities and to reduce unnecessary psychiatric hospitalizations. In addition to this proposal to create two inpatient psychiatric units for children and adolescents, Upstate is in the process of developing a child and adolescent psychiatry intensive outpatient program (IOP) to provide an intensive intermediate level of psychiatric care for children and adolescents who are transitioning from hospitalization to outpatient treatment and those who are at-risk for hospitalization. Currently, Syracuse is the only community from Albany to Buffalo that does not provide this intermediate level of care.

Compliance with Applicable Codes, Rules, and Regulations

The medical staff will continue to ensure that the procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and expertise. The facility's admissions policy includes anti-discrimination provisions regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures are performed in accordance with all applicable federal and state codes, rules, and regulations.

Prevention Agenda

University Hospital SUNY Health Science Center states that the proposed project will advance local Prevention Agenda priorities by collaborating on goals related to well-being and mental and substance use disorder prevention.

Upstate is implementing interventions to support three goals of the 2019-2024 New York State Prevention Agenda which are (1) Promote well-being and prevent mental and substance use disorders; (2) Support and enhance children and adolescents' social-emotional development and relationships; and (3) Increase supports for children and youth with special health needs. These interventions include:

- Collaboration in developing the community health assessment and improvement plan
- Community engagement

Upstate engaged non-profits, hospitals, and local health departments in their Prevention Agenda efforts. They cite data indicators that are tracked to measure progress toward achieving local Prevention Agenda goals, including:

- New York State Department of Health County Health Assessment Indicators, Bureau of Vital Statistics, and Prevention Agenda Dashboard.
- New York State Planning and Research Cooperative System (SPARCS).
- Expanded Behavioral Risk Factor Surveillance System.
- County Health Rankings.
- Focus groups of community members and local organizations.

Conclusion

The CNY region is in need of an expanded continuum of care for children and adolescent behavioral health services in order to allow youth to receive appropriate levels of care in their own communities and to reduce unnecessary psychiatric hospitalizations. This proposal will enhance the continuum of care by allowing children and adolescents to receive appropriate levels of inpatient mental health care closer to home. 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, moveable equipment, and fees of \$3,086,375 are as follows:

Renovation & Demolition	\$1,848,386
Design Contingency	184,839
Construction Contingency	184,839
Architect/Engineering Fees	143,104
Other Fees	20,000
Movable Equipment	686,336
CON Application Fee	2,000
Additional CON Fees	<u>16,871</u>
Total Project Cost	<u>\$3,086,375</u>

The applicant will fund project costs with equity.

Incremental Operating Budget

The applicant has provided the first- and third-year operating budgets, in 2022 dollars:

	<u>Current Year</u>		<u>First Year</u>		<u>Third Year</u>	
	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>
<u>Revenues</u>						
Medicaid-FFS	\$891.26	\$1,364,526	\$1,344.79	\$7,183,875	\$1,344.79	\$7,183,875
Medicaid-MC	\$981.22	6,988,242	\$1,209.21	14,372,643	\$1,209.21	14,372,643
Medicare-FFS	\$1,043.84	3,069,936	\$1,043.84	3,069,936	\$1,043.84	3,069,936
Medicare-MC	\$1,198.86	2,885,644	\$1,198.86	2,885,644	\$1,198.86	2,885,644
Commercial-FFS	\$1,845.63	6,601,804	\$1,845.63	6,601,804	\$1,845.63	6,601,804
Commercial -MC		0	\$2,205.32	2,097,264	\$2,205.32	2,097,264
Private Pay	\$12.65	898	\$12.65	898	\$12.65	898
All Other	\$1,035.58	424,588	\$1,035.58	424,588	\$1,035.58	424,588
Other Operating*		130,851		407,353		407,353
Non- Operating**		0		<u>1,333,333</u>		<u>1,333,333</u>
Total Revenues		\$21,466,489		\$38,377,338		\$38,377,338

<u>Expenses</u>	<u>Current Year</u>		<u>First Year</u>		<u>Third Year</u>	
	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>	<u>Per Diem</u>	<u>Total</u>
Operating	\$1,137.86	\$20,548,527	\$1,303.47	\$35,956,217	\$1,303.47	\$35,956,217
Capital	<u>0</u>	<u>0</u>	<u>\$33.61</u>	<u>927,154</u>	<u>\$33.08</u>	<u>912,524</u>
Total Expenses	\$1,137.86	\$20,548,527	\$1,337.08	\$36,883,371	\$1,336.55	\$36,868,741
Net Income		<u>\$917,962</u>		<u>\$1,493,967</u>		<u>\$1,508,597</u>
Patient Days		18,059		27,585		27,585

* Represents estimated professional revenue that physicians would bill, collect, and remit to Upstate as part of the professional services agreement that will be put into place.

** Includes State Support via a 3-year VAP funding (public notice published 8-25-21 in NYS Register)

The following is noted concerning the submitted inpatient behavioral health services operating budget:

- Current year information reflects all of Upstate's inpatient psychiatric units (adult and adolescent).
- The projected utilization is based upon Upstate's experience and its knowledge of the service area, which is Central NY(CNY).
- The applicant reports that no rate history exists for the dual-diagnosis unit. The Medicaid rates for the dual-diagnosis unit were assumed to reflect a rate that allows the hospital to break even from operations and are based on ongoing discussions with OMH to establish such a rate. Professional (physician) revenue is based on specific billable CPT codes for physician services and the rates earned by the physicians for those services.
- Commercial revenue reflects projections of what Upstate expects to contract for with the primary commercial payors in the hospital's service area. The professional (physician) revenue is based on specific billable CPT codes for physician services and the rates earned by the physicians for those services.
- The breakeven utilization is projected at 26,497 patient days in the first year.
- The expense assumptions are as follows:
 - Staffing levels for the new units were developed by hospital management in concert with physician leadership;
 - Fringe benefit expense is based on Upstate's experience, at approximately 43% of salary expense;
 - Professional fees reflect physicians' services and were estimated based on the hospital's experience;
 - Supply costs, purchased services, and other direct expenses were based on the hospital's experience.

Utilization, broken down by payor source for the first and third year is summarized below:

<u>Payor</u>	<u>Current Year</u>		<u>Year One</u>		<u>Year Three</u>	
Medicaid FFS	1,531	8.48%	5,342	19.36%	5,342	19.36%
Medicaid MC	7,122	39.44%	11,886	43.08%	11,886	43.08%
Medicare FFS	2,941	16.28%	2,941	10.66%	2,941	10.66%
Medicare MC	2,407	13.33%	2,407	8.73%	2,407	8.73%
Commercial FFS	3,577	19.81%	3,577	12.97%	3,577	12.97%
Commercial -MC	0	0.00%	951	3.45%	951	3.45%
Private Pay	71	0.39%	71	0.26%	71	0.26%
All Other	<u>410</u>	<u>2.27%</u>	<u>410</u>	<u>1.49%</u>	<u>410</u>	<u>1.49%</u>
Total	18,059	100%	27,585	100%	27,585	100%

Transfer Jurisdiction

The applicant has submitted an executed agreement, Acknowledge of Intent to Transfer Jurisdiction of Building 7 from OMH to SUNY. SUNY intends to seek permission and approval of the SUNY Board of Trustees to accept and approve the transfer of jurisdiction. Ownership of Building 7 will remain with the People of the State of New York and will be under the professional jurisdiction of SUNY. SUNY will assume a part of the outstanding bond debt related to Building 7 not to exceed the fair market value as summarized in BFA Attachment B.

Capability and Feasibility

The total project cost of \$3,086,375 will be met with equity from accumulated funds. SUNY will assume a part of the outstanding bond debt related to Building 7 at the time of the transfer of jurisdiction, but in no event will SUNY's obligation exceed the fair market value (FMV) of the building. As of May 2021, the outstanding principal on the bond debt associated with Building 7 was \$8,925,957 at stated terms. The debt will continue to be financed with personal income tax (PIT) revenue bonds and be treated consistently with other debt services of Upstate. The transaction will not involve defeasing existing debt and re-issuing new debt. Review SUNY's 2020 certified financial statement and June 30, 2021 internal statement shows sufficient liquid resources to meet funding requirements (BFA Attachment A).

Working capital is estimated at \$6,144,790 based on two months of third-year expenses, which will be funded from operations. SUNY's 2020 certified financial statements (BFA Attachment A) show \$310.8M in working capital available to meet equity and working capital requirements. As of June 30, 2021, SUNY had \$239.6M in cash and a positive working capital ratio. The operating losses in 2020 and 2021 are attributable to increased staffing and supply costs and lower revenue due to decreases in the number of surgical cases, non-COVID-related inpatient admissions, and ambulatory care visits as a result of the COVID-19 pandemic. Upstate is working to address the loss from operations by monitoring expenses, reopening services that were curtailed during the pandemic, and investing resources and capital with a focus on return on investment (ROI).

The submitted budget indicates an incremental net income of \$1,493,967 and \$1,508,597 in years one and three, respectively. The budget appears reasonable.

Conclusion

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

Attachments

- BFA Attachment A State University of New York Upstate Medical University, 2019 - 2020 Certified Financial Statement and June 30, 2021 Internal Financial Statement
- BFA Attachment B Legal Agreement



Project # 212149-C
Hospice of Jefferson County/Palliative Care of Jefferson County

Program: Hospice
Purpose: Construction

County: Jefferson
Acknowledged: November 3, 2021

Executive Summary

Description

Hospice of Jefferson County, Inc., an existing not-for-profit, Article 40 hospice located at 1398 Gotham Street, Watertown, is seeking approval to certify four additional hospice residence beds and decertify two dually certified inpatient beds at the existing eight-bed hospice. Upon completion of the CON, the hospice will have 12 Residence-only beds and no Inpatient beds. Hospice of Jefferson County Inc. is approved to serve Jefferson and St. Lawrence counties. Currently, the facility averages three patients per day on the admission waiting list.

This addition will include enhanced acoustic material to be incorporated into the structure which will allow patients with dementia to receive care without disturbing other patients and their families. In addition, due to the COVID 19 pandemic, the HVAC system will be enhanced to improve air flow and add filtration and ionization. Two of the new rooms will have the capacity to be converted to negative pressure rooms to allow us to care for a hospice patient with an air borne infection.

OPCHSM Recommendation

Contingent Approval

Need Summary

The applicant currently manages a wait list to enter their facility. Adding four residence beds will allow the hospice to accommodate ongoing and sustained demand.

Program Summary

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance.

Financial Summary

Total project costs of \$2,207,196 will be met as follows: Equity of \$200,000 via accumulated funds, Fundraising of \$1,310,000, Government Grants of \$307,196 and other Grants of \$390,000. The applicant projects an excess or revenues of \$139,014 and \$167,319 during the first and third years. The projected incremental 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 contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 4006(9)(b) states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of thirty-hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of fundraising that is acceptable to the Department of Health. (BFA)
3. Submission of grant funding that is acceptable to the Department of Health. (BFA)
4. Submission of government grant funding that is acceptable to the Department of Health. (BFA)

Approval conditional upon:

1. This project must be completed by **July 15, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **April 15, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]

Council Action Date

February 10, 2022

Need and Program Analysis

Project Description

Hospice of Jefferson County Inc., an existing Article 40 hospice located at 1398 Gotham Street, Watertown, 13601, is seeking approval to certify four additional hospice residence beds and decertify two dually certified inpatient beds at the existing eight-bed hospice. The Hospice will use Inpatient Swing Beds at Samaritan Medical Center in Watertown on a as needed basis to cover any need for this service that arises. Upon completion of the CON, the hospice will have 12 Residence-only beds and no Inpatient beds. Hospice of Jefferson County Inc is approved to provide the following services in Jefferson and St. Lawrence counties:

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

Hospices can be certified to operate a residence unit of three to 16 beds. While operating eight residence and 2 inpatient beds, Hospice of Jefferson County's a daily census from September 30, 2018 through September 30, 2021 averaged 6.79 with a wait list averaging three patients per day.

Typically, patients near their end of life would prefer to remain at home or in a more home-like setting. However, often there is no available alternative to placement in a nursing facility. Thus, a patient is transferred to a higher than necessary level of care unit until suitable placement can be made which may not be appropriate if the patient's acuity level is high. The applicant's proposal will allow additional hospice patients to meet their life closure goals of remaining "at home" to die, avoiding nursing home or hospital admission.

The residence is staffed 24/7 with a compilation of LPN's, RN's, RN charge nurse(s), Hospice aides (HHA) and support services staff. In order to staff the additional beds, the applicant intends to add one home health aide per shift seven days per week. One full-time Registered Nurse will be added to cover 3PM – 11PM shifts and weekends.

The applicant intends to incorporate enhanced acoustic material into the structure of the four new rooms to allow for the care of patients with dementia behaviors without disturbing other patients and their families. The applicant intends for two of the new rooms to be able to convert to negative pressure rooms to allow for the care of patients with airborne infections while improving the safety of staff, patients, and families. Additionally, in response to the COVID-19 pandemic, the residence's HVAC system will be enhanced to improve air flow and add filtration and ionization. Lastly, the applicant intends to add additional family and staff space as part of this project. These spaces include an additional family room, a meditation room, and a solarium.

Conclusion

Adding four residence beds will accommodate demand. Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance.

Financial Analysis

Total Project Cost and Financing

New Construction	\$1,519,600
Renovation and Demolition	77,000
Site Development	176,000
Design Contingency	168,000
Construction Contingency	84,000
Architect/Engineering Fees	174,000
CON Fee	2,000
Additional Processing Fee	<u>6,596</u>
Total Project Cost	\$2,207,196

The applicant's financing plan is as follows:

Equity	\$200,000
Fundraising	1,310,000
Government Grants	307,196
Grants	<u>390,000</u>
Total	\$2,207,196

Operating Budget

The applicant has submitted an incremental operating budget, in 2022 dollars, for the first and third years, summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>			
Medicare	\$394,994	\$227,247	\$239,854
Medicaid	273,979	129,897	137,092
Private Pay	26,425	153,501	162,004
Other	<u>348,575</u>	<u>0</u>	<u>0</u>
Total Revenues	\$1,043,973	\$510,645	\$538,950
<u>Expenses</u>			
Operating	\$843,817	\$306,478	\$306,478
Capital	<u>126,238</u>	<u>65,153</u>	<u>65,153</u>
Total Expenses	\$970,055	\$371,631	\$371,631
Excess Revenues	\$73,918	\$139,014	\$167,319
Utilization (Patient Days)	2,440	1,314	1,314

The following is noted with respect to the submitted budget:

- Utilization will be 100% Medicare.
- The applicant has indicated that when patients stay in their residence, they are paid separately for their routine hospice care and the associated room and board fee. Medicare pays for almost all of their patients' routine hospice care, but Medicare does not pay the associated room and board fee for those patients who stay in the residence. Approximately 55% of these patients pay their room and board fee privately. For the remaining 45% of patients, their room and board fee are paid by Medicaid or Medicare replacement policies.
- Expense and utilization assumptions are based on historical experience.

Capability and Feasibility

Total project costs of \$2,207,196 will be met as follows: Equity of \$200,000 via accumulated funds from hospice operations, Fundraising of \$1,310,000, Government Grants of \$307,000 and other Grants of \$390,000. BFA Attachment A is the September 30, 2019 and September 30, 2020 certified financial statements of Hospice of Jefferson County, Inc. The applicant has indicated that they have received \$410,000 in CARES funding.

The submitted budget indicates an excess of revenues over expenses of \$139,014 and \$167,319 during the first and third years, respectively. Revenues are based on current reimbursement methodologies for inpatient hospice beds. The submitted budget appears reasonable.

As shown on BFA Attachment A, the entity had an average positive working capital position and an average positive net asset position from the period October 1, 2018 through September 30, 2020.

Conclusion

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	September 30, 2019 and September 30, 2020 certified financial statements of Hospice of Jefferson County.
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**Project # 212113-C
North Shore University Hospital**

Program: Hospital
Purpose: Construction

County: Nassau
Acknowledged: October 21, 2021

Executive Summary

Description

North Shore University Hospital (NSUH), a 756-bed, voluntary not-for-profit, Article 28 acute care hospital at 300 Community Drive, Manhasset (Nassau County), seeks approval to fit out the 5th and 6th-floor core and shell space in the eight-story addition being constructed at the hospital's main campus and to certify 38 intensive care unit (ICU) beds.

This application amends and supersedes CON 172212, which included shell space to be reclassified as Article 28 space at a later time and approval of 18 ICU beds, which are included in the 38 net new ICU beds in this CON. The additional 20 ICU beds will be acquired through an intra-network transfer of 20 Medical/Surgical beds from Long Island Jewish Valley Stream (LIJVS) hospital. Northwell Healthcare, Inc. is the active parent and co-operator of both hospitals. Upon completion of this transfer, NSUH's will have 794 beds including 135 ICU beds.

The new building, known as the Advanced Surgical Pavilion (ASP), is being constructed to replace undersized and antiquated operating rooms and to renovate and expand post-surgical and critical care unit space. The proposed project will expand the capacity of the facility's surgical programs and related critical care services to meet volume demands and the increasingly complex needs of NSUH's patient population.

NSUH is a member of the Northwell Health Obligated Group.

OPCHSM Recommendation

Contingent approval

Need Summary

The addition of 38 ICU beds will address NSUH's existing needs and future growth. A modernized critical care infrastructure with expanded capacity will play an important role in ensuring access to advanced tertiary and quaternary services for patients in the region.

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 \$560,705,671 includes \$338,562,858 approved under CON 172212-C. The project cost will be met via equity of \$56,070,567 and the issuance of tax-exempt bonds for a 30-year term at 4% interest for the remaining \$504,635,104. The budget is as follows:

	<u>Incremental Budget</u>	
	<u>Year One</u>	<u>Year Three</u>
Revenues	\$83,323,800	\$166,647,700
Expenses	<u>111,194,000</u>	<u>163,647,700</u>
Net Income	(\$27,870,200)	\$3,645,300

	<u>Incremental Enterprise Budget</u>	
	<u>Year One</u>	<u>Year Three</u>
Revenues	\$1,811,945,400	\$1,895,269,300
Expenses	<u>1,719,011,600</u>	<u>1,770,820,000</u>
Net Income	\$92,933,800	\$124,449,300

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. Included with the submission must be a sources and uses statement and debt amortization schedule, for both new and refinanced debt. [BFA]
3. Submission of acceptable responses to resolve four architectural and two electrical outstanding DD review comments that remain open in DrChecks. [DAS]

Approval conditional upon:

1. This project must be completed by **August 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must be completed by **May 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The 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 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

February 10, 2022

Need and Program Analysis

Background

The applicant reports over the last five years, the overall inpatient volume has increased. Trends in medical/surgical discharges have shown a near 10% increase. The construction of the ASP and the greater critical care capacity will ensure NSUH can meet the needs of its patient communities in the future. NSUH projects growth in the hospital's critical care average daily census by its planned program drivers. The hospital anticipates ongoing growth resultant from demographic shifts and ensuring access to advanced services requiring extensive post-operative care. They also anticipate a rising volume of patient transfers to its facility from both within and outside of Northwell's coordinated network of providers. The increased capacity in critical care, particularly with rooms built to modern standards, will also equip the hospital with the necessary space to withstand large-scale emergencies and disasters.

Staffing is expected to increase as a result of this construction/expansion project by 74.4 FTEs in Year One of the completed project and increase by 74.9 FTEs by Year Three of the completed project.

Analysis

The primary services area is Nassau County, and the secondary service area includes Suffolk and Queens Counties. The population of Nassau County in 2010 was 1,339,532 with 204,681 individuals (15.3%) who are 65 and over. This population group (65 and over) is estimated to grow to 301,494 by 2025 and represent 21.4% of the projected population of 1,410,875. According to Data USA, in 2019, 95.7% of the population of Nassau County has health coverage as follows:

Employer Plans	58.9%
Medicaid	10.4%
Medicare	13.7%
Non-Group Plans	12.4%
Military or VA	0.9%

20 of the 38 total ICU beds that are a part of this project will come from an intra-network transfer and conversion of medical/surgical beds from LIJVS. The charts below show the current and proposed beds at NSUH and LIJVS:

North Shore University Hospital Beds			
Bed Type	Current	Change	Proposed
AIDS	30		30
Bone Marrow Transplant	4		4
Coronary Care	15		15
Intensive Care	97	38	135
Maternity	73		73
Medical / Surgical	486		486
Neonatal Continuing Care	5		5
Neonatal Intensive Care	32		32
Neonatal Intermediate Care	14		14
Total	756	38	794

LIJ Valley Stream Hospital Beds			
Bed Type	Current	Change	Proposed
Coronary Care	8		8
Intensive Care	8		8
Pediatric	20		20
Medical / Surgical	248	-20	228
Total	284	-20	264

The historical utilization of NSUH and LIJVS beds is as depicted below:

North Shore: Inpatient Bed Utilization							
	Beds 2016-2018	2016	2017	2018	Beds 2019-2020	2019	2020
Medical/Surgical*	614	100.0%	97.9%	100.0%	632	100.0%	95.6%
Obstetric	73	80.8%	79.5%	82.2%	73	79.5%	60.3%
High-risk Neonates	51	47.1%	51.0%	43.1%	51	47.1%	43.1%
Total	738	95.3%	92.8%	95.4%	756	97.8%	88.8%

Source SPARCS

* For SPARCS utilization calculations, all bed types, except as broken out, are rolled into the Medical/Surgical category.

LIJ Valley Stream: Inpatient Bed Utilization						
	Beds	2016	2017	2018	2019	2020
Medical/Surgical*	264	47.7%	43.9%	46.2%	46.2%	45.8%
Pediatric	20	0%	0%	0%	0%	0%
Total	284	44.4%	40.8%	43.0%	43.0%	42.6%

Source SPARCS

* For SPARCS utilization calculations, all bed types, except as broken out, are rolled into the Medical/Surgical category.

NSUH anticipates a rising need for tertiary services and is pursuing ongoing physician recruitment and programmatic growth to meet the needs of its service area. They are the only major hospital in the Long Island region that provides advanced quaternary services, such as heart and liver transplants for adults. The hospital anticipates the demographics of its large service area will trend toward an older and sicker patient population. Case complexity is expected to increase with comorbidities, longer lengths of stay, and post-operative care across the care continuum. A modernized critical care infrastructure with expanded capacity will play an important role in ensuring access to advanced tertiary and quaternary services for patients in the region.

Even before the pandemic, NSUH was experiencing strong growth in ICU volume over the last several years.

Historical Trend of NSUH ICU Cases						
Discharges	2015	2016	2017	2018	2019	% Change
Total	1,951	1,776	2,357	2,627	3,391	73.8%

Source: NSUH Institutional Cost Reports 2015 - 2019; Prepared by the Office of Strategic Planning at Northwell Health

As a major tertiary and quaternary provider of advanced medical and surgical care in the Long Island region, NSUH, based on the trends and demographic shifts, also anticipates a rising volume of patient transfers to its facility from both within and outside of Northwell's coordinated network of providers. Taken as a whole, NSUH projects ICU average daily census to increase by over 25% by 2025, after completion of the CON.

Projected NSUH ICU Average Daily Census			
	2021	2023	2025
ICU	95	112	119

Compliance with Applicable Codes, Rules, and Regulations

The medical staff will continue to ensure that the procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and expertise. The facility's admissions policy includes anti-discrimination provisions regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures are performed in accordance with all applicable federal and state codes, rules, and regulations.

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, 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

NSUH is implementing interventions to support two goals of the 2019-2024 New York State Prevention Agenda:

1. Early detection/screening
2. Educational workshops and seminars

The application states that NSUH engaged Long Island Health Collaborative, a partnership of hospitals, county health departments, academic institutions, non-profits, and the business sector in their Prevention Agenda efforts. NSUH cites data indicators that it tracks to measure progress toward achieving local Prevention Agenda goals, including:

- Decreasing disparities
- Services provided

In 2019 the applicant spent \$7,821,203 on community health improvement services, representing 0.27% of total operating expenses.

Conclusion

Approval of this project will result in a modern state-of-the-art facility, with increased capacity to meet the needs of an aging and increasingly complex patient population. 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

Background

Total project costs of \$560,705,671 includes the \$338,562,858 approved under CON 172212-C. The project cost will be met via equity of \$56,070,567 and the issuance of tax-exempt bonds for a 30-year term at 4% interest for the remaining \$504,635,104. Citigroup Global Markets Inc. has provided a letter of interest to underwrite the bonds to be issued through the Dormitory Authority of the State of New York (DASNY) using tax-exempt financing. BFA Attachment A is the Financial Statement of Northwell Health, Inc., showing the availability of sufficient resources to meet the equity requirements. The projected first-year loss is due to the interest and depreciation expenses associated with the project. Without these expenses, the facility would show positive operating income in the first year. The third-year contribution margin was sufficient to absorb all incremental costs leading to a positive net income,

The CFO of Northwell Health, Inc. has submitted a letter attesting that Northwell Healthcare, Inc. is committed to supporting the project to serve the needs of the community and will provide financial support to absorb budgeted operating losses in Year One at NSUH related to this project.

Total Project Cost and Financing

The total project cost of \$560,705,671 includes the \$338,562,858 approved under CON 172212, detailed as follows:

	Prior Approved Total Project Costs via CON 172212	Amended Total Project Costs
New Construction	\$201,969,788	\$332,810,835
Renovation & Demolition	12,200,000	12,527,279
Temporary Utilities	50,000	600,000
Asbestos Abatement/ Removal	400,000	595,000
Design Contingency	13,509,677	3,015,212
Construction Contingency	8,686,207	18,445,352
Planning Consultant Fees	150,000	3,352,600
Architect/Engineering Fees	13,050,000	22,312,477
Construction Manager Fees	600,000	2,362,127
Other Fees	2,263,798	9,887,863
Movable Equipment	70,750,000	125,483,061
Financing Costs	16,324,617	26,244,863
Application Fee	2,000	2,000
Processing Fee	<u>1,550,527</u>	<u>3,067,002*</u>
Total Project Cost	\$338,562,858	\$560,705,671

**Due to increased project costs, the application processing fee has increased to \$3,067,002. The applicant paid \$1,550,527 based on the previously approved total project cost under CON 172212. Therefore, the facility shall pay the Department the remaining application processing fee balance of \$1,516,475.*

The applicant's financing plan appears as follows:

Equity	\$56,070,567
Tax-Exempt Bonds (30-year term, 4% interest)	<u>\$504,635,104</u>
Total	\$560,705,671

Citigroup Global Markets Inc. has provided a letter of interest to underwrite the bonds to be issued through DASNY using tax-exempt financing. NSUH is a member of the Northwell Health Obligated Group.

Incremental Operating Budget

The applicant has submitted an incremental operating budget, in 2022 dollars, for the first and third years, summarized as follows:

	<u>First Year</u>		<u>Third Year</u>	
	<u>Per Discharge</u>	<u>Total</u>	<u>Per Discharge</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid -FFS	\$96,691	\$7,445,200	\$96,691	\$14,890,400
Medicaid-MC	\$70,843	11,901,600	\$70,843	23,803,200
Medicare -FFS	\$8,916	4,431,400	\$8,925	8,862,900
Medicare-MC	\$69,981	19,104,800	\$70,109	38,209,500
Commercial -MC	\$109,630	37,383,800	\$109,630	74,767,700
All Other	\$45,627	<u>3,057,000</u>	45,289	<u>6,114,000</u>
Total		\$83,323,800		\$166,647,700

<u>Expenses</u>	<u>First Year</u>		<u>Third Year</u>	
	<u>Per Discharge</u>	<u>Total</u>	<u>Per Discharge</u>	<u>Total</u>
Operating	\$38,637	\$54,981,100	\$37,821	\$107,600,000
Capital	<u>\$39,503</u>	<u>56,212,900</u>	<u>\$19,473</u>	<u>55,402,400</u>
Total Expenses	\$78,140	\$111,194,000	\$57,294	\$163,002,400
Net Income (Loss)		<u>(\$27,870,200)</u>		<u>\$3,645,300</u>
Discharges		1,423		2,845

Incremental utilization by payor source for the first and third year is summarized below:

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Discharges</u>	<u>%</u>	<u>Discharges</u>	<u>%</u>
Medicaid FFS	77	5.41%	154	5.41%
Medicaid MC	168	11.81%	336	11.81%
Medicare FFS	497	34.93%	993	34.90%
Medicare MC	273	19.18%	545	19.16%
Commercial MC	341	23.96%	682	23.97%
All Other	<u>67</u>	<u>4.71%</u>	<u>135</u>	<u>4.75%</u>
Total	1423	100%	2845	100%

The breakeven utilization is projected at 2,782 discharges in the third year.

Northwell Health's internal cost accounting system was used to generate the revenue, expense, utilization, and payor rate assumptions based upon the inpatient DRGs applicable to the program. The CFO of Northwell Health, Inc. has submitted a letter stating that Northwell Healthcare, Inc. is committed to supporting the project to serve the needs of the community and will provide financial support to absorb the budgeted losses.

Capability and Feasibility

The total project cost is \$560,705,671 includes \$338,562,858 previously approved under CON 172212. The project cost will be met with \$56,070,567 in accumulated funds and the remaining \$504,635,104 will be funded via a tax-exempt DASNY bond issuance with a 30-year term at 4% interest. Citigroup has provided a letter of interest to underwrite the bond financing.

Working capital requirements are estimated at \$27,167,067 based on two months of third-year expenses and will be funded from operations. A review of BFA Attachment A shows Northwell Health's 2019-2020 Consolidated Certified Financial Statements and their internal financial statements as of September 30, 2021, indicates the availability of sufficient resources to meet the equity contribution for the project cost and any working capital needs.

The submitted incremental budget indicates a loss in the first year of \$27,870,200 and a third year profit of \$3,645,300. The projected loss is due to the interest and depreciation expenses associated with this project. Without these expenses, the facility would show positive operating income. The CFO of Northwell Health, Inc. has provided a letter stating Northwell Health Care, Inc (NHCI) will provide financial support to absorb the budgeted operational losses to this program. NSUH's aim for the project is to replace existing outdated facilities, accommodate current surgical and critical care volume, and allow for future growth responsive to a patient population with increasingly complex healthcare needs and comorbidities. Revenue and payor rate assumptions are based upon the current experience of the existing volume and payor mix at North Shore University Hospital. The budget is reasonable.

BFA Attachment A shows Northwell Health maintained average positive working capital and net asset positions and achieved an average positive net operating income of \$740,820,000 for the 2019-2020 period and a positive net income of \$686,008,000 for the period ending September 30, 2021.

Conclusion

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

Attachments

BFA Attachment A	2019-2020 Consolidated Certified and 1/1/2021- 9/30/2021 Internal Financial Summary of Northwell Health, Inc.
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Project # 201004-B
Pelham Parkway SC, LLC d/b/a
Pelham Parkway Surgery Center

Program: Diagnostic and Treatment Center County: Bronx
Purpose: Establishment and Construction Acknowledged: February 11, 2020

Executive Summary

Description

Pelham Parkway SC, LLC d/b/a Pelham Parkway Surgery Center, an existing New York State limited liability company, requests approval to establish and construct a multi-specialty Article 28 Ambulatory Surgery Center (ASC) to be located on the first floor of 1000 Pelham Parkway South, Bronx (Bronx County). The surgical specialties to be provided will include Orthopedic, Ophthalmology, Podiatry, and Vascular Access Surgery. Other physicians have expressed an interest in providing gastroenterology surgery services at the center, but no commitments have yet been made. The proposed center will be housed in a five-story, multi-use medical building that contains the following entities: Morningside Nursing & Rehabilitation Center, a 314 bed Article 28 Residential Health Care Facility (RHCF); Morningside Assisted Living Program (ALP), a 40-bed ALP; and Morningside Dialysis Center, LLC d/b/a Cassena Care Dialysis at Morningside, a 21-station Article 28 chronic renal dialysis center. Upon completion of renovations, the ASC will have four operating rooms and two GI procedure rooms. The current space is unoccupied and was formerly used for RHCF administrative and executive offices that have been relocated to other areas including off-site locations.

The proposed operator of the ASC is as follows:

Table with 2 columns: Member, %
Proposed Operator: Pelham Parkway SC, LLC
Members: Pasquale DeBenedictis (33.34%), Alex Solovey (33.33%), Solomon Rutenberg (33.33%)

All three proposed members will be managing members of the ASC and are currently operating entity members of the RHCF, ALP and Dialysis Center housed in the building.

Samar Syed Razza, MD, who is Board Certified in Internal Medicine, will be the Medical Director of the Center. The applicant will enter into a Transfer and Affiliation Agreement with Bronx Lebanon Hospital Center, located 2 miles (4 minutes travel time) from the proposed ASC, for backup and emergency care.

OPCHSM Recommendation

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

Need Summary

The applicant projects 1,823 procedures in Year One and 2,202 in Year Three, with Medicaid at 6.0% 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 costs of \$8,393,727 will be met with \$1,259,059 in equity from the proposed members and a bank loan for \$7,134,668 at 6.0% interest with a ten-year term and an amortization period of 20 years. Peapack-Gladstone Bank has provided a letter of interest for the financing at the stated terms. The budget is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$5,540,376	\$6,908,327
Expenses	<u>4,501,294</u>	<u>5,898,718</u>
Net Income	\$1,039,082	\$1,009,609

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the centers commitment to meet the health care needs of the community, including the provision of services to those in need, regardless of ability to pay. The statement shall also include a commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. (RNR)
4. 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)
5. Submission of an executed Licensing Agreement, acceptable to the Department of Health. (BFA)
6. Submission of an executed loan commitment, acceptable to the Department of Health. (BFA)
7. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01.
8. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01.
9. Submission of a photocopy of the applicant's executed Certificate of Assumed Name, acceptable to the Department. (CSL)
10. Submission of fully executed sublease, acceptable to the Department. (CSL)
11. Submission of a photocopy of an executed amendment of the applicant's articles of organization, acceptable to the Department. (CSL)
12. Submission of a photocopy of the applicant's fully executed operating agreement, acceptable to the Department. (CSL)
13. Submission of a list of members and managers of the applicant's second-level member, acceptable to the Department. (CSL)
14. Submission of a photocopy of an executed amendment of the applicant's second-level member's articles or organization, acceptable to the Department. (CSL)

15. Submission of a photocopy of the applicant's second-level member's fully executed operating agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **July 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **April 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. (RNR)
4. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospitals/docs/hcs_access_forms_new_clinics.pdf. 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

February 10, 2022

Need and Program Analysis

Program Description

Pelham Parkway SC, LLC d/b/a/ Pelham Parkway Surgery Center seeks approval for the establishment and construction of a multi-specialty ambulatory surgery center to be located at 1000 Pelham Parkway South in Bronx (Bronx County). The proposed center will be housed in a multi-use building which contains a skilled nursing facility, an assisted living program, and a dialysis center..

Proposed Operator	Pelham Parkway SC, LLC
Doing Business As	Pelham Parkway Surgery Center
Site Address	1000 Pelham Parkway South Bronx, New York 10461 (Bronx County)
Surgical Specialties	Multi-Specialty, to initially include: Orthopedics Podiatry Vascular Access Ophthalmology
Operating Rooms	4
Procedure Rooms	2
Hours of Operation	Monday Friday 7:00 am to 6:00 pm through
Staffing (1st / 3rd Year)	14.3 FTEs / 24.3 FTEs
Medical Director	Syed Samar Raza, M.D.
Emergency, In-Patient & Back-up Support Services Agreement and Distance	Bronx Lebanon Hospital 4.9 miles / 14 minutes
After-hours access	The patient will be provided with discharge instructions that included information on when to call their surgeon, primary care physician, or 911 when the surgery center is closed. The Center will also have an answering machine that will provide instructions for the patient to contact their surgeon, primary care physician, or 911.

The Center will initially provide orthopedic, ophthalmology, podiatry, and vascular access surgery services and expects to provide gastroenterology services in the near future.

Analysis

The service area consists of Bronx County. The population of Bronx County in 2010 was 1,385,108 with 464,959 individuals (33.6%) who are 45 and over, which are the primary population group utilizing ambulatory surgery services. Per PAD projection data, this population group (45 and over) is estimated to grow to 595,345 by 2025 and represent 38.0%% of the projected population of 1,567,988. According to Data USA, in 92.1% of the population of Bronx County has health coverage as follows:

Employer Plans	31.3%
Medicaid	42.3%
Medicare	6.9%
Non-Group Plans	11.0%
Military or VA	0.4%

The table below shows the number of patient visits for ambulatory surgery centers in Bronx County for 2018 through 2020. 2020 utilization was impacted by COVID 19.

Spec Type	Facility Name	Total Patient Visits		
		2018	2019	2020
Gastroenterology	Advanced Endoscopy Center	11,008	11,310	7,686
Multi	Ambulatory Surgery Center of Greater NY	8,905	8,836	4,939
Multi	Avicenna ASC, Inc	5,249	6,200	4,516
Multi	Downtown Bronx ASC ²	2,115	3,508	0
Multi	East Tremont Medical Center ^{1,2}	0	0	0
Multi	Empire State Ambulatory Surgery Center	3,827	5,633	5,062
Ophthalmology	Eye Surgery Center of NY ³	3,327	3,973	1,544
Gastroenterology	Mid-Bronx Endoscopy Center	4,514	6,363	4,721
Gastroenterology	New York GI Center	9,291	9,512	6,310
Multi	Triborough ASC (opened 12/24/20)	N/A	N/A	N/A
Total Visits		48,236	55,335	34,778

¹ No SPARCS data located for 2018 or 2019

² No SPARCS data located for 2020

³ 2020 data is for a partial year

The number of projected procedures is 1,823 in Year One and 2,202 in Year Three with Medicaid at 6.0% and Charity Care at 2.0% each year. These projections are based on the current practices of participating surgeons. Of the procedures moving to the new ASC, 21% are currently performed in a hospital, 36% are currently performed in another ASC and the remaining 43% are performed in an office-based setting. The table below shows the projected payor source utilization for first and third years.

Payor	Year One		Year Three	
	Volume	%	Volume	%
Commercial FFS	456	25.01%	507	23.02%
Commercial MC	328	17.99%	440	19.98%
Medicare MC	839	46.02%	1,013	46.00%
Medicaid MC	109	5.98%	132	6.00%
Private Pay	55	3.02%	66	3.00%
Charity Care	36	1.98%	44	2.00%
Total	1,823	100.00%	2,202	100.00%

The Center initially plans to obtain contracts with the following Medicaid Managed care plans: Health First, Affinity Health Plan, Age Well New York LLC, and Cigna. The Center will work collaboratively with local Federally Qualified Health Centers (FQHCs) such as: Urban Health, The Institute for Family Health, Acacia Health Network, Perry Avenue Family Medical Center and Doctors United within the service area to provide service to the under-insured in their service area. The Center has developed a financial assistance policy with a sliding fee scale to be utilized when the Center is operational.

Character and Competence

The proposed members and managers of Pelham Parkway SC, LLC is:

Name	Interest
Pasquale DeBenedictis	33.34%
Alex Solovey	33.33%
Soloman Rutenberg	33.33%
Total	100.0%

Pasquale DeBenedictis is a Managing Member and Chief Financial Officer of Cassena Care. He also operates multiple nursing homes and other health related facilities, including dialysis and adult homes. His job functions include the day-to-day financial concerns of the business, billing, employee resources, and compliance services. Mr. DeBenedictis discloses ownership interest in the following healthcare facilities:

<i>Barwell Nursing Home</i>	<i>11/2003-12/2017</i>
<i>East Neck Nursing and Rehabilitation Center</i>	<i>02/2005-present</i>
<i>JOPAL@ St. James</i>	<i>10/2010-05/2018</i>
<i>Petit Fleur Nursing Home</i>	<i>12/2012-05/2018</i>
<i>Workman's Circle Multicare Center</i>	<i>07/2013-present</i>
<i>Shoreview Nursing and Rehabilitation</i>	<i>06/2014-present</i>
<i>Morningside Acquisition I, LLC</i>	<i>07/2014-present</i>
<i>Peninsula Nursing and Rehabilitation Center</i>	<i>08/2014-present</i>
<i>Upper East Side Rehabilitation and Nursing Center</i>	<i>06/2015-present</i>
<i>Sea-Crest Nursing and Rehabilitation</i>	<i>07/2015-present</i>
<i>Fordham Nursing and Rehab</i>	<i>08/2016-present</i>
<i>Long Beach Nursing and Rehabilitation Center</i>	<i>08/2016-present</i>
<i>Workman's Circle Dialysis Center</i>	<i>08/2015-present</i>
<i>East Neck Dialysis Center</i>	<i>09/2015-present</i>
<i>Cassena Care Dialysis at Peninsula</i>	<i>11/2016-present</i>
<i>Morningside Dialysis Center</i>	<i>11/2016-present</i>
<i>Hillside Manor Certified Home Care Agency</i>	<i>10/2017-present</i>
<i>Sea-Crest Dialysis Center</i>	<i>09/2017-present</i>
<i>Downtown Brooklyn Nursing and Rehabilitation Center</i>	<i>Pending</i>
<i>Margaret Tietz Nursing and Rehabilitation Center</i>	<i>02/2019-present</i>
<u><i>Out-of-State</i></u>	
<i>Cassena Care at Stamford</i>	<i>02/2016-present</i>
<i>Cassena Care at New Britain</i>	<i>02/2016-present</i>
<i>Cassena Care at Norwalk</i>	<i>07/2013-present</i>

Soloman Rutenberg is the CEO of Workman's Circle Multicare Center, a multicare center. His job duties include participating in floor rounds, meeting with vendors, participating in Quality Assurance and Corporate Compliance, meeting with various administrators, Department Heads, and Directors. He works with key personnel implementing new programs regarding reimbursement. Mr. Rutenberg discloses ownership interest in the following healthcare facilities:

<i>Workman's Circle Multicare Center</i>	<i>08/2012-present</i>
<i>Shoreview Nursing and Rehabilitation</i>	<i>06/2014-present</i>
<i>Morningside Acquisition, III LLC (ALP)</i>	<i>Pending</i>
<i>Morningside Acquisition, III LLC (LHCSA)</i>	<i>Pending</i>
<i>Centerlight Certified Home Health Agency</i>	<i>Pending</i>
<i>Sea-Crest Nursing and Rehabilitation</i>	<i>07/2015-present</i>
<i>Workman's Circle Dialysis Center</i>	<i>08/2015-present</i>
<i>Mills Pond Nursing and Rehabilitation Center</i>	<i>05/2014-05/2018</i>
<i>Terrace Health Care Center</i>	<i>06/2015-08/2016</i>
<i>Morningside Nursing and Rehabilitation Center</i>	<i>07/2014-present</i>
<i>Upper East Side Rehabilitation and Nursing Center</i>	<i>03/2016-present</i>
<i>Morningside Dialysis Center</i>	<i>07/2019-present</i>
<i>Fordham Nursing and Rehabilitation</i>	<i>08/2016-present</i>
<i>Sea-Crest Dialysis Center</i>	<i>09/2017-present</i>
<i>Long Beach Nursing and Rehabilitation Center</i>	<i>03/2017-present</i>
<i>Hillside Manor Certified Home Care Agency</i>	<i>10/2017-present</i>
<i>Downtown Brooklyn Nursing and Rehabilitation Center</i>	<i>06/2018-present</i>
<i>Margaret Tietz Nursing and Rehabilitation Center</i>	<i>02/2019-present</i>
<u><i>Out-of-State</i></u>	
<i>Cassena Care at Stamford</i>	<i>02/2019-present</i>
<i>Cassena Care at New Britain</i>	<i>02/2016-present</i>

Alex Solovey is the Director of Rehabilitation at Theradynamics, a therapy company. He provides physical therapy services to and at health entities. He works with other therapists on programs geared towards individuals who receive dialysis treatments. He understands the fragility of patients residing in skilled nursing facilities. Mr. Solovey discloses ownership interest in the following healthcare facilities:

<i>Barnwell Nursing and Rehabilitation</i>	<i>11/2003-12/2017</i>
<i>East Neck Nursing and Rehabilitation Center</i>	<i>02/2005-present</i>
<i>JOPAL at St. James</i>	<i>10/2010-05/2018</i>
<i>Petit Fleur Nursing Home</i>	<i>12/2012-05/2018</i>
<i>Workman's Circle Multicare Center</i>	<i>07/2013-present</i>
<i>Shoreview Nursing and Rehabilitation</i>	<i>06/2014-present</i>
<i>Morningside Acquisition, I LLC</i>	<i>07/2014-present</i>
<i>Morningside Acquisition, III LLC (ALP)</i>	<i>Pending</i>
<i>Morningside Acquisition, III LLC (LHCSA)</i>	<i>Pending</i>
<i>Peninsula Nursing and Rehabilitation Center</i>	<i>08/2014-present</i>
<i>Upper East Side Rehabilitation and Nursing Center</i>	<i>06/2015-present</i>
<i>Sea-Crest Nursing and Rehabilitation</i>	<i>07/2015-present</i>
<i>Long Beach Nursing and Rehabilitation</i>	<i>08/2016-present</i>
<i>Workman's Circle Dialysis</i>	<i>08/2015-present</i>
<i>East Neck Dialysis Center</i>	<i>08/2015-present</i>
<i>Cassena Care at Peninsula</i>	<i>11/2016-present</i>
<i>Morningside Dialysis Center</i>	<i>07/2019-present</i>
<i>Fordham Nursing and Rehabilitation</i>	<i>08/2016-present</i>
<i>Hillside Certified Home Care Agency</i>	<i>10/2017-present</i>
<i>Sea-Crest Dialysis Center</i>	<i>09/2017-present</i>
<i>Downtown Brooklyn Nursing and Rehabilitation Center</i>	<i>06/2018-present</i>
<i>Margaret Tietz Nursing and Rehabilitation Center</i>	<i>02/2019-present</i>

Out-of-State

<i>Cassena Care at Stamford</i>	<i>02/2016-present</i>
<i>Cassena Care at New Britain</i>	<i>02/2016-present</i>
<i>Cassena Care at Norwalk</i>	<i>07/2013-present</i>

Syed Samar Raza, MD is the proposed Medical Director. He is board certified in Internal Medicine with a focus in Hospital Medicine. He is the current Chief Medical Officer of Cassena Car, providing oversight of all the physicians providing care at the Cassena facilities focusing on standardization of processes, reviewing, and providing current clinical guidelines to physicians, prioritizing quality improvement initiatives, and coordinating community relationships. He is also the current site Medical Director of East Neck Nursing and Rehab Center, providing oversight and coordination of medical care to all patients in each facility. He received his medical degree from the Ross University School of Medicine in Dominica. He completed his Internal Medicine residency at Maryland General Hospital. Dr. Raza discloses offices held in the healthcare facilities:

<i>Cassena Care</i>	<i>07/2019-present</i>
<i>Southside Hospital</i>	<i>01/2019-present</i>
<i>East Neck Nursing and Rehab Center</i>	<i>06/2019-present</i>
<i>Huntington Hospital</i>	<i>11/2010-12/2013</i>
<i>J. T. Mather Hospital</i>	<i>09/2007-10/2010</i>

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.

The applicants disclosed multiple legal actions.

A civil action was filed December 10, 2014 in the Supreme Court of the State of New York, Suffolk County. The suit was filed on behalf resident by the Estate Representative who allege medical malpractice and development of a sacral ulcer against Petit Fleur. The action was settled in January 2019 through the defense's insurance counsel.

A civil action was disclosed on January 15, 2016 in the Supreme Court of the State of New York, Nassau County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and theft of resident's property against Long Beach Nursing Home. The case was dismissed by the court on January 11, 2017.

A civil action filed on November 10, 2016 in the Supreme Court of the State of New York, Nassau County. The suit alleged negligence and medical malpractice. The case was dismissed on January 3, 2017 based on the defendant's motion to dismiss the plaintiff's summons and complaint based on failure to state a cause of action.

A civil suit was filed on May 3, 2018 in the Supreme Court of the State of New York State, Bronx County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and allegations of professional liability against Workman's Circle related to wound care issues and development of a sacral ulcer. The case is being actively by the insurance defense counsel.

A civil suit was filed on February 2, 2020 in the Supreme Court of the State of New York, Columbia County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and allegations of negligence, ulcers, dehydration, and malnutrition against Barnwell. The action was discontinued against Messrs. Solovey and DeBenedictis on June 24, 2020.

A civil suit was filed on May 3, 2020 in the Supreme Court of the State of New York, Bronx County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and allegations of negligence, ulcers, dehydration, and malnutrition against Workman's Circle. The action is being defended by the insurance's defense counsel.

A civil suit was filed on May 26, 2020 in the Supreme Court of the State of New York, New York County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and care related allegations due to a fall against Dewitt Rehab & Nursing. The action is being actively defended by the insurance's defense counsel.

A civil suit was filed on May 26, 2020 in the Supreme Court of the State of New York, Queens County on behalf of the resident by the Estate Representative who allege medical malpractice and care related allegation due to wound care issues/failure to treat pressure ulcers against Margaret Tietz Center for Nursing. The allegations relate to are being actively defended by the insurance's defense counsel.

A civil suit was filed on August 18, 2020 in the Supreme Court of the State of New York, Suffolk County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and failure/negligence in preventing pressure ulcers against Mills Pond. The action is being discontinued.

A civil suit was filed on October 27, 2020 in the Supreme Court of the State of New York, New York County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and allegations of negligence and failure to treat pressure ulcers against Upper East Side. These allegations are being defended by insurance's defense counsel.

A civil suit was filed on January 16, 2021 in the Supreme Court of the State of New York, Suffolk County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and professional liability relation to pressure ulcers and wrongful death against Downtown Brooklyn Nursing Home. The lawsuit was dismissed and refiled on April 29, 2021.

A civil suit was filed on April 16, 2021 in the Supreme Court of the State of New York, Suffolk County. The suit was filed on behalf of the resident by the Estate Representative who allege medical malpractice and

allegations of pressure ulcers and public health law violations against St. James. The action was dismissed with prejudice on September 17, 2021 against the facility and Messrs. DeBenedictis and Solovey.

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.

Barnwell Nursing Home

- The Department issued a Stipulation and Order (S&O) dated November 13, 2015 and fined Barnwell \$15,000 for the results of a survey that was completed on February 1, 2013 and September 26, 2013. Deficient practice was cited in the area of: Quality of care, Significant Medication Errors; Administration; Quality Assurance; Free from Mistreatment, Neglect, and Misappropriation of Property, and Quality of Care, Highest Practicable Potential.
- The Department issued a Stipulation and Order (S&O) dated November 3, 2015, and fined Barnwell \$6,000 based on an investigation that was completed February 1, 2013. Deficient practice was found in the following areas: Quality of Care-Free of Significant Med Errors and Administration-Effective Administration/Resident Well-Being/Quality Assurance Agency Committee Members/Meet Quarterly/Plans. Specifically, the facility failed to ensure that residents who were newly admitted or readmitted, received their physician-ordered medications in a timely manner. Additionally, the facility failed to follow the standard of practice in administering medications. Also, the Quality Assurance program failed to have a procedure in place to identify and investigate medications that were not administered and/or not administered on time, due to the unavailability of medications from the pharmacy.
- The Department issued a Stipulation and Order (S&O) dated January 12, 2014 and fined Barnwell \$2,000 for the results of a survey that was completed on March 13, 2012. Deficient practice was cited in the area of: Quality of Care, Accidents/Supervision.

East Neck Nursing and Rehabilitation and Center

- The Department issued a Stipulation and Order (S&O) dated November 3, 2015, and fined East Neck Nursing and Rehabilitation \$6,000 based on an investigation that was completed on March 21, 2014. Deficient practice was found in the following areas: Resident Rights-Right to Refuse, Formulate Advance Directives, Administration-Effective Administration/Resident Well Being, and Administration-Quality Assurance Agency (QAA) Committee Members/Meet Quarterly/Plans. Specifically, the facility failed to establish and implement an effective system for communicating each resident's advanced directive choices to the interdisciplinary team and follow physician's order. Additionally, the administration failed to ensure that there was a system in place to ensure that each resident's right to accept or refuse medical treatment and formulate an advance directive was maintained in accordance with State law and failed to provide a quality assessment program to provide for such.
- East Neck is being Investigated by the Attorney General's Office with respect to services provided by the facility from January 1, 2012 through December 31, 2014.

Long Beach Nursing and Rehab

- The Department issued a Stipulation and Order (S&O) dated September 29, 2020 and fined \$4,000. Long Beach Nursing and Rehab for the results of an Infection Control Survey completed on July 27, 2020. Deficient practice was cited in the area: Infection Control.
- The Department issued a Stipulation and Order (S&O) dated November 4, 2021 and fined Long Beach Nursing and Rehabilitation Center \$2,000 in the area of Infection Control based on an investigation dated July 13, 2021. The facility failed to maintain an infection prevention and control program and to ensure hand hygiene occurs.

Workmen's Circle Multicare Center

- The Department issued a Stipulation and Order (S&O) dated November 15, 2021 and fined Workmen's Circle \$10,000 based on an investigation on May 11, 2021 the facility was fined based on deficiencies found during the survey for Quality of Care -Free of Accident Hazards/supervision/devices. Staff did not properly transfer a resident, resulting in a fall and injury.

Morningside Nursing and Rehabilitation Center

- The Department issued a Stipulation and Order (S&O) dated July 10, 2020 and fined Morningside \$6,000 based on findings from a survey that was completed on May 20, 2020. Deficient practice was cited in the area Infection Control.

Upper East Side Rehabilitation and Nursing Center

- The Department issued a Stipulation and Order (S&O) dated May 10, 2018 and fined Upper East Side \$12,000 based on findings from a survey that was completed on February 20, 2108. Deficient practice was cited in the following areas: Residents Free from Significant Med Errors and Physician Visits-Review Care/notes/orders. Specifically, the facility failed to ensure that the Primary Medical Doctor reviewed and confirmed telephone medication orders before signing off on the orders. This resulted in the PMD anticipating signing off on orders for Simethicone 80 mg but actually signing off on orders Methadone 40 mg two tablets by mouth every 6 hours. The resident received this incorrect medication and required transport *to the hospital*.

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 Applicant will participate in community health events and with local religious institutions to ensure that the local organizations are aware of the services available. If the patient does not have a relationship with a primary care physician, the Center seeks to align with local hospitals, including Bronx-Lebanon Hospital and will notify any patient who comes to the Center without a primary care physician of the primary care services offered by the hospital affiliates. The Applicant plans on using an electronic medical record (EMR) system from the onset of initial services.

Conclusion

Approval of this project will increase access to a variety of outpatient surgical specialties to the residents of Bronx County. The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Costs

The total project cost for renovations and movable equipment is estimated at \$8,393,727, as follows:

Renovation & Demolition	\$4,120,000
Design Contingency	206,000
Construction Contingency	412,000
Architect/Engineering Fees	360,500
Other Fees (Consulting)	128,750
Movable Equipment	2,813,652
Financing Costs	130,681
Interim Expense	174,242
Application Fee	2,000
Additional Processing Fee	<u>45,902</u>
Total Project Cost	\$8,393,727

The financing for this project will be as follows:

Cash	\$1,259,059
Construction loan (10 years, 20 year-amortization, 6% interest)	<u>7,134,668</u>
Total Funds	\$8,393,727

Peapack-Gladstone Bank provided a letter of interest for the bank loan. Pasquale DeBenedictis and Solomon Rutenberg have provided affidavits to fund the balloon payment with personal equity should terms acceptable to the Department of Health be unavailable at the time of refinancing. BFA Attachment A shows that the members of Pelham Parkway SC, LLC have sufficient resources to fund the equity contribution for project costs and the balloon payment.

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for Years One and Three, summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Proc.</u>	<u>Total</u>	<u>Per Proc.</u>	<u>Total</u>
<u>Revenues</u>				
Commercial FFS	\$4,045.96	\$1,844,958	\$4,218.30	\$2,138,676
Commercial MC	\$3,374.92	1,106,975	\$3,544.21	1,559,451
Medicare MC	\$2,697.44	2,263,149	\$2,785.65	2,821,864
Medicaid MC	\$2,667.58	290,766	\$2,659.84	351,099
Private Pay	\$2,683.58	147,597	\$2,700.35	178,223
Bad Debt		<u>(113,069)</u>		<u>(140,986)</u>
Total Revenue		\$5,540,376		\$6,908,327
<u>Expenses</u>				
Operating	\$1,664.54	\$3,034,460	\$2,007.59	\$4,420,709
Capital	<u>804.63</u>	<u>1,466,834</u>	<u>671.21</u>	<u>1,478,009</u>
Total Expense	\$2,469.17	\$4,501,294	\$2,678.80	\$5,898,718
Net Income		<u>\$1,039,082</u>		<u>\$1,009,609</u>
Total Procedures		1,823		2,202
Cost/Procedure		\$2,469.17		\$2,678.80

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	25.01%	23.02%
Commercial MC	17.99%	19.98%
Medicare MC	46.02%	46.00%
Medicaid MC	5.98%	6.00%
Private Pay	3.02%	3.00%
Charity Care	<u>1.98%</u>	<u>2.00%</u>
Total	100.00%	100.00%

The following is noted with respect to the submitted budget:

- Projected utilization is based upon the estimated surgical volume provided by surgeons who have indicated interest in performing surgeries at the proposed center.
- Expenses are based on historical data from similar ASCs in New York State and reflect the experiences of the proposed members who operate other health related facilities.
- The Medicare rate is based on the 2019 Medicare rate schedule, Medicare fees are based on location of service and previous experience of proposed operators.
- Commercial rates are projected based on a percentage of the 2019 Medicare fee-for-service (FFS) rate, ranging from 200% for Commercial FFS payors, and 150% for Commercial Managed Care payors.

Agreements

BFA Attachment B details the following:

- The terms of an executed lease agreement for the site.
- The terms of a draft license agreement for the space.

The applicant has submitted an affidavit confirming that the lease and licensing agreements are non-arm's length agreements as common ownership exists between the manager(s) / member(s) of Pelham Parkway SC, LLC as licensee, and Morningside Acquisition I, LLC as licensor to the proposed Center who is also a tenant to Morningside Acquisition II, LLC the landlord and owner of the real property.

The applicant has submitted letters from two NYS licensed realtors attesting to the reasonableness of the per square footage rental.

Capability and Feasibility

The total project costs of \$8,393,727 will be met with \$1,259,059 equity from the proposed members and a bank loan for \$7,134,668 at 6.0% interest with a ten-year term and an amortization period of 20 years. Peapack-Gladstone Bank has provided a letter of interest for the loan at the stated terms. The proposed members have provided affidavits to fund the balloon payment with personal equity should terms acceptable to the Department of Health be unavailable at the time of refinancing. BFA Attachment A, the proposed members' net worth statements, shows the members of Parkway SC, LLC have sufficient resources to fund the equity contribution for project costs and the balloon payment.

Working capital requirements are estimated at \$983,120 based on two months of third year expenses. The working capital will be funded through members equity. BFA Attachment A shows sufficient funds available.

The submitted budget projects a net income of \$1,039,082 and \$1,009,609 during the first and third years of operations, respectively. Medicare and Medicaid reimbursement rates are based on the current and projected federal and state government rates for FASCs. The budget appears reasonable.

BFA Attachment C is the Pro-Forma balance sheet for Pelham Parkway SC, LLC, which shows the operation will start with \$1,750,619 in members' equity.

Conclusion

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

Supplemental Information

DOH Comment

The Department reached out to proximate hospitals asking for information on the impact of the proposed ambulatory surgery center (ASC). None of the hospitals responded. Therefore, in the absence of comments from hospitals near the ASC, the Department finds no basis for reversal or modification of the recommendation for approval of this application based on public need, financial feasibility and owner/operator character and competence.

Attachments

BHFP Attachment	Map
BFA Attachment A	Proposed Net Worth Statements
BFA Attachment B	Legal Agreements
BFA Attachment C	Pro-Forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a new multi-specialty ambulatory surgery center to be located at 1000 Pelham Parkway South, Bronx in currently vacant space in a multi-use building that includes Morningside Nursing and Rehabilitation Center, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

201004 B

Pelham Parkway SC, LLC d/b/a Pelham
Parkway 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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
3. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the centers commitment to meet the health care needs of the community, including the provision of services to those in need, regardless of ability to pay. The statement shall also include a commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. (RNR)
4. 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)
5. Submission of an executed Licensing Agreement, acceptable to the Department of Health.
(BFA)
6. Submission of an executed loan commitment, acceptable to the Department of Health. (BFA)
7. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01.
8. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01.
9. Submission of a photocopy of the applicant's executed Certificate of Assumed Name, acceptable to the Department. (CSL)
10. Submission of fully executed sublease, acceptable to the Department. (CSL)
11. Submission of a photocopy of an executed amendment of the applicant's articles of organization, acceptable to the Department. (CSL)

12. Submission of a photocopy of the applicant's fully executed operating agreement, acceptable to the Department. (CSL)
13. Submission of a list of members and managers of the applicant's second-level member, acceptable to the Department. (CSL)
14. Submission of a photocopy of an executed amendment of the applicant's second-level member's articles or organization, acceptable to the Department. (CSL)
15. Submission of a photocopy of the applicant's second-level member's fully executed operating agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **July 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **April 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. (RNR)
4. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospitals/docs/hcs_access_forms_new_clinics.pdf.
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 # 192211-B
Beach Channel D&TC, LLC d/b/a
Beach Channel Diagnostic and Treatment Center

Program: Diagnostic and Treatment Center County: Queens
Purpose: Establishment and Construction Acknowledged: October 30, 2019

Executive Summary

Description

Beach Channel D&TC, LLC (Beach Channel), a to-be-formed New York State limited liability company, requests approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) at 50-15 Beach Channel Drive, Far Rockaway (Queens County). The applicant requests certification for Medical Services - Primary Care, Medical Services - Other Medical Specialties, Physical Therapy, and Occupational Therapy to provide primary care, physician specialties, including diagnostic radiology and physical and occupational therapy services. Upon Public Health and Health Planning Council (PHHPC) approval, the D&TC will be known as Beach Channel Diagnostic & Treatment Center.

The D&TC will be housed in a newly renovated space on the first floor of a building owned by Beach 50th Street, LLC (landlord) and leased to Cardiff Bay Center, LLC (lessee). The applicant will sublease the D&TC space from Cardiff Bay Center, LLC. There is a relationship between landlord, lessee, and sublessee in that the entities have members in common.

The four-story building currently houses the Peninsula Nursing and Rehabilitation Center, a 200-bed residential health care facility (RHCF) operated by Cardiff Bay Center, LLC, and Quality Kidney Care, an Article 28 chronic renal dialysis center operated by Peninsula Continuum Services, LLC. The D&TC will be a separate and distinct facility with a dedicated entrance separate from the RHCF entry. The applicant's goal is to complement the existing services available within the building to serve

the residents of the Rockaway and Broad Channel areas of Queens County. The residents of the RHCF may use the D&TC services, however, primary care physician services are provided by the RHCF credentialed attending physicians, thus the D&TC will not be providing primary care to the RHCF residents.

The proposed members of Beach Channel D&TC, LLC are:

Table with 2 columns: Members, %
Members: Pasquale DeBenedictis (30%), Alex Solovey (30%), Leopold Friedman (30%), Soloman Rutenberg (10%)

Syed Samar Raza, MD, who is Board-Certified in Internal Medicine, will serve as Medical Director and will be a practicing physician at the D&TC. The applicant will enter into a Transfer and Affiliation Agreement with Mount Sinai-South Nassau Community Hospital located 10.9 miles (37 minutes travel time) from the proposed D&TC for backup and emergency care.

OPCHSM Recommendation
Contingent Approval

Need Summary

The applicant projects 5,185 in Year One and 10,260 in Year Three with Medicaid at 35% and Charity Care at 3% each year.

Program Summary

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

Financial Summary

The total project cost of \$1,276,882 for leasehold improvements to the space will be funded by the sublandlord via equity. Proposed member Pasquale DeBenedictis, who is a member of the landlord and sublandlord entities, has submitted an affidavit confirming he will personally fund any capital requirements to meet project costs if additional capital resources are needed. The budget is summarized below:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$725,706	\$1,436,294
Expenses	\$773,197	\$1,178,663
Gain/(Loss)	(\$47,491)	\$257,631

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 an executed sublease (license) agreement, acceptable to the Department. [BFA]
4. Submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
5. The submission of Engineering (MEP) Drawings, per SHC guidelines, for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
6. Submission of a photocopy of the applicant's Certificate of Assumed Name, acceptable to the Department. [CSL]
7. Submission of a photocopy of the applicant's executed proposed Articles of Organization, acceptable to the Department. [CSL]
8. Submission of a photocopy of an executed Lease Agreement, acceptable to the Department. [CSL]

Approval conditional upon:

1. This project must be completed by **February 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [PMU].
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **November 1, 2022**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Council Action Date

February 10, 2022

Need and Program Analysis

Project Proposal

Proposed Operator	Beach Channel D&TC, LLC
To Be Known As	Beach Channel Diagnostic and Treatment Center
Site Address	5015 Beach Channel Drive, Far Rockaway (Queens County)
Services	Medical Services - Primary Care Medical Services - Other Medical Specialties Infectious disease Gastroenterology Pain management Orthopedics Oncology Cardiology Urology Diagnostic Radiology Physical Therapy Occupational Therapy
Hours of Operation	Monday through Friday, 8 AM to 6 PM As needed the hours can be expanded or modified to address additional needs.
Staffing (1st Year / 3rd Year)	7.94 FTEs / 13.13 FTEs
Medical Director(s)	Syed Samar Raza, MD
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Mount Sinai - South Nassau Community Hospital. 10.9 miles / 37 minutes away.

The center will be located at the site of Peninsula Nursing and Rehabilitation Center, a 200-bed residential health care facility (RHCF). Primary care physician services are provided by the RHCF credentialed attending physicians, thus the D&TC will not be providing primary care to the RHCF residents. However, the residents will have the option of utilizing the other medical specialties within the center at their discretion.

Analysis

The primary service area is the neighborhoods of Rockaway and Broad Channel and the extended service area is Queens County. The population of Queens County was 2,230,772 in 2010 and is projected to grow to 2,508,764 by 2025, an increase of 12.5%. The Rockaway section of Queens County is a Medicaid Eligible Health Professional Shortage Area for Primary Care services, per HRSA. According to Data USA, in 2019, 90.7% of the population of Queens County has health coverage as follows:

Employer Plans	43.4%
Medicaid	25.7%
Medicare	10.5%
Non-Group Plans	10.8%
Military or VA	0.3%

The applicant projects 5,185 visits in Year One and 10,260 in Year Three with Medicaid utilization at 35% and charity care at 3%. The applicant is committed to serving all persons in need without regard to the ability to pay or source of payment.

Character and Competence

The members of Beach Channel, LLC are:

<u>Name</u>	<u>Interest</u>
Pasquale DeBenedictis, <i>Manager</i>	30%
Alex Solovey, <i>Manager</i>	30%
Leopold Friedman	30%
Soloman Rutenberg	10%
Total	100%

Pasquale DeBenedictis is currently employed as the Managing Member and Chief Financial Officer of Cassena Care, LLC. He has an interest in the day-to-day financial concerns of the business. Cassena Care provides back-office operational support, including but not limited to billing, accounts payable, employee resources, and compliance services. Cassena care also provides back-office services for non-health-related entities, including Theradynamics Rehab. He was previously employed in the Account and Finance Department of Theradynamic Rehab and was the Controller of Hillside Manor Certified Home Health Agency, where he was responsible for the financial stability of the organization. He was the Chief Financial Officer of Center for Nursing and Rehabilitation and was responsible for the accounts receivable and accounts payable to improve cash flow. This included the renegotiation of managed care contracts and payment terms with vendors. He spent 14 years as the Controller of Carillion Nursing and Rehabilitation.

Alex Solovey is a licensed Physical Therapist that is currently employed as Director of Rehabilitation at Theradynamics, a Rehabilitation and Occupational Therapy facility. He provides therapy services to and at various health entities via private practice. He takes interest in the operational components of therapy services at related nursing homes. He has taken his therapy background and worked with the therapists on programs geared toward individuals who receive dialysis treatments, as the patients can be chair-bound for many hours. He previously was employed as Director of Operations at Hillside Manor Certified Home Health Agency, a certified home health agency, and was also the Chief Operating Officer at Center for Nursing and Rehabilitation, a nursing and rehabilitation center.

Soloman. Rutenberg is currently employed as Chief Executive Officer at Workmen's Circle Multicare Center, a skilled nursing facility. He has leveraged his experience into understanding the formal complexities of maintaining and updating various nursing homes. He works with key personnel to implement new programs with the ever-changing landscape of reimbursement and has regular interaction with community administrators, Medical Directors and Directors of Nursing, and key staff to address challenges and how they will address potential challenges. He previously was employed as an Assistant Administrator at Kingsbridge Heights.

Leopold Friedman is currently an operating member of Peninsula Center for Extended Care and Rehabilitation, a skilled nursing facility where he oversees the day-to-day operations of the facility. He is also the Chief Executive Officer of Advanced Care Staffing, a staffing organization that provides staffing services to licensed home care agencies. He is responsible for the overall performance of the organization and works with staff to make sure there is a constant database of available resources to meet the client's needs. He has recently been working with staff to train for higher levels of education (LPN top RN).

Dr. Syed Samar Raza is the proposed Medical Director. He is the current Chief Medical Officer at Cassena Care, Woodbury, a residential health care facility where he has been providing oversight of all the physicians providing care at the facility and ensuring that the best care is being provided by focusing on standardization of processes, reviewing and providing current clinical guidelines to physicians, prioritizing quality improvement initiatives, and coordinating community relationships. Dr. Raza is also the current site Medical Director of East Neck Nursing & Rehabilitation Center, where, he has been providing administrative oversight and coordination of medical care to all patients in each facility. Dr. Raza received his medical degree from Ross University School of Medicine in 1999 and is Board Certified in Internal Medicine with a focused practice in Hospital Medicine.

Staff from the Division of Hospitals and Diagnostic & Treatment Centers (DHDTTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Pascale DeBenedictis, Leopold Friedman, Soloman Rutenberg, and Alex Solovey disclosed multiple legal actions, as follows.

Alex Solovey

- A civil suit was filed on March 25, 2016 in the Supreme Court of the State of New York, Bronx County. The suit was filed against Excellence Rehab and Physical Therapy, P.C. by a patient who alleged negligence in relation to alleged injuries sustained during the provision of physical therapy services. The action was discontinued with prejudice as to Mr. Solovey on April 23, 2018.
- A civil suit was filed on September 29, 2020 in the United States District Court, Eastern District. The suit was filed against Mr. Solovey on behalf of an employee who alleged employment violations. The case was settled in May 2021.

Leopold Friedman

- A civil suit was filed on July 14, 2017 in the Supreme Court of the State of New York, Bronx County. The suit was filed against Kingsbridge Heights Rehabilitation Center on behalf of the resident by the Estate Representative, who alleged wrongful death and negligence in relation to alleged pressure ulcers. The case is settled pending Surrogate Court Approval.
- A civil suit was filed on March 4, 2020 in the Supreme Court of the State of New York, New York County against The Plaza Rehab & Nursing Center on behalf of the resident by the Administrator of the Estate who allege medical malpractice, negligence, and wrongful death relating to alleged pressure ulcers and dehydration. This case is currently in discovery
- A civil suit was filed on December 11, 2020 in the Supreme Court of the State of New York, New York County against the Plaza Rehab & Nursing Center on behalf of the resident by the Administrator of the Estate who alleges negligence relating to the treatment of blisters and ulcers to the ankle. The case is in discovery.
- A civil suit was filed on October 13, 2021 in the Supreme Court of the State of New York, New York County. The suit was filed against Hudson Pointe at Riverdale Center for Nursing and Rehabilitation on behalf of the resident by the Administrator of the Estate who allege medical malpractice and wrongful death from alleged urinary tract infection. The case is still in litigation.

Pascale DeBenedictis and Alex Solovey

- A civil action was filed on December 10, 2014 in the Supreme Court of the State of New York, Suffolk County. The suit was filed against Sayville Nursing and Rehabilitation Center on behalf of the resident by the Estate Representative who alleged medical malpractice and negligence in the alleged development of a sacral ulcer. The action was settled in January 2019
- A civil suit was filed on February 12, 2020 in the Supreme Court of the State of New York, Columbia County. The suit was filed against Barnwell Nursing & Rehabilitation Center on behalf of the resident by the Estate Representative who alleged medical malpractice and negligence relating to ulcers, dehydration, and malnutrition. The action was discontinued against Alex Solovey and Pascale DeBenedictis on June 24, 2020.

Pascale DeBenedictis and Leopold Friedman

- A civil suit was filed on January 16, 2021 in the Supreme Court of the State of New York, Suffolk County. The suit was filed on behalf of the resident by the Estate Representative against Downtown Brooklyn Nursing Home who alleges medical malpractice, wrongful death, and negligence in relation to alleged pressure ulcers. The lawsuit was dismissed and refiled on April 29, 2021. It is still in active litigation.

Pascale DeBenedictis, Leopold Friedman, and Alex Solovey

- A civil action was filed on January 15, 2016 in the Supreme Court of New York State in Nassau County. The suit was filed against Long Beach Nursing Home d/b/a Komanoff Center on behalf of the resident by the Estate Representative, who alleged medical malpractice and negligence related to the alleged theft of property and care issues. The case was dismissed on January 11, 2017
- A civil suit was filed on May 26, 2020 in the Supreme Court of the State of New York, New York County. The suit was filed against Upper East Side on behalf of the resident by the Estate Representative who allege medical malpractice and negligence relating to alleged ulcers, dehydration, and malnutrition. The case is still in litigation.
- A civil suit was filed on October 27, 2020 in the Supreme Court of the State of New York, New York County. The suit was filed against Upper East Side on behalf of the resident by the Estate Representative who alleges medical malpractice and negligence in relation to alleged pressure ulcers. The case is in active litigation.

Pascale DeBenedictis, Alex Solovey, and Soloman Rutenberg

- A civil suit was filed on May 3, 2018 in the Supreme Court of the State of New York, Bronx County. The suit was filed against Workmen's Circle Multicare Center on behalf of the resident by the Estate Representative who alleges medical malpractice and negligence relating to alleged wound care and sacral. The case is in litigation.
- A civil suit was filed on August 18, 2020 in the Supreme Court of the State of New York, Suffolk County. The suit was filed against Mills Pond Nursing & Rehabilitation Center on behalf of the resident by the Estate Representative who alleges medical malpractice and negligence relating to alleged pressure ulcers. The action is being discontinued against Messrs. DeBenedictis, Rutenberg, and Solovey.
- A civil suit was filed on April 16, 2021 in the Supreme Court of the State of New York, Suffolk County. The suit was filed against Mills Pond Nursing & Rehabilitation Center on behalf of the resident by the Estate Representative who alleges medical malpractice and negligence in relation to alleged pressure ulcers. The action was dismissed with prejudice on September 17, 2021.

Pascale DeBenedictis, Leopold Friedman, Soloman Rutenberg, and Alex Solovey

- A civil suit was filed on May 26, 2020 in the Supreme Court of the State of New York, Queens County against Margaret Tietz Center for Nursing on behalf of the resident by the Estate Representative who allege medical malpractice and negligence related to alleged wound care issues/failure to treat pressure ulcers. The case is still in active litigation.

Leopold Friedman Out of State Legal Actions from the State of Florida

- A civil suit was filed on June 20, 2019 in the Middle District Court of Florida of the State of Florida, on behalf of the Purchaser alleging a Dispute regarding old A/R of facilities purchased against Leopold Friedman and 919 Old Winter Haven Reality, LLC et al. The lawsuit is Open and Pending.
- A civil suit was filed on December 18, 2020 in the Circuit Court of Florida, Pinellas County on behalf of a resident by the Estate Representative, who alleges wrongful death, breach of fiduciary duty, negligence, abuse, and neglect in relation to alleged infections, poor hygiene, pressure ulcers, weight loss, understaffing, and failure to follow doctor's orders. The case is in litigation.
- A civil suit was filed on May 12, 2021 in the Circuit Court of the State of Florida, Pinellas County against Kensington Gardens Rehab and Nursing Center on behalf of the Estate Representative who alleges violations in nursing home resident's rights and negligence resulting in injuries, including Urinary Tract Infection, Urosepsis with septic shock, a fall resulting in a right eye contusion, and death. The case is in discovery.
- A civil suit was filed on August 17, 2021 in the Circuit Court of the State of Florida, Duval County against Fouraker Hills, et al. on behalf of the son (POA) of the resident who alleges resident right violations, negligence, breach of fiduciary duty and abuse and neglect in relation to alleged bruising, infections, pressure ulcers, poor hygiene, and fungal wounds to the scalp. The case is in active litigation.
- A civil suit was filed on November 2, 2021 in the Circuit Court of the State of Florida, Polk County Auburndale Oaks, et al. on behalf of the Estate of a Resident, which alleges resident rights violations, wrongful death, assault, breach of fiduciary duty, and abuse and neglect in relation to alleged, falls,

pressure ulcers on the coccyx, right ankle, heel and shin, contractures, poor nutrition, infections and understaffing. The case is in active litigation.

- Leopold Friedman discloses a claim in Pre-Suit Status in the Circuit Court of the State of Florida, Pinellas County against Kensington Gardens Rehab and Nursing Center on behalf of the Estate of a Resident, which alleges resident rights violations and wrongful, pressure ulcers, infections, and the failure to follow doctor's orders. No Lawsuit has been filed to date

Additionally, the staff from the DHDTC 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, as well as, information from other states. 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.

Pascale DeBenedictis, Leopold Friedman, and Alex Solovey disclosed ownership in the following facilities in **New York State**, which have had enforcements and other actions, as listed below.

The Grand Nursing and Rehabilitation at Barwell (f/k/a Barnwell Nursing Home and Rehabilitation Center)

- The Department issued a Stipulation and Order (S&O) dated November 3, 2015, and fined The Grand Nursing and Rehabilitation at Barnwell \$12,000 based on an investigation that was completed September 26, 2013. Deficient practice was found in the following areas: Resident Behavior and Facility Practices-Investigate/Report Allegations/Individuals and Provide Care/Services for Highest Well Being. Specifically, the facility failed to ensure that all alleged violations involving mistreatment, neglect, or abuse were reported immediately to the administrator of the facility and that all alleged violations were thoroughly investigated. Also, the facility did not provide the necessary care and services to attain or maintain the highest practicable physical and psychosocial wellbeing in accordance with the comprehensive assessment and plan of care.
- The Department issued a Stipulation and Order (S&O) dated November 3, 2015, and fined The Grand Nursing and Rehabilitation at Barnwell \$6,000 based on an investigation that was completed February 1, 2013. Deficient practice was found in the following areas: Quality of Care-Free of Significant Med Errors and Administration-Effective Administration/Resident Well-Being/Quality Assurance Agency Committee Members/Meet Quarterly/Plans. Specifically, the facility failed to ensure that residents who were newly admitted or readmitted, received their physician-ordered medications in a timely manner. Additionally, the facility failed to follow the standard of practice in administering medications. Also, the Quality Assurance program failed to have a procedure in place to identify and investigate medications that were not administered and/or not administered on time, due to the unavailability of medications from the pharmacy.
- The Department issued a Stipulation and Order (S&O) dated January 12, 2014, and fined The Grand Nursing and Rehabilitation at Barnwell \$2,000 based on an investigation that was completed on March 13, 2012. Deficient practice was in the following area: Quality of Care-Free of Accidents/Hazards/Supervision/devices.

East Neck Nursing and Rehabilitation and Center

- The Department issued a Stipulation and Order (S&O) dated November 3, 2015, and fined East Neck Nursing and Rehabilitation \$6,000 based on an investigation that was completed on March 21, 2014. Deficient practice was found in the following areas: Resident Rights-Right to Refuse, Formulate Advance Directives, Administration-Effective Administration/Resident Well Being, and Administration-Quality Assurance Agency (QAA) Committee Members/Meet Quarterly/Plans. Specifically, the facility failed to establish and implement an effective system for communicating each resident's advanced directive choices to the interdisciplinary team and follow physician's order. Additionally, the administration failed to ensure that there was a system in place to ensure that each resident's right to accept or refuse medical treatment and formulate an advance directive was maintained in accordance with State law and failed to provide a quality assessment program to provide for such.
- East Neck is being Investigated by the Attorney General's Office with respect to services provided by the facility from January 1, 2012 through December 31, 2014.

Upper Eastside Rehabilitation and Nursing Center

- The Department issued a Stipulation and Order (S&O) dated May 10, 2018 and fined Upper Eastside Rehabilitation and Nursing Center \$12,000 based on an investigation that was completed on February 20, 2018. Deficient practice was identified in the following areas: Quality of Care-Residents Free of Significant Med Error and Physician Visits-Review Care/Notes/Orders. Specifically, the facility did not ensure that a resident was given the correct medication that was ordered. The facility did not ensure that the Primary Medical Doctor reviewed and confirmed telephone medication orders before signing the orders.

Bronx Gardens Rehabilitation and Nursing Center

- The Department issued a Stipulations and Order (S&O) dated January 11, 2017, and fined Bronx Gardens Rehabilitation and Nursing Center \$10,000 based on an investigation that was completed on August 11, 2016. Deficient practice was identified in the following area: Quality of Care-Resident Free of Significant Med Errors. Specifically, the facility did not ensure that the resident received the correct medication. The resident received narcotic medication intended for the resident's roommate and required transport to the hospital.

The Citadel Rehabilitation and Nursing Center at Kingsbridge

- The Department issued a Stipulation and Order (S&O) dated November 29, 2016, and fined The Citadel Rehabilitation and Nursing Center at Kingsbridge \$4,000 based on an investigation completed on August 1, 2016. Deficient practice was found in the following areas: Quality of Care-Free of accidents and Hazards/Supervision/Devices and Effective Administration/Resident Well Being. Specifically, the facility failed to ensure that the side rails exceeded the FDA recommendation that spaces between the bedside rails should be no larger than 4 3/4 inches. The Administrator failed to ensure that there were systems in place to provide a safe environment.

Long Beach Nursing and Rehabilitation Center

- The Department issued a Stipulation and Order (S&O) dated September 29, 2020, and fined Long Beach Nursing and Rehab for \$4,000, the results of an Infection Control Survey completed on July 27, 2020. Deficient practice was cited in the area: Infection Control for two citations issued.
- The Department issued a Stipulation and Order (S&O) dated November 4, 2021, and fined Long Beach Nursing and Rehabilitation Center \$2,000 in the area of Infection Control based on an investigation dated July 13, 2021. The facility failed to maintain an infection prevention and control program and to ensure hand hygiene occurs.

Morningside Nursing and Rehabilitation Center

- The Department issued a Stipulation and Order (S&O) dated July 10, 2020, and fined Morningside \$6,000 based on findings from a survey that was completed on May 20, 2020. Deficient practice was cited in the area of Infection Control.

Workmen's Circle Multicare Center

- The Department issued a Stipulation and Order (S&O) dated November 15, 2021, and fined Workmen's Circle \$10,000 based on an investigation on May 11, 2021, the facility was fined based on deficiencies found during the survey for Quality of Care -Free of Accident Hazards/supervision/devices. Staff did not properly transfer a resident, resulting in a fall and injury.

New Riverdale Rehabilitation and Nursing Center

- The Department issued a Stipulation and Order (S&O) dated October 2021 and fined New Riverdale \$10,000 based on an investigation on April 30, 2021, the facility was fined for deficiencies related to Quality of Care for Free of Accident Hazards/supervision/devices, resulting in an injury to the resident who received a second-degree burn.

Leopold Friedman disclosed ownership interest in the following **out of state facilities** that have recent enforcement actions imposed:

Sea Breeze Rehabilitation and Nursing Center

- On April 24, 2019, the State of Florida Agency for Health Care Administration issued a Final Order and fined Sea Breeze Rehabilitation and Nursing Center \$1,000 and assigned conditional licensure status for deficiencies found on a survey that concluded on August 16, 2018. Specifically, the facility failed to ensure that it had on file a current disaster preparedness plan.

Oak Haven Rehabilitation and Nursing Center

- Oak Haven has been placed on the Special Focus Facility List in 2019. Deficiencies were cited in Quality of Care and Quality of Life, Resident Rights, Resident Assessment, Care Planning, Pharmacy Services and Administration from 7/28/16, 9/22/17, and Immediate Jeopardy was identified at the 12/13/18 survey. The facility was fined \$147,689.00 for Substandard Quality of Care on 11/6/2018 for deficiencies over the past three years.

The Sands at South Beach Center

- On February 7, 2019, the facility was surveyed and cited in Infection Control for failing to ensure an appropriate assessment and documentation was completed for a resident requiring the Influenza vaccination. The facility was fined \$11,025.00 dated 2/7/19.

Pascale Debenedictis and Alex Solvey disclosed ownership interest in the following **out of state facilities** that have recent enforcement actions imposed:

Cassena Care at Stamford

- On August 16, 2018, the facility was fined \$3,060 based on deficiencies found during a survey for Quality of Care. Specifically, the facility failed to turn and position a patient and the resident developed a Stage 3 pressure ulcer. The resident was observed in the same position for four hours.
- On August 23, 2018, the facility was fined \$11,000 for deficiencies related to Resident Behavior and Facility Practices. Specifically, the facility failed to protect the resident from the wrongful use of the resident's belongings or money. The resident gave money to two staff members.

Cassena Care at Norwalk

- On April 9, 2018, the facility was fined \$13,003 for deficiencies related to Quality of Care-Free of Accident Hazards/Supervision/Devices. Specifically, the facility failed to ensure that the resident was supervised appropriately and failed to ensure that the resident did not exit the facility. The resident eloped from the facility and was found wandering and brought to the hospital. The elopement risk assessment conducted identified the resident as high risk.
- On July 13, 2017, the facility was fined \$24,780 for deficiencies related to Quality of Care-Free of Accident Hazards/Supervision/Devices. Specifically, the facility failed to initiate interventions and increased supervision for confused residents with repeated falls and failed to ensure staff handled the transfer of residents appropriately using a mechanical lift.
- On September 15, 2016, the facility was fined \$2,316 for deficiencies related to Quality of Care-Residents Free from Significant Med Errors. Specifically, the facility failed to ensure that medications were administered in accordance with the physician's orders. A resident medication was not given for a total of two months. The resident was supposed to receive the medications in the morning and evening. The medication was documented as given. The resident was sent to an acute care facility for an evaluation and a blood test revealed that there was an undetectable level in the blood.

Cassena Care at New Britain

- On August 16, 2018, the facility was fined \$21,060 for deficiencies related to Quality of Care-Provide Care/Highest Well Being. Specifically, the facility failed to ensure vital signs and/or an abdominal assessment were conducted when the resident was identified with a change in status. The patient had critical labs. There was no RN assessment of the resident. The resident was transferred to the hospital where he expired.
- On September 15, 2016, the facility was fined \$17,821 for Quality of Care-Provide Care/Highest Well Being and Quality of Care-Free of Accident Hazards/Supervision/Devices. Specifically, the facility

failed to document vital signs and ensure medications were ordered in a timely manner after an allergic reaction and failed to ensure that another resident received the appropriate care and supervision. The resident ate a peanut butter sandwich and began exhibiting signs of an anaphylactic reaction. The resident has a peanut allergy. The facility did use an epi-pen and the patient was transferred to the hospital. The second resident eloped from the facility through an emergency exit door and was found outside the facility.

Conclusion

Approval for this project will provide for improved access to a variety of medical services for residents within the area of Rockaway and Broad channel, as well as the surrounding communities of Queens County. The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Costs and Financing

The project costs for renovation and movable equipment are estimated at \$1,276,882.

Renovation & Demolition	\$798,170
Design Contingency	\$75,000
Construction Contingency	\$75,000
Architect/Engineering Fees	\$77,826
Other Fees	\$75,000
Moveable Equipment	\$166,913
Application Fee	\$2,000
Processing Fee	<u>\$6,973</u>
Total Project Cost	\$1,276,882

Cardiff Bay Center, LLC (sublandlord) will fund the leasehold improvements via \$1,276,882 cash. BFA Attachments B and C are, respectively, the 2019-2020 certified financial statements and the internal financial statement for Cardiff Bay Center, LLC as of July 31, 2021, which indicated liquid resources may not be sufficient to fund the leasehold improvements. Proposed member Pasquale DeBenedictis, who is also a member of the landlord and sublandlord entities, has submitted an affidavit confirming he will personally fund any capital requirements to meet project costs if additional resources are needed. BFA Attachment A shows the ability of this member to meet project costs.

Operating Budget

The applicant has submitted the year one and year three operating budget, in 2022 dollars, as summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Revenues</u>				
Commercial FFS	\$164.95	\$239,501	\$164.99	\$474,012
Medicare FFS	\$135.10	\$34,992	\$135.00	\$69,255
Medicare MC	\$107.98	\$111,974	\$108.00	\$221,616
Medicaid FFS	\$167.46	\$86,306	\$167.33	\$170,813
Medicaid MC	\$125.50	\$164,287	\$125.50	\$325,152
Private Pay	\$189.82	<u>\$88,646</u>	\$190.08	<u>\$175,446</u>
Total Revenue		\$725,706		\$1,436,294

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Expenses</u>				
Operating	\$108.53	\$562,612	\$93.33	\$957,530
Capital	<u>\$40.62</u>	<u>\$210,585</u>	<u>\$21.55</u>	<u>\$221,133</u>
Total Expenses	\$149.15	\$773,197	\$114.88	\$1,178,663
Gain/(Loss)		<u>(\$47,491)</u>		<u>\$257,631</u>
Visits		5,185		10,260

The following is noted with respect to the submitted budget:

- Medicaid revenue projections are based on the Medicaid Freestanding APG Base Rates using Full APG Investment as obtained from the Department's website for freestanding clinics downstate, excluding the capital component to be conservative in the projections.
- For other payors, the applicant identified the most prevalent HCPCS codes used for their Medicare recipients based on the operators' experience.
- The Medicare Part B fee schedule was used to determine the calculation for the Medicare composite rate.
- Expenses are based on the salaries and employee benefits expenses for 7.94 FTE staff in Year One and 13.13 FTE staff in Year Three, plus medical supplies and capital costs related to depreciation and rent. By Year Three, direct care staff will include 1.13 FTE Physicians, 1.0 FTE RN, 0.5 FTE Physicians' Assistant, 0.5 FTE Nurse Practitioner, and 1.03 FTE Physical Therapists.

Utilization by payor source for outpatient visits is as follows:

<u>Payor</u>	<u>Year One</u>	<u>Year Three</u>
Commercial FFS	28%	28%
Medicare FFS	5%	5%
Medicare MC	20%	20%
Medicaid FFS	10%	10%
Medicaid MC	25%	25%
Private Pay	9%	9%
Charity Care	<u>3%</u>	<u>3%</u>
Total	100%	100%

Agreements

BFA Attachment D details:

- The submitted executed amended and restated master lease for the building. The master lease agreement is a non-arm's length arrangement as the landlord and tenant entities have related members. Specifically, the members of Beach 50th Street LLC and Cardiff Bay Center, LLC are as follows: Pasquale DeBenedictis (25.05%), Alex Solovey (25.05%), Leopold Friedman (24.90%), Michael Melnicke (25%).
- The draft license agreement for the proposed D&TC space, including the terms, rate, and provisions of the submitted documentation. The license agreement is a non-arm's length agreement, as there are common members between the sublessor and licensee. The applicant has submitted rent reasonableness 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 a property similar to this location and size.

Capability and Feasibility

The total project cost of \$1,276,882 will be funded via equity from Cardiff Bay Center, LLC for the fit-out of existing space. BFA Attachment B, the 2019-2020 certified financial statements of Cardiff Bay Center, LLC, indicates enough funds to meet the equity requirement; however, BFA Attachment C, the entity's internal financial statements as of September 30, 2021, indicates a negative working capital position, a positive member equity position and net loss of \$673,766. Pasquale DeBenedictis submitted an affidavit confirming he will personally fund capital requirements if additional equity is needed for the construction

and equipment costs. Review of BFA Attachment A, the proposed members' net worth summaries, reveals sufficient equity to meet project costs.

The working capital requirement is estimated at \$196,444, based on two months of third-year expenses. Working capital will be funded via members' equity in proportion to their ownership. BFA Attachment A is the members' net-worth statement, which indicates enough resources to provide funding. BFA Attachment E is the pro forma balance sheet of Beach Channel Diagnostic and Treatment Center as of the first day of operations, which indicates a positive equity position of \$196,444.

The submitted budget reflects a net operating loss of \$47,491 and a net income of \$257,631 in Years One and Three, respectively. The first-year loss will be offset by operations represented in BFA Attachment E. Revenues are based on the current reimbursement methodologies for Primary Care and Medical Services – Other Medical Specialties. The submitted budget appears reasonable.

Conclusion

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

Attachments

BHFP Attachment	Map
BFA Attachment A	Members Net-worth Statement
BFA Attachment B	Cardiff Bay Center, LLC Certified (2019-2020) Financial Statement
BFA Attachment C	Cardiff Bay Center, LLC Internal September 30, 2021 Financial Statement.
BFA Attachment D	Master Lease and License Agreements
BFA Attachment E	Pro Forma (Beach Channel D&TC)

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to Establish and construct a diagnostic and treatment center to be located at 50-15 Beach Channel Drive, Far Rockaway, in Peninsula Nursing and Rehabilitation Center, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

192211 B

FACILITY/APPLICANT:

Beach Channel D&TC, LLC d/b/a Beach
Channel Diagnostic and Treatment Center

APPROVAL CONTINGENT UPON:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
3. Submission of an executed sublease (license) agreement, acceptable to the Department. [BFA]
4. Submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
5. The submission of Engineering (MEP) Drawings, per SHC guidelines, for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
6. Submission of a photocopy of the applicant's Certificate of Assumed Name, acceptable to the Department. [CSL]
7. Submission of a photocopy of the applicant's executed proposed Articles of Organization, acceptable to the Department. [CSL]
8. Submission of a photocopy of an executed Lease Agreement, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **February 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [PMU].
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **November 1, 2022**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf.
Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

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



Project # 211085-B
KD Hudson Ventures, LLC d/b/a Avalon Medical Group

Program: Diagnostic and Treatment Center County: Orange
Purpose: Establishment and Construction Acknowledged: April 14, 2021

Executive Summary

Description

KD Hudson Ventures, LLC d/b/a Avalon Medical Group, an existing New York State limited liability company, requests approval to establish and construct a diagnostic and treatment center at 121 Executive Drive, New Windsor, New York.

The Center will operate in leased space providing primary medical care, specialty medical services, physical therapy, and occupational therapy services. The specialty medical services will include cardiology, dermatology, orthopedic, pain management, neurology, neurosurgery, physical medicine and rehabilitation, and allergy testing. Yelena Shubina, MD. will be Medical Director of the Center.

Through this project, several private practices currently located at 244 Broadway, Newburgh, New York will be relocated and consolidated into the proposed Article 28 D&TC. The applicant indicates operations will expand beyond that of the private practices to accommodate additional visits through an increase in staff and a broader range of services to include orthopedic, physical medicine and rehabilitation, therapy services.

The members of KD Hudson Ventures, LLC are:

Table with 2 columns: Member, Interest. Rows: Arthur Kostanian (50%), Sergey Denevich (50%)

OPCHSM Recommendation

Contingent Approval

Need Summary

The center will offer primary care and other medical specialty services in a Health Professional Shortage Area for Primary Care Services. The applicant projects 34,335 visits in Year One and 37,771 in Year Three with Medicaid utilization of 35% and Charity Care of 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

Project costs of \$2,361,979 will be met as follows: Equity of \$236,198 via the proposed members and a bank loan of \$2,185,781 at an interest rate of 5.25% for a five-year term. The projected budget is:

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 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 working capital loan that is acceptable to the Department of Health. (BFA)
3. Submission of a bank loan that is acceptable to the Department of Health. (BFA)
4. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
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. This project must be completed by **May 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **February 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov [HSP]

Council Action Date

February 10, 2022

Need and Program Analysis

Description

Proposed Operator	KD Hudson Ventures, LLC
To Be Known As	Avalon Medical Group
Site Address	121 Executive Drive New Windsor, New York 12553 (Orange County)
Specialties	Medical Services – Primary Care Medical Services-Other Medical Specialties Radiology Services (x-ray) Cardiology Dermatology Orthopedics Pain Management Neurology Neurosurgery (medical visits only) Allergy/Allergy Testing Physiatry Physical Therapy Occupational Therapy
Hours of Operation	Sunday through Thursday 9:00 am to 6:00 pm Friday 9:00 am to 1:00 pm
Staffing (1st Year / 3rd Year)	20.4 FTEs / 21.8 FTEs
Medical Director(s)	Yelena Shubina, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Garnet Health Medical Center 22.6 miles / 29 minutes away

Background and Analysis

The primary service area is Orange County. The population of Orange County in 2010 was 378,813 and is estimated to grow to 391,144 by 2025, an increase of 3.3%. Orange County is designated as a Health Professional Shortage Area for Primary Care services for Medicaid eligible. According to Data USA, in 2019, 92.3% of the population of Orange County has health coverage as follows:

Employer Plans	50.7%
Medicaid	17.3%
Medicare	11.0%
Non-Group Plans	12.9%
Military or VA	0.5%

The applicant projects 34,335 visits in Year One and 37,771 in Year Three with Medicaid utilization of 35% and Charity Care of 2%. 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 KD Hudson Ventures LLC are:

Name	Interest
Arthur Kostonian	50.00%
Sergey Denevich	50.00%
Total	100.00%

Arthur Kostanian is the Chief Executive Officer of Kostanian Consulting and Associates. He provides general administrative, marketing, and consulting services to health care providers. He was an owner of Montvale Surgical Center for over three years and was responsible for developing, monitoring, and controlling the staffing needs, operations, budget, and purchasing plan as well as continuous monitoring of operations to ensure compliance with goals and budgets. He also reviewed and approved the hiring and disciplinary actions and/or discharge of employees. He was previously a Paralegal.

Sergey Denevich has been the President of Skazka LLC for over 11 years. He provides administrative assistance and services to health care practices; consulting; marketing; bookkeeping, payroll submission; staffing; and agreements review and evaluation. He was the Administrator of City Medical Diagnostics for over one year. He reviewed and approved the hiring and disciplinary action and/or discharge of employees and supervised. He was previously a Paralegal.

Dr. Yelena Shubina, the proposed Medical Director, is a Hospitalist at Staten Island University Hospital. She was previously a Hospitalist at Nazareth Hospital in Pennsylvania. She received her medical degree from Ross University School of Medicine in the West Indies. She is board certified in Internal Medicine.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and 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.

Sergey Denevich was arrested for Assault in the 2nd Degree and Operating a Motor Vehicle under the Influence of Drugs or Alcohol on October 11, 2004. The charges were filed on March 31, 2006 and Sergey Denevich pled guilty on June 27, 2006. He was sentenced to 364 days imprisonment for each charge, the sentences ran concurrently.

Sergey Denevich was named in a civil suit by GEICO under the federal RICO act for Racketeering and Corrupt Organization on November 22, 2010. Sergey Denevich was employed as an Administrator at City Medical Diagnostics, an imaging facility, and was individually named, along with his employer in a suit alleging non-physician operation and control over physician professional practices. The charges were dismissed, without prejudice, against Sergey Denevich on August 15, 2011.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

Total project cost, which is for renovation and the acquisition of moveable equipment, is estimated at \$2,361,979, further broken down as follows:

Renovation and Demolition	\$1,485,247
Site Development	5,146
Design Contingency	148,525
Construction Contingency	148,525
Planning Consultant Fees	15,439
Architect Engineering Fees	119,396
Other Fees (Consultant)	61,757
Moveable Equipment	246,117
Financing Costs	42,516
Interim interest Expense	74,402
CON Fee	2,000
Additional Processing Fee	<u>12,909</u>
Total Project Cost	\$2,361,979

The applicant's financing plan appears as follows:

Equity	\$236,198
Bank Loan (5.25% interest rate for a five-year term)	<u>\$2,125,781</u>
Total	\$2,361,979

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for the first and third years, summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Revenues</u>				
Commercial FFS	\$100.12	\$378,168	\$98.33	\$408,552
Commercial MC	\$85.10	\$905,806	\$83.56	\$978,451
Medicare FFS	\$83.45	\$458,480	\$81.92	\$495,020
Medicare MC	\$70.92	\$73,050	\$69.64	\$78,898
Medicaid MC	\$121.81	\$1,463,715	\$128.54	\$1,699,407
Private Pay	\$16.67	<u>\$11,450</u>	\$16.38	<u>\$12,369</u>
Total Revenues		\$3,290,669		\$3,672,697
<u>Expenses</u>				
Operating	\$84.27	\$2,893,264	\$82.77	\$3,126,388
Capital	<u>\$10.41</u>	<u>\$357,619</u>	<u>\$8.37</u>	<u>\$316,284</u>
Total Expenses	\$94.67	\$3,250,883	\$91.15	\$3,442,672
Net Income		<u>\$39,786</u>		<u>\$230,025</u>
Utilization (Visits)		34,335		37,771

The following is noted with respect to the submitted budget:

- Revenues are based on current reimbursement rates for the type of services they are providing.
- The applicant has indicated that the increase in visits from the first year to the third year is because primary medical care services are projected to grow at the highest level. These are relatively new services at the current private practice site, so the growth rate will be higher, relative to the existing practices.
- The applicant will enter into a lease with annual lease rental payments of \$90,000. The applicant has indicated that the lease agreement will be an arm's length lease arrangement and the applicant has provided two real estate letters attesting to the reasonableness of the per square foot rental.

Utilization broken down by payor source during the first and third years is as follows:

	<u>Year One</u>	<u>Year Three</u>
Commercial FFS	11.00%	11.00%
Commercial MC	31.00%	31.00%
Medicare FFS	16.00%	16.00%
Medicare MC	3.00%	3.00%
Medicaid MC	35.00%	35.00%
Private Pay	2.00%	2.00%
Charity Care	<u>2.00%</u>	<u>2.00%</u>
Total	100.00%	100.00%

Capability and Feasibility

Total project costs of \$2,361,979 will be met as follows: Equity of \$236,198 via the proposed members and a bank loan of \$2,185,781 at an interest rate of 5.25% for a five-year term. The applicant provided a bank letter of interest in support of the financing.

Working capital requirements are estimated at \$573,778, which is equivalent to two months of third year expenses. The applicant will finance \$286,839 at an interest rate of 5.25% for a five-year term. The applicant provided a bank letter of interest in support of the financing. BFA Attachment A is the net worth statements of the proposed members, which indicates the availability of sufficient funds for the equity contribution. The applicant provided an affidavit indicating that equity will be provided disproportionate to ownership interests. BFA Attachment B is the pro forma balance sheet as of the first day of operation, which indicates a positive net asset position of \$523,087.

The submitted budget indicates a net income of \$39,786 and \$230,025 during the first and third years, respectively. Revenues are based on current reimbursement methodologies for the type of services they are providing. The submitted budget appears reasonable.

Conclusion

Subject to the noted contingencies, the applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	Personal Net Worth Statement
BFA Attachment B	Pro Forma Balance Sheet
BFA Attachment C	Lease Agreement

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a Diagnostic and Treatment Center to be located at 121 Executive Drive, New Windsor for primary and specialty care through the relocation, consolidation, and conversion of multiple private practices, 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:

211085 B

FACILITY/APPLICANT:

KD Hudson Ventures, LLC d/b/a
Avalon Medical Group

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 working capital loan that is acceptable to the Department of Health. (BFA)
3. Submission of a bank loan that is acceptable to the Department of Health. (BFA)
4. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
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. This project must be completed by **May 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **February 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf.
Questions may be directed to the Division of Hospitals and Diagnostic & Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov [HSP]

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



Project # 211201-E
MVNY Partners I, LLC d/b/a
U.S. Renal Care Faxton Dialysis

Program: Diagnostic and Treatment Center **County:** Oneida
Purpose: Establishment **Acknowledged:** July 21, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000 which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year three</u>
Revenues	\$6,704,022	\$7,604,386
Expenses	<u>\$6,050,514</u>	<u>\$6,750,622</u>
Net Income	\$653,508	\$853,764

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine, and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services, and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

<u>Revenues</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
Medicaid-FFS	\$219.88	\$96,307	\$220.15	\$103,910
Medicaid-MC	\$239.97	234,689	\$240.02	253,217
Medicare-FFS	\$260.01	3,016,166	\$260.00	1,903,450
Medicare-MC	\$319.99	1,891,123	\$319.93	3,551,845
Commercial-FFS	\$699.81	1,119,703	\$660.15	1,357,278
Commercial-MC	\$499.66	342,766	\$500.20	440,675
Private Pay	\$256.86	56,252	\$257.17	60,693
All Other	\$260.21	118,914	\$260.25	128,302
Bad Debt		<u>-171,898</u>		<u>-194,984</u>
Total		\$6,704,022		\$7,604,386
<u>Expenses</u>				
Operating	\$251.34	\$5,501,353	\$262.59	\$6,201,338
Capital	<u>\$25.09</u>	<u>549,161</u>	<u>\$23.26</u>	<u>549,284</u>
Total	\$276.43	\$6,050,514	\$285.85	\$6,750,622
Net Income		\$653,508		\$853,764
Total Treatments		21,888		23,616
Cost per Treatment		\$276.43		\$285.85

Utilization broken down by payor source during Year One and Year Three is as follows:

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid-FFS	438	2.00%	472	2.00%
Medicaid-MC	978	4.47%	1,055	4.47%
Medicare-FFS	11,600	53.00%	7,321	31.00%
Medicare-MC	5,910	27.00%	11,102	47.00%
Commercial-FFS	1,600	7.31%	2,056	8.71%
Commercial-MC	686	3.13%	881	3.73%
Private Pay	219	1.00%	236	1.00%
All Other	<u>457</u>	<u>2.09%</u>	<u>493</u>	<u>2.09%</u>
Total	21,888	100%	23,616	100%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Lukes's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from

COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners I, LLC as the new operator of the 36-station chronic renal dialysis center located at 1676 Sunset Avenue, Utica, currently operated by Faxton-St. Lukes, 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:

211201 E

MVNY Partners I, LLC d/b/a U.S. Renal
Care Faxton Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date.
[PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 211202-B
MVNY Partners II, LLC d/b/a
U.S. Renal Care St. Luke's Home Dialysis

Program: Diagnostic and Treatment Center **County:** Oneida
Purpose: Establishment and Construction **Acknowledged:** May 24, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year three</u>
Revenues	\$1,367,372	\$1,530,262
Expenses	\$1,297,918	\$1,418,673
Net Income	\$69,454	\$111,589

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
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21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

<u>Revenues</u>	Year One		Year Three	
	Per Treat	Total	Per Treat	Total
Medicaid-FFS	\$220.70	\$19,642	\$220.09	\$20,909
Medicaid-MC	\$239.86	47,971	\$239.75	51,066
Medicare-FFS	\$259.99	615,139	\$260.02	383,011
Medicare-MC	\$320.07	385,690	\$320.06	714,701
Commercial-FFS	\$700.49	228,360	\$659.69	273,111
Commercial-MC	\$499.33	69,906	\$500.97	88,672
Private Pay	\$254.93	11,472	\$254.44	12,213
All Other	\$260.77	24,252	\$260.78	25,817
Bad Debt		<u>-35,060</u>		<u>-39,238</u>
Total		\$1,367,372		\$1,530,262
<u>Expenses</u>				
Operating	\$258.99	\$1,156,144	\$268.33	\$1,275,118
Capital	<u>\$31.76</u>	<u>141,774</u>	<u>\$30.21</u>	<u>143,555</u>
Total	\$290.75	\$1,297,918	\$298.54	\$1,418,673
 Net Income		 <u>\$69,454</u>		 <u>\$111,589</u>
 Total Treatments		 4,464		 4,752
Cost per Treatment		\$290.75		\$298.54

Utilization broken down by payor source during Year One and Year Three is as follows:

<u>Payor</u>	Year One		Year Three	
	Treatments	%	Treatments	%
Medicaid-FFS	89	1.99%	95	2.00%
Medicaid-MC	200	4.48%	213	4.48%
Medicare-FFS	2,366	53.01%	1,473	31.01%
Medicare-MC	1,205	26.99%	2,233	46.99%
Commercial-FFS	326	7.30%	414	8.71%
Commercial-MC	140	3.14%	177	3.72%
Private Pay	45	1.01%	48	1.01%
All Other	<u>93</u>	<u>2.08%</u>	<u>99</u>	<u>2.08%</u>
Total	4,464	100%	4,752	100%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment, and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Lukes's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019 including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021 the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from

COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners II, LLC as the operator of the 8-station dialysis center located at 1650 Champlin Ave, Utica, currently operated by Faxton-St. Luke's and certify Home Hemo and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211202 B

MVNY Partners II, LLC d/b/a U.S. Renal
St. Luke's Home Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date.
[PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 211203-B
MVNY Partners III, LLC d/b/a
U.S. Renal Care Masonic Care Community Dialysis

Program: Diagnostic and Treatment Center **County:** Oneida
Purpose: Establishment and Construction **Acknowledged:** May 27, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$2,425,982	\$2,643,180
Expenses	<u>\$2,310,335</u>	<u>\$2,477,503</u>
Net Income	\$115,647	\$165,677

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Assignment and Assumption of Lease and Landlord Consent, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
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21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid FFS	\$220.56	\$34,848	\$220.21	\$36,115
Medicaid MC	\$239.75	85,110	\$239.69	88,205
Medicare FFS	\$259.98	1,091,376	\$260.05	661,565
Medicare MC	\$320.06	684,288	\$319.98	1,234,483
Commercial FFS	\$699.75	405,156	\$659.77	471,737
Commercial MC	\$500.11	124,027	\$500.53	153,161
Private Pay	\$257.65	20,354	\$257.26	21,095
Other	\$260.78	43,028	\$259.26	44,593
Bad Debt		<u>(62,205)</u>		<u>(67,774)</u>
Total Revenues		2,425,982		\$2,643,180
<u>Expenses</u>				
Operating	\$257.02	\$2,035,635	\$267.97	\$2,199,751
Capital	<u>\$34.68</u>	<u>274,700</u>	<u>\$33.84</u>	<u>277,752</u>
Total Expenses	\$291.71	\$2,310,335	\$301.80	\$2,477,503
Net Income		<u>\$115,647</u>		<u>\$165,677</u>
Treatments		7,920		8,209
Cost per Treatment		\$291.71		\$301.80

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

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid FFS	158	1.99%	164	2.00%
Medicaid MC	355	4.48%	368	4.48%
Medicare FFS	4,198	53.01%	2,544	30.99%
Medicare MC	2,138	26.99%	3,858	47.00%
Commercial FFS	579	7.31%	715	8.71%
Commercial MC	248	3.31%	306	3.73%
Private Pay	79	1.00%	82	1.00%
All Other	<u>165</u>	<u>2.08%</u>	<u>172</u>	<u>2.10%</u>
Total	7,920	100%	8,209	100%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Lukes's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of

unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners III, LLC as the operator of the 20-station dialysis center located at 2150 Bleeker St., Utica, currently operated by Faxton-St. Lukes and certify Home Hemo and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211203 B

MVNY Partners III, LLC d/b/a U.S. Renal
Care Masonic Care Community Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Assignment and Assumption of Lease and Landlord Consent, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)

23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 211204-B
MVNY Partners IV, LLC d/b/a
U.S. Renal Care Rome Dialysis

Program: Diagnostic and Treatment Center **County:** Oneida
Purpose: Establishment and Construction **Acknowledged:** May 21, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year three</u>
Revenues	\$1,632,025	\$1,854,863
Expenses	<u>\$1,512,828</u>	<u>\$1,699,003</u>
Net Income	\$119,197	\$155,860

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
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21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDTC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

<u>Revenues</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
Medicaid-FFS	\$219.09	\$23,443	\$220.38	\$25,344
Medicaid-MC	\$239.56	57,256	\$239.92	61,899
Medicare-FFS	\$259.99	734,198	\$259.94	464,256
Medicare-MC	\$319.90	460,339	\$320.02	866,304
Commercial-FFS	\$700.67	272,559	\$659.45	331,043
Commercial-MC	\$499.62	83,436	\$499.92	107,482
Private Pay	\$258.36	13,693	\$255.22	14,803
All Other	\$263.15	28,946	\$262.97	31,293
Bad Debt		<u>-41,845</u>		<u>-47,561</u>
Total		\$1,632,025		\$1,854,863
<u>Expenses</u>				
Operating	\$250.19	\$1,333,032	\$264.07	\$1,521,053
Capital	<u>\$33.75</u>	<u>179,796</u>	<u>\$30.89</u>	<u>177,950</u>
Total	\$283.94	\$1,512,828	\$294.96	\$1,699,003
Net Income		<u>\$119,197</u>		<u>\$155,860</u>
Total Treatments		5,328		5,760
Cost per Treatment		\$283.94		\$294.96

Utilization broken down by payor source during Year One and Year Three is as follows:

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid-FFS	107	2.01%	115	2.00%
Medicaid-MC	239	4.49%	258	4.48%
Medicare-FFS	2,824	53.01%	1,786	31.01%
Medicare-MC	1,439	27.01%	2,707	47.00%
Commercial-FFS	389	7.30%	502	8.70%
Commercial-MC	167	3.13%	215	3.73%
Private Pay	53	.99%	58	1.01%
All Other	<u>110</u>	<u>2.06%</u>	<u>119</u>	<u>2.07%</u>
Total	5,328	100%	5,760	100%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Lukes's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from

COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

- | | |
|------------------|--|
| BFA Attachment A | Net Worth Statements for the members of AICA Holdings, LLC |
| BFA Attachment B | Allocation of Combined Purchase Price by Clinic |
| BFA Attachment C | Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021 |
| BFA Attachment D | Post-Closing Organizational Chart |
| BFA Attachment E | Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021. |
| BFA Attachment F | Agreements and Contracts |
| BFA Attachment G | Pro-Forma Balance Sheets |
| BFA Attachment H | USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023 |

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners IV, LLC as the operator of the 16-station dialysis center located at 91 Perimeter Rd, Rome currently operated by Faxton-St Lukes and certify Home Hemodialysis and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211204 B

MVNY Partners IV, LLC d/b/a U.S. Renal
Care Rome Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
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25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 211205-B
MVNY Partners V, LLC d/b/a
U.S. Renal Care Herkimer Dialysis

Program: Diagnostic and Treatment Center **County:** Herkimer
Purpose: Establishment and Construction **Acknowledged:** May 21, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year three</u>
Revenues	\$1,367,372	\$1,530,262
Expenses	<u>\$1,297,266</u>	<u>\$1,411,897</u>
Net Income	\$70,106	\$118,365

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2020

Proposal

Upon approval of the CONs below, all seven Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

<u>Revenues</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
Medicaid-FFS	\$220.70	\$19,642	\$220.09	\$20,909
Medicaid-MC	\$239.86	47,971	\$239.75	51,066
Medicare-FFS	\$259.99	615,139	\$260.02	383,011
Medicare-MC	\$320.07	385,690	\$320.06	714,701
Commercial-FFS	\$700.49	228,360	\$659.69	273,111
Commercial-MC	\$499.33	69,906	\$500.97	88,672
Private Pay	\$254.93	11,472	\$254.44	12,213
All Other	\$260.77	24,252	\$260.78	25,817
Bad Debt		<u>-35,060</u>		<u>-39,238</u>
Total		\$1,367,372		\$1,530,262
 <u>Expenses</u>				
Operating	\$262.28	\$1,170,805	\$270.48	\$1,285,331
Capital	<u>\$28.33</u>	<u>126,461</u>	<u>\$26.63</u>	<u>126,566</u>
Total	\$290.61	\$1,297,266	\$297.11	\$1,411,897
 Net Income		 <u>\$70,106</u>		 <u>\$118,365</u>
 Total Treatments		 4,464		 4,752
Cost per Treatment		\$290.61		\$297.11

Utilization broken down by payor source during Year One and Year Three is as follows:

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid-FFS	89	1.99%	95	2.00%
Medicaid-MC	200	4.48%	213	4.48%
Medicare-FFS	2,366	53.01%	1,473	31.01%
Medicare-MC	1,205	26.99%	2,233	46.99%
Commercial-FFS	326	7.30%	414	8.71%
Commercial-MC	140	3.14%	177	3.72%
Private Pay	45	1.01%	48	1.01%
All Other	<u>93</u>	<u>2.08%</u>	<u>99</u>	<u>2.08%</u>
Total	4,464	100%	4,752	100%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment, and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Lukes's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from

COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023 as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners V, LLC as the operator of the 8-station dialysis center located at 201 E State St, Herkimer currently operated by Faxton-St Lukes, and certify Home Hemo and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211205 B

MVNY Partners V, LLC d/b/a U.S. Renal
Care Herkimer Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 211206-B
MVNY Partners VI, LLC d/b/a
U.S. Renal Care Hamilton Dialysis

Program: Diagnostic and Treatment Center **County:** Madison
Purpose: Establishment and Construction **Acknowledged:** May 21, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively, and both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$1,040,960	\$1,186,607
Expenses	\$992,128	\$1,111,920
Net Income/Loss	\$48,832	\$74,687

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Assignment and Assumption of Lease and Landlord Consent, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
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21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid FFS	\$220.80	\$14,573	\$220.00	\$15,840
Medicaid MC	\$240.49	35,592	\$240.29	38,687
Medicare FFS	\$259.98	421,949	\$260.00	252,720
Medicare MC	\$320.16	307,354	\$320.00	564,480
Commercial FFS	\$700.57	195,460	\$659.83	233,580
Commercial MC	\$501.64	66,217	\$499.49	82,916
Private Pay	\$257.94	8,512	\$257.00	9,252
Other	\$260.78	17,994	\$260.77	19,558
Bad Debt		<u>(26,691)</u>		<u>(30,426)</u>
Total Revenues		1,040,960		\$1,186,607
 <u>Expenses</u>				
Operating	\$252.37	\$835,350	\$265.46	\$955,660
Capital	<u>\$47.36</u>	<u>156,778</u>	<u>\$43.41</u>	<u>156,260</u>
Total Expenses	\$299.74	\$992,128	\$308.87	\$1,111,920
 Net Income				
		<u>\$48,832</u>		<u>\$74,687</u>
 Treatments				
		3,310		3,600
Cost per Treatment		\$299.74		\$308.87

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

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid FFS	66	1.99%	72	2.00%
Medicaid MC	148	4.47%	161	4.47%
Medicare FFS	1,623	49.03%	972	27.00%
Medicare MC	960	29.00%	1,764	49.00%
Commercial FFS	279	8.43%	354	9.83%
Commercial MC	132	3.99%	166	4.61%
Private Pay	33	1.00%	36	1.00%
All Other	<u>69</u>	<u>2.08%</u>	<u>75</u>	<u>2.08%</u>
Total	3,310	100.00%	3,600	100.00%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Luke's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of

unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners VI, LLC as the operator of the 8-station dialysis center located at 10 Easton St, Hamilton currently operated by Faxton-St Lukes, and certify Home Hemo and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211206 B

MVNY Partners VI, LLC d/b/a U.S. Renal
Care Hamilton Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Assignment and Assumption of Lease and Landlord Consent, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)

23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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*.



Department of Health | **Public Health and Health Planning Council**

Project # 211207-B
MVNY Partners VII, LLC d/b/a
U.S. Renal Care Oneida Dialysis

Program: Diagnostic and Treatment Center **County:** Madison
Purpose: Establishment and Construction **Acknowledged:** May 26, 2021

Executive Summary

Description

U.S. Renal Care, Inc., through a subsidiary and in partnership with two local physicians, seeks approval to acquire seven dialysis centers currently operated by Faxton-St. Luke's Healthcare. Each location will be owned and operated by a separate limited liability corporation, MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC.

CON	Proposed Operator	Facility (proposed d/b/a)	Stations
211201	MVNY Partners I, LLC	U.S. Renal Care Faxton Dialysis 1676 Sunset Ave, Utica	36
211202	MVNY Partners II, LLC	U.S. Renal Care St. Luke's Home Dialysis 1650 Champlin Ave, Utica	8
211203	MVNY Partners III, LLC	U.S. Renal Care Masonic Care Community Dialysis 2150 Bleeker St, Utica	20
211204	MVNY Partners IV, LLC	U.S. Renal Care Rome Dialysis 91 Perimeter Rd, Rome	16
211205	MVNY Partners V, LLC	U.S. Renal Care Herkimer Dialysis 201 E. State St, Herkimer	8
211206	MVNY Partners VI, LLC	U.S. Renal Care Hamilton Dialysis 10 Easton St, Hamilton	8
211207	MVNY Partners VII, LLC	U.S. Renal Care Oneida Dialysis 131 Main St, Oneida	8

All seven operators are identical in structure, as indicated in the following chart:

Member	%
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC (90%) (U.S. Renal Care, Inc. subsidiary)	
AICA Holdings, LLC (10%)	
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc. All the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc. AICA Holdings, LLC is comprised of two local nephrologists. As of December 31, 2020, U.S. Renal Care, Inc. (USRC) operated 332 outpatient End-Stage Renal Disease (ESRD) centers located in 32 states.

On March 1, 2021, Faxton-St. Luke's Healthcare entered into an Operating Asset Transfer Agreement (OATA) with MVNY Partners, LLC, the sole member of all seven proposed operators, for the sale and acquisition of the dialysis centers for \$3,000,000. Faxton-St. Luke's Healthcare also sold non-Article 28 assets to MVNY Partners LLC for \$7,000,000, which are not part of this CON application.

In the proposed transactions, MVNY Partners, LLC will convey its interest in each of the seven locations to the respective proposed operator LLCs for the allocated amounts indicated in the table, per the Bill of Sale, Assignment and Assumption Agreement (BSAAA). The applicant states the members will pay it from equity. The OATA and BSAAA will be effectuated upon approval by the Public Health and Health Planning Council (PHHPC).

Purchase Price Allocation by CON	
CON 211201	\$1,297,059
CON 211202	\$255,882
CON 211203	\$529,412
CON 211204	\$264,706
CON 211205	\$264,706
CON 211206	\$158,824
CON 211207	\$229,412

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in the number of stations. After approval, all seven sites will provide Home Training and Support services.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There are no project costs associated with this application. The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc., and \$300,000 from AICA Holdings, LLC's members. BFA Attachments A and E are the net worth summary of AICA Holdings, LLC, members and the Financial Statement of U.S. Renal Care, Inc., respectively. Both statements demonstrate sufficient resources to meet the equity requirements. The projected budget for the subject site is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$1,312,511	\$1,471,392
Expenses	<u>\$1,260,843</u>	<u>\$1,385,912</u>
Net Income/Loss	\$51,668	\$85,480

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 transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
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23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

Approval conditional upon:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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

February 10, 2022

Need Analysis

Proposal

Upon approval of the CONs below, all seven of Faxton- St. Luke's Healthcare outpatient dialysis centers will be acquired by USRC and two local nephrologists. There will be no changes to the number of stations at the sites, located in Oneida, Herkimer, and Madison counties. Six of the sites will add Home Hemodialysis and Home Peritoneal Dialysis Training and Support services (one site already provides the service) in keeping with the CMS and New York State goal of increasing the availability and use of these modalities.

CON	Facility	Stations	County	New Services	Proposed Medical Director
211201	USRC Faxton 1676 Sunset Ave, Utica	36	Oneida	None	Ahmad Mian
211202	USRC St. Luke's 1650 Champlin Ave, Utica	8	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211203	USRC Masonic 2150 Bleeker St, Utica	20	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211204	USRC Rome 91 Perimeter Rd, Rome	16	Oneida	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211205	USRC Herkimer 201 E. State St, Herkimer	8	Herkimer	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Ahmad Mian
211206	USRC Hamilton 10 Easton St, Hamilton	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge
211207	USRC Oneida 131 Main St, Oneida	8	Madison	Home Hemodialysis and Home Peritoneal Dialysis Training and Support	Charles Eldredge

Analysis

The primary service areas of the facilities are their respective counties. The use of dialysis is most prevalent in those aged 65+ and in nonwhite populations. Comparisons between the counties and New York State for these groups are shown below.

	Oneida County	Herkimer County	Madison County	New York State
Population (2019)	228,671	61,319	70,941	19,453,561
Ages 65 and Over	19.2%	21.2%	18.9%	16.9%
Nonwhite	14.0%	4.0%	5.4%	30.4%

Source: U.S. Census 2019

Conclusion

There will be no change in the number of stations at any of the sites. After approval, all sites will offer Home Hemodialysis and Home Peritoneal Dialysis Training and Support services to further the goal of reducing in-center dialysis where possible.

Program Analysis

Character and Competence

The proposed membership of MVNY Partners I, LLC, MVNY Partners II, LLC, MVNY Partners III, LLC, MVNY Partners IV, LLC, MVNY Partners V, LLC, MVNY Partners VI, LLC, and MVNY Partners VII, LLC are identical, as indicated in the chart below.

<u>Member</u>	<u>Interest</u>
MVNY Partners, LLC	100%
MVNY Partners Holdings, LLC	(90%)
<u>Managers</u>	
Mark Caputo	
Mary Dittrich, MD	
Lynelle McLain	
Steve Nottingham	
James Shelton	
Thomas Weinburg	
AICA Holdings, LLC	(10%)
Charles Eldredge, MD (50%)	
Ahmad Mian, MD (50%)	
Total	100%

MVNY Partners Holdings, LLC is a subsidiary of U.S. Renal Care, Inc., and all of the managers of MVNY Partners Holdings, LLC are employed by U.S. Renal Care, Inc.

Ahmad Mian, MD is a practicing Nephrologist and currently the Medical Director of MVHS Regional Dialysis Program. He is a partner at Mohawk Valley Nephrology Associates and the current Treasurer of MVHS Medical Staff. He received his medical degree from Ross University School of Medicine in Dominica and completed his residency in Internal Medicine and Nephrology fellowship at Drexel University College of Medicine. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Mian will be the Medical Director for three of the seven locations.

Charles Eldredge, MD is a practicing Nephrologist. He has owned multiple private practices in Nephrology and Internal Medicine and is a founding partner of Mohawk Valley Nephrology Associates. He is the Medical Director of Faxton-St. Luke's Health Care Dialysis Unit, and is the Treasurer of the Executive Committee and Chairman of the Nurse-Physician Liaison Committee. He received his medical degree from Stony Brook College of Medicine and completed his Internal Medicine residency and Nephrology fellowship at the University of Michigan. He is board-certified in Internal Medicine with a sub-certification in Nephrology. Dr. Eldredge will be the Medical Director for four of the seven locations.

Mark Caputo is the Chief Executive Officer and President of U.S. Renal Care, Inc. where he develops and executes strategic plans; drives operational effectiveness; meets company clinical, operational, and financial goals, and represents the company with the press, public, and professional organizations. He was previously employed as the Managing Partner for Joint Ventures at Fresenius Medical Care. He served as Chairman of the Board of Sound Physicians and was previously employed as CEO of Liberty Dialysis.

Mary Dittrich, MD is the Chief Medical Officer of U.S. Renal Care, Inc. She is the current President of Liberty Administrative Services and is a Consultant for Remedy Partner after previously being their Senior Medical Director. She is the Chief Medical Officer for Glacier Administrative Services and Liberty Health Partners. She was the Medical Director of Liberty Dialysis in Anchorage and Boise. She received her medical degree from the University of Colorado Health Sciences Center and completed her residency in Internal Medicine and Nephrology Fellowship at the University of Washington. She is board certified with a sub-certification in Nephrology.

Lynelle McLain is the Chief Accounting Officer of U.S. Renal Care, Inc. where she manages the Corporate Controller and team, Facility Level Controller and team, Treasury Department, Financial Reporting Team, and Accounts Payable. She reviews and publishes financial statements in accordance with GAAP; reviews and publishes the quarterly lender compliance certificates; reviews and publishes quarterly distribution calculations; and participates and assists with the category management projects. She oversees the monthly financial close process and distribution of financial statements, the annual financial audit and audited financial statements, the quarterly lender financial reporting, and the accuracy of work produced by the accounting department personnel; and oversees and manages the cash position of the company.

Steven Nottingham is the Senior Vice President of Strategic Partnerships of U.S. Renal Care, Inc. where he is responsible for driving profitable growth in 380 dialysis clinics. He is responsible for organizational design and structure for home dialysis and accelerating growth and home penetration, strategizing with the Manage Care and Value Base Teams for solutions to enhance relationships, and creating narrow network. Previously, he was the President of the East Division, the General Manager of the Western Group at Fresenius Kidney Care, the Executive Vice President of Emerging Business and Customer Experience at Iron Mountain Corporation, the Executive Vice President of Product Management, the Senior Vice President of Western US, Senior Vice President of Midwest US, Vice President of Los Angeles and Southwest Territory, and the General Manager of Los Angeles.

James Shelton is the Executive Vice President and Chief Financial Officer of U.S. Renal Care, Inc., where he is responsible for directing the fiscal functions of the corporation and providing strategic leadership for the company by working with the Executive Management Team to establish long-range goals, strategies, plans, and policies, as well as for the overall direction, coordination, and evaluation of the Accounting and Financial Department. He enhances and/or develops, implements, and enforces policies and procedures of the organization by way of systems that will improve the overall operation and effectiveness of the corporation.

Thomas Weinberg is the Executive Vice President, General Counsel, and Secretary of U.S. Renal Care, Inc., where his responsibilities include the representation and protection of the Company in all legal matters and challenges. He heads the law and risk management functions of the Company, serves as Corporate Secretary for the parent company, and coordinates all representation by others. He assists the CEO, parent board, and other subsidiary boards with governance, corporate compliance, and tax-exempt status and in the planning and strategic development process for all aspects of the organization.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Mary Dittrich, Steven Nottingham, James Shelton, and Thomas Weinberg, disclosed U.S. Renal Care, Inc (USRC) acquired Dialysis Corporation of America (DCA), a Florida corporation (nka Dialysis Company of America, LLC), in June 2010. In February 2010, prior to the USRC's acquisition of DCA, DCA received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) with respect to an investigation related to alleged improper Medicare and Medicaid billing at certain DCA clinics. No non-DCA facilities owned by U.S. Renal Care were involved in the above-referenced investigation and litigation. DCA fully cooperated with the inquiry. The investigation related to two qui tam suits with the Department of Justice and private litigants.

United States ex. rel. Davis v. Dialysis Corporation of America, Inc., Case No. 1:08-cv-02829 (D. Md); and United States ex. rel. Harris, et al. v. DCA, Case No. 1:09-cv-02457-JKB (D. Md). USRC denied any impropriety or liability by DCA in both cases but determined that it should settle these cases with the U.S government and the private litigants. The Davis case was settled on May 17, 2013, and the Harris case was settled September 12, 2014. Both suits have been dismissed.

Dr. Eldredge disclosed involvement in two malpractice lawsuits. On October 22, 2018, a malpractice suit was filed against Mohawk Valley Nephrology Associates, the hospital, Mohawk Valley Health System, and other physicians by the patient's son. He alleges her cause of death was due to a medication she received erroneously. She received 10 doses of methadone 10 mg. The methadone was erroneously copied from another patient's medication list by a nurse on the admission previous to her final admission and ordered by the physician on her final admission. The patient had been admitted on her final admission and had refused all treatment. The case is in the discovery phase.

The second malpractice suit was filed on July 23, 2019 by the administrator of the estate, the other individuals. They allege the patient was a college student brought in by her roommate because of confusion and was admitted on April 8, 2019. She had bilateral frontal cerebral contusions and hemorrhages and a bruised left orbit. She was seen by neurology and neurosurgery that day. She quickly deteriorated on April 9th and was taken to the OR for an intercranial drain. On April 10th, 2019 Dr. Eldredge was consulted for polyuria and hyponatremia, felt to be central diabetes insipidus. She was medically managed. She remained on life support for several days. Dr. Eldredge was never served for this case. He was notified on October 3rd, 2019 when asked to sign an affidavit for change of venue to Utica. The case is in the discovery phase.

Additionally, the staff from the DHDC 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 took the following enforcement action against U.S. Renal Care, Inc affiliated facilities:

- On April 7, 2017, the Department issued a Stipulation and Order (S&O) and \$2,000 fine for surveillance findings of December 9, 2016 related to construction prior to Department of Health approval.

Star Ratings - Dialysis Facility Compare (DFC)

U.S. Renal Care, Inc operates over 300 dialysis centers, nine of which are located in New York. DSI Newburgh Dialysis, Inc. is a subsidiary of U.S. Renal Care, Inc. The below chart lists the Star Ratings for all dialysis centers that USRC operates or is affiliated within NYS.

Facility	Address	STAR Rating
U.S. Renal Care Tonawanda	3161 Eggert Road Tonawanda, NY 14150	***
U.S. Renal Care Amherst Dialysis	2880 Sheridan Avenue Tonawanda, NY 14150	**
U.S. Renal West Cheektowaga Dialysis	2681 Harlem Road Cheektowaga, NY 14225	****
U.S. Renal Care Williamsville Dialysis	7964 Transit Road Suite 8-A Williamsville, NY 14221	**
DSI Dutchess Dialysis	2585 South Road Poughkeepsie, NY 12601	***
DSI Newburgh Dialysis	39 North Plank Road Newburgh, NY 12550	***
U.S. Renal Care Cheektowaga Dialysis	2875 Union Rd Suite C/D Cheektowaga, NY 14225	**
U.S. Renal Care Pelham Parkway Dialysis	1400 Pelham Parkway South Bronx, NY 10461	***
U.S. Renal Care South Flushing Dialysis	71-12 Park Ave Flushing, NY 11365	*****

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

The applicant has submitted an operating budget for the subject site for the first and third years, in 2022 dollars, which is summarized below:

	<u>Year One</u>		<u>Year Three</u>	
	<u>Per Treat</u>	<u>Total</u>	<u>Per Treat</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid FFS	\$218.74	\$18,374	\$220.70	\$19,642
Medicaid MC	\$239.98	44,876	\$239.86	47,971
Medicare FFS	\$260.03	532,022	\$260.06	313,373
Medicare MC	\$320.01	387,533	\$320.05	699,955
Commercial FFS	\$700.14	246,449	\$659.77	289,639
Commercial MC	\$499.95	83,491	\$499.11	102,816
Private Pay	\$255.52	10,732	\$254.93	11,472
Other	\$260.78	22,688	\$260.77	24,252
Bad Debt		<u>(33,654)</u>		<u>(37,728)</u>
Total Revenues		1,312,511		\$1,471,392
<u>Expenses</u>				
Operating	\$247.65	\$1,034,177	\$259.25	\$1,157,310
Capital	<u>\$54.28</u>	<u>226,666</u>	<u>\$51.21</u>	<u>228,602</u>
Total Expenses	\$301.93	\$1,260,843	\$310.46	\$1,385,912
Net Income		<u>\$51,668</u>		<u>\$85,480</u>
Treatments		4,176		4,464
Cost per Treatment		\$301.93		\$310.46

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

<u>Payor</u>	<u>Year One</u>		<u>Year Three</u>	
	<u>Treatments</u>	<u>%</u>	<u>Treatments</u>	<u>%</u>
Medicaid FFS	84	2.01%	89	1.99%
Medicaid MC	187	4.48%	200	4.48%
Medicare FFS	2,046	48.99%	1,205	26.99%
Medicare MC	1,211	29.00%	2,187	48.99%
Commercial FFS	352	8.43%	439	9.83%
Commercial MC	167	4.00%	206	4.61%
Private Pay	42	1.01%	45	1.01%
All Other	<u>87</u>	<u>2.08%</u>	<u>93</u>	<u>2.08%</u>
Total	4,176	100.00%	4,464	100.00%

The following is noted with respect to all seven submitted budgets:

- The current operator, Faxton-St. Luke's Healthcare, indicated they did not receive any CARES Act funding for their seven dialysis clinics. The current operator has also not received previous State support for these programs.
- Medicaid and Medicare revenues are based upon the payors' current reimbursement methodologies, while the commercial rates are based on USRC's established contracts within the proposed center's service area.
- Expenses are based on current market rates and USRC's contracted rates. Expenses include consideration for the average clinical utilization of medications and medical supplies, utilities, equipment, and professional fees.
- Utilization is based upon the service area experience and industry trends.
- The submitted budgets are reasonable

In BFA Attachment G, the following are provided:

- The terms of the executed Operating Asset Transfer Agreement (OATA) for the seven dialysis centers that will be effectuated upon PHHPC approval of the CONs.
- The terms of the draft Bill of Sale, Assignment and Assumption Agreement (BSAAA) that will be effectuated upon PHHPC approval of this application. 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 transferor to the contrary, to be liable for any Medicaid overpayments made to the facility and/or surcharges, assessments, or fees due from the Seller 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 Seller of its ability and responsibility. Currently, the facility has no outstanding Medicaid audit liabilities or assessments.
- The terms of the executed lease and draft lease assignments for each site. The applicant has submitted affidavits stating the leases are arm's length arrangements and have provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rates.
- The terms of the draft Administrative Services Agreements (ASA). Each site will enter into an administrative services agreement with Dialysis Newco, LLC, which is an upstream parent of the MVNY Partners Holding, LLC. However, each licensed operator retains ultimate authority, responsibility, and control of the operations. There is common ownership between the applicant and the ASA provider, as shown on, the post-closing organization chart, BFA Attachment D. The applicant has submitted an executed attestation acknowledging understanding of the statutory and regulatory required reserve powers that cannot be delegated, and that they will not willfully engage in any such illegal delegations of authority.

Faxton-St. Luke's Healthcare and U.S. Renal Care, Inc. ("USRC"), entered into an Administrative Services Agreement as of March 1, 2021. USRC will assist the hospital in the continued operation of the dialysis business by providing certain non-clinical business and administrative services until the earlier of the dialysis business transfer date or termination of the Administrative Services Agreement. The current monthly fee is \$80,000 for all seven locations, per the applicant.

Capability and Feasibility

The \$3,000,000 purchase price for the seven dialysis centers will be funded via equity, \$2,700,000 from U.S. Renal Care, Inc. and \$300,000 from AICA Holdings, LLC's members. There are no project costs associated with this application.

Working capital is estimated based on two months of first-year expenses. U.S. Renal Care and AICA Holding's members will contribute the working capital in proportion to their membership interest. BFA Attachment H is the pro forma balance sheets for each facility.

The submitted budgets are reasonable. The individual members' net worth statements (BFA Attachment A) show sufficient liquid resources to meet their portion of the project's equity requirements.

BFA Attachment D is the U.S. Renal Care, Inc.'s NYS-affiliated dialysis centers and their income statement for 2020 and June 30, 2021, which shows positive net income. BFA Attachment F is USRC and Subsidiaries' 2019-2020 certified financial statements and their internal quarterly report as of May 31, 2021. These financial reports reflect both the predecessor and successor organizations for the company that entered into a merger agreement with several sponsors including Bain Capital, Summit Partners, and Revelstoke Capital to acquire approximately 95% of the outstanding equity interest in the company. This acquisition closed on June 28, 2019 and total consideration paid for the Company was \$801.0 million.

The financial statements and quarterly reports indicate the entity maintained positive working capital and net asset positions for the relevant time periods. The net profit was \$28,618,000 after taxes in 2019, including a one-time transaction and legal cost of \$96.8 million. In 2020 they had a net loss after taxes of \$29,898,000, and as of May 31, 2021, the loss increased to \$36,070,607. The applicant indicated that in addition to higher general and administrative expenses for investments in quality and growth, the COVID-19 pandemic increased the mortality rates among dialysis patients resulting in approximately \$33 million reduction in revenue in 2020 and \$30 million through May 2021. USRC also had over \$9 million of

unreimbursed pandemic expenses in 2020 and \$15.2 million through May 2021. With the recovery from COVID-19 underway, USRC projects a profit of \$21,626,251 in 2022 and \$52,864,304 in 2023, as shown on BFA Attachment I. USRC has sufficient liquid resources available to cover its portion of equity requirements.

Conclusion

The applicants have demonstrated the capability to proceed in a financially feasible manner

Attachments

BFA Attachment A	Net Worth Statements for the members of AICA Holdings, LLC
BFA Attachment B	Allocation of Combined Purchase Price by Clinic
BFA Attachment C	Affiliated USRC New York State Dialysis Centers and the New York State Consolidated Financial Statement for 2020 and June 30, 2021
BFA Attachment D	Post-Closing Organizational Chart
BFA Attachment E	Financial Summary of USRC and Subsidiaries Certified 2019-2020 and Unaudited Internal Quarterly Report as of May 31, 2021.
BFA Attachment F	Agreements and Contracts
BFA Attachment G	Pro-Forma Balance Sheets
BFA Attachment H	USRC & Subsidiaries Projected Internal Income Statement for 2022 and 2023

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish MVNY Partners VII, LLC as the operator of the 8-station dialysis center located at 131 Main St., Oneida currently operated by Faxton-St. Luke's and certify Home Hemo and Home Peritoneal Dialysis Training & Support 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:

FACILITY/APPLICANT:

211207 B

MVNY Partners VII, LLC d/b/a U.S.
Renal Care Oneida Dialysis

APPROVAL CONTINGENT UPON:

1. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
2. Submission of an executed Administrative Services Agreement, acceptable to the Department. (BFA)
3. Submission of an executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (BFA)
4. Submission of an executed Assignment of Lease, acceptable to the Department. (BFA)
5. Submission of a photocopy of a Certificate of Assumed Name, acceptable to the Department. (CSL)
6. Submission of a photocopy of an amended and executed Articles of Organization, acceptable to the Department. (CSL)
7. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. (CSL)
8. Submission of a photocopy of an amended and executed Administrative Services Agreement, acceptable to the Department. (CSL)
9. Submission of a photocopy of an amended and executed Lease Agreement, acceptable to the Department. (CSL)
10. Submission of a photocopy of an amended and executed Assignment of Lease Agreement, acceptable to the Department. (CSL)
11. Submission of a photocopy of an amended and executed Assignment and Assumption of Lease and Landlord Consent, acceptable to the Department. (CSL)
12. Submission of a photocopy of an amended and executed Bill of Sale, Assignment and Assumption Agreement, acceptable to the Department. (CSL)
13. Submission of a photocopy of an amended and executed General Assignment, Assumption, Conveyance and Bill of Sale Agreement, acceptable to the Department. (CSL)
14. Submission of a photocopy of an amended and executed Articles of Organization for AICA Holdings, LLC, acceptable to the Department. (CSL)
15. Submission of a photocopy of an amended and executed Operating Agreement for AICA Holdings, LLC, acceptable to the Department. (CSL)
16. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners, LLC, acceptable to the Department. (CSL)
17. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners, LLC, acceptable to the Department. (CSL)
18. Submission of a photocopy of an amended and executed Certificate of Authority for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
19. Submission of a photocopy of an amended and executed Company Agreement for MVNY Partners Holdings, LLC, acceptable to the Department. (CSL)
20. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Newco, LLC, acceptable to the Department. (CSL)
21. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Newco, LLC, acceptable to the Department. (CSL)
22. Submission of a photocopy of an amended and executed Certificate of Authority for Dialysis Holdco, LLC, acceptable to the Department. (CSL)

23. Submission of a photocopy of an amended and executed Company Agreement for Dialysis Holdco, LLC, acceptable to the Department. (CSL)
24. Submission of a photocopy of the Certificate of Authority for U.S. Renal Care, Inc., acceptable to the Department. (CSL)
25. Submission of a photocopy of an amended and executed Leaseback Agreement, acceptable to the Department. (CSL)

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the Public Health and Health Planning Council Recommendation Letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
https://www.health.ny.gov/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 # 202185-E Wellbound II LLC

Program: Certified Home Health Agency Purpose: Establishment

County: Westchester Acknowledged: November 5, 2020

Executive Summary

Description

Wellbound II LLC requests approval to be established as the new operator of Bethel Nursing Home Company Certified Home Health Agency (CHHA) located at 2042 Albany Post Road, Suite 2, Croton-on-Hudson (Westchester County). The CHHA is certified to serve Bronx, New York, Putnam, Queens, and Westchester counties and is licensed to provide the following services: Home Health Aide, Medical Social Services, Medical Supplies, Equipment and Appliances, Nursing, Nutrition Personal Care, Occupational Therapy, Physical Therapy, Respiratory Therapy, and Speech-Language Pathology Therapy. After Public Health and Health Planning Council (PHHPC) approval, the CHHA will be located at 485 Kings Highway, Brooklyn (Kings County).

On August 13, 2020, Bethel Nursing Home Company, Inc., the current owner and operator of the CHHA, and Amber Court of Home, LLC entered into an Asset Purchase Agreement (APA), whereby Amber Court at Home, LLC agreed to purchase the operations and certain assets of the CHHA. Amber Court at Home, LLC will assign its interest under the APA to Wellbound II LLC. 485 Kings Corp. (Landlord) will enter into a Lease Agreement with Wellbound II LLC (as tenant). 485 Kings Corp., is unrelated to Wellbound II LLC.

Ownership of the CHHA after the requested change is as follows:

Table with 2 columns: Members, Percent. Rows: Robert Snyder (50%), Raphael Weiss (50%).

OPCHSM Recommendation

Contingent Approval

Need Summary

There will be no change in services or counties served 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 §3606(2).

Financial Summary

There are no project costs associated with this proposal. The purchase price for the CHHA assets is \$1,000,000, of which \$100,000 was already paid as a down payment. The remaining \$900,000 balance will be met via equity from the proposed members. The proposed budget is as follows:

Table with 3 columns: Budget, 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 contingent upon:

1. Submission of an executed building lease, acceptable to the Department of Health (Department). [BFA]
2. Submission of a photocopy of amended and executed Lease Agreement, acceptable to the Department. [CSL]

Approval conditional upon:

1. This project must be completed by one year from the date of the recommendation letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]

Council Action Date

February 10, 2022

Need and Program Analysis

Program Description

Bethel Nursing Home Company Certified Home Health Agency is an existing CHHA that has established relationships with hospitals and other health providers in its service area and has an existing patient base. The CHHA serves the following counties: Bronx, New York, Putnam, Queens, and Westchester. The services currently offered are Home Health Aide, Medical Social Services, Medical Supplies, Equipment and Appliances, Nursing, Nutrition Personal Care, Occupational Therapy, Physical Therapy, Respiratory Therapy, and Speech-Language Pathology Therapy. There will be no changes in services or counties served as a result of this application. Upon approval of this project, the agency will be located at 485 Kings Highway, Brooklyn, 11223 in Kings County.

Character and Competence Review

The membership of Wellbound II LLC is as follows:

Robert Snyder (50%)

COO, Aljud Management Corp

Affiliations

- Amber Court at Home, LLC d/b/a Wellbound (CHHA) (2014 – Present)
- Arista Home Care, LLC (LHCSA) (2017 – Present)
- Amber Court of Smithtown (ALP) (February 2018 – Present)
- Amber Court @ Suffolk County LLC (LHCSA) (February 2018 – Present)
- Amber Court of Westbury (ALP) (2015 – Present)
- Amber Court of Elizabeth (NJ) (ALR) (2008 – Present)
- Visiting Services, LLC d/b/a Visiting Docs (D&TC) (January 2020 – Present)

Raphael Weiss (50%)

CFO, Aljud Management Corp

Affiliations

- Amber Court at Home, LLC d/b/a Wellbound (CHHA) (2014 – Present)
- Arista Home Care, LLC (LHCSA) (2017 – Present)
- Amber Court of Smithtown (ALP) (February 2018 – Present)
- Amber Court @ Suffolk County LLC (LHCSA) (February 2018 – Present)
- Amber Court of Westbury (ALP) (2015 – Present)
- Amber Court of Elizabeth (NJ) (ALR) (2008 – Present)
- Visiting Services, LLC d/b/a Visiting Docs (D&TC) (January 2020 – Present)

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the Office of the Inspector General Exclusion List.

Facility Compliance/Enforcement

The compliance history for the above-noted affiliations is as follows:

- Amber Court at Smithtown was fined \$5,000.00 pursuant to a Stipulation and Order for surveillance findings on December 17, 2018, and August 19, 2019. The inspections found violations of Article 7 of the Social Services Law and 18 NYCRR Part 487.7(f)(5).
- Amber Court of Westbury was fined \$50.00 pursuant to a Stipulation and Order for surveillance findings on December 30, 2020. The inspection found violations of 18 NYCRR Part 485.11(b).

The State of New Jersey did not respond to the out-of-state compliance request. The applicant submitted affidavits attesting to the compliance history of Amber Court of Elizabeth, which states that there have been no enforcement actions taken against them.

Quality Measures

CHHA Quality of Patient Care Star Ratings*	
CHHA Name	Quality of Care Rating
<u>Subject Facility</u> Bethel Nursing Home Company, Inc. d/b/a Bethel Nursing Home Company CHHA	4 out of 5 stars
<u>Currently Operated by Applicants</u> Amber Court at Home, LLC d/b/a Wellbound	1.5 out of 5 stars

*CMS data as of July 21, 2021

The CHHA currently owned by the applicant members, Amber Court at Home, LLC d/b/a Wellbound, resides at 2004 Mcdonald Avenue, Suite 2-a Brooklyn, NY 11223 and is certified to provide the following services in Bronx, Kings, Nassau, New York, Queens, Richmond, and Suffolk counties:

- Home Health Aide
- Medical Social Services
- Medical Supplies Equipment and Appliances
- Nursing
- Nutritional
- Personal Care
- Therapy - Occupational
- Therapy - Physical
- Therapy - Speech Language Pathology

The CHHA has a star rating of 1.5 out of 5 stars as of July 21, 2021. The applicant stated that the star rating does not necessarily reflect the agency's quality of care and that the CHHA has met or exceeded the state and/or national averages in seven of the fourteen quality measures relating to preventing patient harm, preventing unplanned hospitalizations and patients remaining in the community after discharge.

The applicant states that Amber Court at Home, LLC d/b/a Wellbound primarily serves patients that reside in assisted living facilities. Wellbound's quality rating is below the national average for four outcomes of care measures for improvement in managing daily activities. The applicant cites inaccurate OASIS documentation that does not accurately identify the needs of patients upon initial assessment resulting in outcomes showing little to no improvement upon discharge from home care services. To improve these measures, the agency has established and implemented a plan to educate and train its clinicians on proper OASIS documentation leading to improved scores in this area which will improve the overall CMS Five-Star rating.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3606(2). The change in operator will result in no changes to the service area or the services being provided by the CHHA.

Financial Analysis

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for the current year, and first and third years, which is summarized below:

	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
<u>Revenues</u>			
Commercial MC	\$20,567	\$311,351	\$347,630
Medicare FFS	502,293	1,415,100	1,716,352
Medicaid FFS	5,666	0	0
Medicaid MC	87,377	783,468	871,299
Private Pay	<u>125</u>	<u>0</u>	<u>0</u>
Total Revenues	\$616,028	\$2,509,919	\$2,935,281
<u>Expenses</u>			
Operating	\$967,018	\$2,410,514	\$2,523,078
Capital	<u>31,758</u>	<u>14,400</u>	<u>14,400</u>
Total Expenses	\$998,776	\$2,424,914	\$2,537,478
Net Income (Loss)	(\$382,748)	\$85,005	\$397,803
Utilization (Visits)	5,015	11,969	14,125
Utilization (Hours)	1,873	27,000	33,000

The following is noted regarding the submitted budget:

- Wellbound II LLC is projecting a substantial increase in utilization in years one and three, primarily from projected incremental visits from Medicaid Managed Care and Commercial Managed Care patients, based on the current and projected population characteristics of the service area, including relevant health status indicators and socio-economic status of the service area population.
- The applicant expects to increase utilization of the CHHA by enrolling new patients from the community through community outreach; advertising; reaching out to new health care entities to create a stronger referral system and utilizing the applicant's members' affiliated entities for referrals to the CHHA.
- The projected Commercial and Medicare rate assumptions are based on Bethel's 2018 cost report (i.e., Commercial FFS-\$198.28 per visit; and Medicare FFS-\$201.54 per visit), increased based on 2020 rates and the applicant's member's experience.
- The projected Medicaid rate is based on the applicant's members successfully operating other financially feasible facilities and agencies, including Amber Court at Home CHHA.
- The current operator of the CHHA has confirmed that the CHHA did not receive any CARES Act funding.

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

<u>Payor</u>	<u>Current Year</u>	<u>Year One</u>	<u>Year Three</u>
Commercial MC	8.81%	10.46%	10.72%
Medicare FFS	58.04%	55.77%	57.32%
Medicaid FFS	1.66%	0.00%	0.00%
Medicaid MC	31.45%	31.77%	29.96%
Private Pay	0.04%	0.00%	0.00%
Charity Care	<u>0.00%</u>	<u>2.00%</u>	<u>2.00%</u>
Total	100.00%	100.00%	100.00%

The applicant states their policy is to assess individuals based on income to determine eligibility for reduced fees and/or charity care, including providing uncompensated services to patients lacking the financial resources to pay.

Lease Rental and Asset Purchase Agreements

BFA Attachment B details:

- The Lease Rental Agreement: The applicant has attested that the lease is an arm's length arrangement, as the landlord and tenant have no relationship. The applicant has also submitted letters from two New York realtors attesting to the rent reasonableness.
- The Asset Purchase Agreement: The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement, or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and/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 December 18, 2020, the facility had no outstanding Medicaid liabilities.

Capability and Feasibility

Wellbound II LLC will acquire the CHHA's operations for a total purchase price of \$1,000,000. A down payment of \$100,000 has already been paid and the balance of \$900,000 will be met via equity from the proposed members. The working capital requirement is estimated at \$422,913, based on two months of third-year expenses, and will be funded from the proposed members' equity. BFA Attachment A, the members' net worth statements, reveals sufficient resources to meet the equity and working capital needs.

The submitted budget projects a net income of \$85,005 and \$397,803 in the first and third years, respectively. The budget appears reasonable.

BFA Attachment D is the 2020 certified financial summary and the June 30, 2021 internal financial statements for Bethel Nursing Home Company, Inc., which shows that the CHHA had an operating loss of \$858,739 in 2020 and a loss of \$25,551 through June 30, 2021. The applicant has indicated that the CHHA's financial performance in 2020 was primarily due to the current operator's focus on selling and ceasing the operations of the CHHA. The applicant expects to increase utilization of the CHHA by enrolling new patients from the community through community outreach; advertising; reaching out to new health care entities to create a stronger referral system, and utilizing the applicant's members' affiliated entities for referrals to the CHHA.

BFA Attachment C is the pro forma balance sheet, which shows the entity will start with a positive net asset position of \$1,422,913.

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 Wellbound II LLC
BFA Attachment B	Agreements
BFA Attachment C	Pro Forma Balance Sheet
BFA Attachment D	Financial Summaries for Bethel Nursing Home Company

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3606 of the Public Health Law, on this 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council, and after due deliberation, hereby approves the following application to establish Wellbound II LLC as the new operator of Bethel Nursing Home Company Certified Home Health Agency, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER

APPLICANT/FACILITY

202185 E

Wellbound II LLC

APPROVAL CONTINGENT UPON:

1. Submission of an executed building lease, acceptable to the Department of Health (Department). [BFA]
2. Submission of a photocopy of amended and executed Lease Agreement, acceptable to the Department. [CSL]

APPROVAL CONDITIONED UPON:

1. This project must be completed by one year from the date of the recommendation letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]

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



Project # 202057-B
Premier SC, LLC t/b/k/a
Premier Ambulatory Surgery Center of New York, LLC

Program: Diagnostic and Treatment Center County: Queens
Purpose: Establishment and Construction Acknowledged: August 20, 2020

Executive Summary

Description

Premier SC, LLC, an existing limited liability company, requests approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) to be certified as a multi-specialty freestanding ambulatory surgical center (FASC). The FASC will be located at 176-60 Union Turnpike, Fresh Meadows (Queen County), and will have four operating rooms. All projected cases are currently being performed in the participating physicians' office-based practices. Through this project, the center will bring the office-based medical practices of the physicians into the regulatory environment of an Article 28 FASC.

The proposed ownership is as follows:

Table with 3 columns: Member, Proposed Operator, %

The sole member of the applicant is Premier SC Holdings, Inc., a to-be-formed not-for-profit corporation. The Center will be managed by a Board of Managers appointed by Premier SC Holdings, Inc. The members of the Board of Managers of Premier SC, LLC are the same as the members of the Board of Directors of Premier SC Holdings, Inc. The sole member and passive parent of Premier SC Holdings, Inc. is MediSys Health Network, Inc. an existing not-for-profit corporation.

The proposed medical director is Moustafa Mourad, MD. Jamaica Hospital Medical Center, 3.2 miles, 11 minutes away, will serve as the backup hospital for the Center.

Upon approval of this application by the Public Health and Health Planning Council, Premier SC, LLC will change its name to Premier Ambulatory Surgery Center of New York, LLC.

OPCHSM Recommendation

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

Need Summary

The Center will have four operating rooms. The applicant projects 3,000 procedures in Year One and 3,371 in Year Three with Medicaid at 5% and charity care at 2% each year.

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 \$10,576,961 will be met as follows: An equipment Lease of \$2,294,203, an equipment lease of \$825,364, a loan of \$6,000,000 (3.75% interest rate with 2 rate adjustments at 5-year intervals, 15-year term, 15-year payout), and accumulated cash of \$1,457,394 from MediSys Health Network, Inc.'s

system hospitals operations. The budget is summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues	\$3,819,310	\$4,293,302
Expenses	<u>4,102,640</u>	<u>4,248,977</u>
Net Income/ (Loss)	\$(283,330)	\$44,325

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 a commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to the Department. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
 - a. Data displaying actual utilization including procedures
 - b. Data displaying the breakdown of visits by payor source
 - c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery
 - d. Data displaying the number of emergency transfers to a hospital
 - e. Data displaying the percentage of charity care provided
 - f. The number of nosocomial infections recorded during the year reported
 - g. A list of all efforts made to secure charity cases
 - h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed sublease that is acceptable to the Department. [BFA]
6. Submission of an executed equipment lease (Karl Storz Capital) that is acceptable to the Department. [BFA]
7. Submission of an executed equipment lease (Phillips Medical Capital) that is acceptable to the Department. [BFA]
8. Submission of an executed Restated Articles of Organization, acceptable to the Department. [CSL]
9. Submission of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
10. Submission of an amended and executed Certificate of Incorporation of Premier SC Holdings, Inc., acceptable to the Department. [CSL]
11. Submission of executed Bylaws of Premier SC Holdings, Inc., acceptable to the Department. [CSL]
12. Submission of an amended and executed Sublease Agreement, acceptable to the Department. [CSL]
13. Submission of an amended Master Lease, acceptable to the Department. [CSL]
14. Submission of landlord consent pursuant to Master Lease, acceptable to the Department. [CSL]
15. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
16. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]

Approval conditional upon:

1. This project must be completed by **December 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [PMU]
2. Construction must start on or before **September 1, 2022**, and construction must be completed by **September 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. 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/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. [AER]

Council Action Date

February 10, 2022

Need and Program Analysis

Program Description

Proposed Operator	Premier SC, LLC t/b/k/a Premier Ambulatory Surgery Center of New York, LLC
Site Address	170-60 Union Turnpike Fresh Meadows, New York 11366 (Queens County)
Surgical Specialties	Multi-Specialty, initially including: Gastroenterology General Surgery Ophthalmology Otolaryngology Podiatry Plastic Surgery Urology Vascular Surgery
Operating Rooms	4
Procedure Rooms	0
Hours of Operation	Monday through Friday 7:30 am to 3:30 pm Weekend and/or evening procedures will be available, if needed, to accommodate patient scheduling times.
Staffing (1st Year / 3rd Year)	15.94 FTEs / 16.33 FTEs
Medical Director(s)	Moustafa Mourad, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Is expected to be provided by: Jamaica Hospital Medical Center 3.2 miles / 11 minutes
On-call service Emergency, In-Patient and Backup	Patients who require assistance during off-hours will engage the 24 hours a day, seven (7) day a week on-call service, to immediately refer the patient to the Center's on-call physician.

Analysis

The service area consists of Queens County. The population of Queens County in 2010 was 2,230,722 with 862,706 individuals (38.7%) who are 45 and over, which are the primary population group utilizing ambulatory surgery services. Per PAD projection data, this population group (45 and over) is estimated to grow to 1,084,283 by 2025 and represent 43.2% of the projected population of 2,508,764. According to Data USA, in 2019, 90.7% of the population of Queens County has health coverage as follows:

Employer Plans	43.4%
Medicaid	25.7%
Medicare	10.5%
Non-Group Plans	10.8%
Military or VA	0.27%

The number of projected procedures is 3,000 in Year One and 3,372 in Year Three. These projections are based on the current practices of participating surgeons. The applicant states that all of the procedures are currently being performed in an office-based setting.

The table below shows the projected payor source utilization for Years One and Three.

Payor	Year One		Year Three	
	Volume	%	Volume	%
Commercial FFS	600	20.0%	674	20.0%
Commercial MC	1,260	42.0%	1,416	42.0%
Medicare FFS	150	5.0%	169	5.0%
Medicare MC	600	2.0%	674	20.0%
Medicaid MC	150	5.0%	169	5.0%
Private Pay	30	1.0%	34	1.0%
Charity Care	60	2.0%	67	2.0%
Other	150	5.0%	169	5.0%
Total	3,000	100.0%	3,372	100.0%

The table below shows the number of patient visits for ambulatory surgery centers in Queens County for 2018 through 2020. 2020 visits were significantly impacted by COVID-19.

Spec Type	Facility Name	Patient Visits		
		2018	2019	2020
Ophthalmology	Apex Eye Surgery Center ³	1,864	2,071	389
Multi	Choices Women's Medical Center, Inc ^{1,2}	0	0	0
Multi	CitiMed Surgery Center (opened 11/20/20)	N/A	N/A	N/A
Multi	EMU Health	6,393	7,297	2,947
Gastroenterology	Flushing Endoscopy Center	11,304	8,739	5,275
Multi	Gramercy Surgery Center, Inc.-Queens	1,828	1,818	1,578
Multi	New York Surgery Center Queens, LLC	2,769	1,820	1,676
Multi	North Queens Surgical Center	4,449	7,907	7,440
Multi	Physicians Choice Surgicenter	571	586	537
Gastroenterology	Queens Boulevard ASC, LLC ²	10,662	11,590	0
Gastroenterology	Queens Endoscopy ASC, LLC	12,055	9,663	6,485
Multi	Queens Surgical Center (opened 12/24/20)	N/A	N/A	N/A
Multi	Rockaways ASC Development (opened 5/23/19) ²	N/A	1,798	0
Gastroenterology	The Endoscopy Center of Queens	6,042	7,195	5,477
Ophthalmology	The Mackool Eye Institute ²	6,021	7,988	0
Total Visits		63,958	68,462	31,804

¹ No data for 2018 or 2019.

² No data for 2020

³ 2020 data is for a partial year.

The FASC initially plans to obtain contracts with the following Medicaid Managed care plans: Affinity, Fidelis Care, Healthfirst, Metroplus, and WellCare. The Center will work collaboratively with local Federally Qualified Health Centers (FQHCs) such as Charles B Wang Community Health, Community Healthcare Network, and Joseph P Addabbo Family Health Center to provide service to the under-insured in their service area. The center has developed a financial assistance policy with a sliding fee scale to be utilized when the Center is operational.

Character and Competence

The sole member of Premier SC, LLC is Premier SC Holding, Inc, a to-be-formed not-for-profit corporation. The sole (passive) member of Premier SC Holding, Inc. is MediSys Health Network, Inc., an existing not-for-profit affiliated with Flushing Hospital Medical Center and Jamaica Hospital Medical Center. The Board of Managers of the FASC will be appointed by Premier SC Holdings, Inc. and is identical to the Board of Directors of Premier SC Holding, Inc.:

Board Members	Interest
Premier SC Holding, Inc <i>Nageswara Mandava, M.D, Director</i> <i>Asit Mehta, M.D., Director</i> <i>Robert Mendelson, M.D., Director</i> <i>Alessandro Solinas, M.D., Director</i>	100%
TOTAL	100%

Dr. Nageswara Mandava is a practicing Physician, the Chairman of the Department of Surgery, and the Program Director of the General Surgical Residency at Flushing Hospital Medical Center (13 years). His responsibilities include establishing a vision for the department and effectively communicating the same to the department staff; recruiting and retaining staff to fulfill the mission of the department; working with hospital administration to develop the department's annual budget; overseeing and maintaining a high quality of care for the department's providers; and participating in hospital leadership meetings. He has owned and operated Dr. N. Mandava PC for 31 years. He received his medical degree from Rangaraya Medical College in India and completed his General Surgery Internship at the Catholic Medical College Brooklyn Queens. He is board-certified in Surgery.

Dr. Asit Mehta is a Practicing Physician and has been the Director in the Division of Gastroenterology at TJH Medical Services for over 25 years. He received his medical degree from the NHL Municipal Medical College in India and completed his residency in Internal Medicine at Catholic Medical College Mary Immaculate and his Gastroenterology residency at Catholic Medical College Brooklyn Queens. He is board-certified in Internal Medicine with a sub-certification in Gastroenterology.

Dr. Robert Mendleson is a practicing Physician who has been employed at TJH Medical Services for over 26 years. His responsibilities include providing practice management and practice expertise. He is also responsible for establishing a vision for the department and effectively communicating the same to the department staff; recruiting and retaining staff to fulfill the mission of the department; working with hospital administration to develop the department's annual budget; overseeing and maintaining a high quality of care for the department's providers, and participating in hospital leadership meetings. He is the Chairman of Medicine at Jamaica Hospital Medical Center. He received his medical degree from the Medical College of Pennsylvania and completed his residency in Internal Medicine at NYU School of Medicine and his residency in Cardiovascular Disease at Northshore University Hospital. He is board-certified in Cardiovascular Medicine. Dr. Mendelson discloses board membership on MediSys Management, LLC since 2015, which has a relationship with Flushing Hospital Medical Center, Jamaica Hospital Medical Center, and MediSys Health Network, Inc.

Dr. Alessandro Solinas has been a Practicing Physician at TJH Medical Services for over 22 years and has been the Chairman of Medicine at Flushing Hospital for over eight years. He received his medical degree from the University di Sassari in Italy and completed his residency in Internal Medicine at Jamaica Hospital. He is board-certified in Internal Medicine.

Dr. Moustafa Mourad, the proposed medical director is a Practicing Physician and the Division Chief of Otolaryngology-Head and Neck Surgery at TJH Medical Services. He provides guidance in the operation of the facility to meet the surgical volume. He is also the Director of Ambulatory Surgical Services at New York Specialty Surgery and works closely with surgeons of other specialties to coordinate their ambulatory surgical needs to operate a standalone surgery center. It is the foundational work that he can draw on the essential skills needed for the new endeavor. He was previously employed at Metropolitan Hospital as the Division Chief of Otolaryngology Head and Neck Surgery, Facial Plastic, and Reconstruction Surgery. He received his medical degree from the University of Kentucky College of

Medicine and completed his residency at New York Eye and Ear Infirmary of Mt. Sinai and Beth Israel Hospital.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

The following legal actions against MediSys Management, LLC were disclosed:

1. 2013-United States ex rel. Deshpande, et al. v. The Jamaica Hospital Medical Center, et al., Civil Action No. 13-CV-4030 (E.D.N.Y. Filed July 15, 2013)

On July 15, 2013, Relator Dr. Satish Deshpande on behalf of himself and the United States Government (the U.S. Government) filed the above-referenced action in the United States District Court for the Eastern District of New York (the "Civil Action") against MediSys Health Network, **MediSys Management, LLC**, Jamaica Hospital Medical Center, Flushing Hospital Center and TJH Medical Services, P.C. (collectively, "MediSys"). The U.S. Government conducted an investigation. The U.S. Government alleged that MediSys violated the Stark Law by (1) providing compensation to physicians in the absence of written documentation signed by the parties, and (2) allowing physicians to use hospital space for their private medical practices without complying with the requirements of the Stark Law. The U.S. Government further contended that because of the Stark Law violations, MediSys violated the False Claims Act, by submitting false claims to the Medicare program for services rendered by MediSys to patients that were referred to MediSys by these physicians.

MediSys denied these allegations. The U.S. Attorney's Office, U.S. Department of Justice, and Office of Inspector General entered into a Settlement Agreement, effective August 31, 2017, with MediSys and Relator. In exchange for a release, MediSys agreed to pay \$4,000,000 in installments to the United States. On November 8, 2017, the Civil Action was dismissed.

2. EEOC Charge of Discrimination No. 520-2019-05183C filed September 3, 2019 Robin Haas v. MediSys Management, LLC.

A former employee filed a complaint with the Equal Employment Opportunity Commission (EEOC). The Company is working with outside counsel and their Position Statement was filed with the EEOC on November 11, 2019. The case is pending.

Additionally, the staff from the DHDTTC reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

For those patients who do not identify a primary care provider (PCP), the Applicant plans to work closely with its patients to educate them regarding the availability of primary care services offered by local providers, including a broad array of services offered by the center's back up hospital. Prior to leaving the center, each patient will be provided information concerning the local availability of primary care services. 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 applicant has proposed an operating budget that includes 5% Medicaid and 2% Charity Care, demonstrating the center's expected outreach to this traditionally underserved population.

The center intends on using an Electronic Medical Record (EMR) program and to fully integrate and exchange information with an established Regional Health Information Organization (RHIO) with the capability for clinical referral and event notifications.

Conclusion

Approval of this project will provide increased access to multi-specialty surgery services in an Article 28 setting for the residents of Queens 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 cost, which is for renovations and the acquisition of moveable equipment, is estimated at \$10,576,961, further broken down as follows:

Renovation and Demolition	\$5,508,000
Design Contingency	550,800
Construction Contingency	550,800
Planning Consultant Fees	102,000
Architect/Engineering Fees	469,200
Other Fees (Consultant)	25,500
Moveable Equipment	3,119,567
Financing Costs	60,000
Interim Interest Expense	131,250
CON Fee	2,000
Additional Processing Fee	<u>56,792</u>
Total Project Cost	\$10,576,961

The applicant’s financing plan is:

Equipment Lease 1 (Philips Medical Capital)	\$2,294,203
Equipment Lease 2 (Karl Storz Capital)	825,364
Accumulated Cash of System Hospitals	1,457,394
Mortgage (3.75% Interest Rate with 2 rate adjustments at 5-year intervals, 15-Year Term, 15-Year Payout, Maspeth Federal Savings and Loan)	<u>6,000,000</u>
Total Project Financing	\$10,576,961

Operating Budget

The applicant has submitted an operating budget, in 2020 dollar, for the first and third years of operation, summarized below:

	<u>Year 1 (2023)</u>		<u>Year 3 (2025)</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Revenues</u>				
Medicaid MC	\$973.78	\$146,067	\$981.08	\$165,802
Medicare FFS	\$1,049.20	157,380	\$1,046.40	176,842
Medicare MC	\$891.82	535,091	\$892.08	601,264
Commercial FFS	\$1,678.72	1,007,230	\$1,679.22	1,131,791
Commercial MC	\$1,521.34	1,916,885	\$1,521.14	2,153,940
Private Pay	\$314.77	9,443	\$312.09	10,611
Other	\$314.76	<u>47,214</u>	\$313.92	<u>53,053</u>
Total Revenues		\$3,819,310		\$4,293,303

	<u>Year 1 (2023)</u>		<u>Year 3 (2025)</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Expenses</u>				
Operating	\$653.00	\$1,958,996	\$618.18	\$2,083,891
Capital	\$714.55	<u>\$2,143,644</u>	\$642.27	<u>\$2,165,087</u>
Total Expenses	\$1,367.55	<u>\$4,102,640</u>	\$1,260.45	<u>\$4,248,978</u>
Net Income or (Loss)		<u>(\$283,330)</u>		<u>\$44,325</u>
Utilization (Visits)		3,000		3,371

The following is noted with respect to the submitted budget:

- Expense assumptions are based on the experience of the participating physicians in providing healthcare services to patients through their private practices and other ambulatory surgery centers in New York State.
- The projected utilization for this project is based on the experience of the participating physicians and their estimate of the number of cases they will bring to the FASC. The applicant submitted physician referral letters in support of utilization projections.
- Operating revenues by payor are based on the experience of participating providers, in accordance with the expected collection rate of the FASC.

Lease Rental Agreements

The applicant has submitted an executed master lease agreement and a draft sublease agreement for the site (see BFA Attachment B). The applicant has indicated that the sublease agreement is a non-arm's length lease arrangement in that they share certain board members in common. The applicant submitted real estate letters attesting to the reasonableness of the per square foot rental.

Capability and Feasibility

Total project costs of \$10,576,961 will be met as follows: an equipment lease of \$2,294,203 (5-year term, 5.49% interest rate, \$43,812 monthly payment), an equipment lease of \$825,364 (4-year term, 6.98% interest rate, \$19,757 monthly payment), a mortgage of \$6,000,000 (3.75% interest rate with 2 rate adjustments at 5-year intervals, 15-year term, 15-year payout), and accumulated cash of \$1,457,394 via operations of MediSys Health Network Inc.'s system hospitals. The applicant has provided letters of interest for equipment leases and a loan approval letter.

The working capital requirement for this project is \$614,740 based on two months of Year Three expenses. The applicant has stated that it will be funded through the ongoing operations of MediSys Health Network. BFA Attachment C is the Pro Forma Balance Sheet, which shows \$5,191,701 in Members' Equity on day one of operations.

BFA Attachment A is the October 31, 2021 internal financial statements of MediSys Health Network, which indicates the availability of sufficient funds for the equity contribution. The internal financial statements indicate that MediSys Health Network had negative working capital, a positive net asset position, and a positive net income of \$43,443,315 as of October 31, 2021.

The submitted budget projects a net loss in Year One of \$283,300 and a net income of \$44,325 by Year Three. MediSys has supplied a loss mitigation letter stating that the loss in Year One of operations will be funded by MediSys Health Network, Inc. from cash and investments.

The Year One loss is contributed to start-up costs and the ramp-up of inpatients. Revenues are based on current reimbursement methodologies for ambulatory surgery services. The submitted budget appears reasonable.

Conclusion

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

Supplemental Information

DOH Comment

The Department reached out to proximate hospitals asking for information on the impact of the proposed ambulatory surgery center (ASC). None of the hospitals responded. Therefore, in the absence of comments from hospitals near the ASC, the Department finds no basis for reversal or modification of the recommendation for approval of this application based on public need, financial feasibility and owner/operator character and competence.

Attachments

BHFP Attachment	Map
BFA Attachment A	Internal financial statements of MediSys Health Network as of October 31, 2021
BFA Attachment B	Lease and Sub-Lease Agreements
BFA Attachment C	Pro-Forma Balance Sheets

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a new multi-specialty freestanding ambulatory surgery center with four (4) operating rooms to be located at 176-60 Union Turnpike, Fresh Meadows, 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:

202057 B

FACILITY/APPLICANT:

Premier SC, LLC t/b/k/a Premier Ambulatory
Surgery Center of New York, LLC

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. 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 a commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
3. Submission of a signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to the Department. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
 - a. Data displaying actual utilization including procedures
 - b. Data displaying the breakdown of visits by payor source
 - c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery
 - d. Data displaying the number of emergency transfers to a hospital
 - e. Data displaying the percentage of charity care provided
 - f. The number of nosocomial infections recorded during the year reported
 - g. A list of all efforts made to secure charity cases
 - h. A description of the progress of contract negotiations with Medicaid managed care plans.[RNR]
4. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
5. Submission of an executed sublease that is acceptable to the Department. [BFA]
6. Submission of an executed equipment lease (Karl Storz Capital) that is acceptable to the Department. [BFA]
7. Submission of an executed equipment lease (Phillips Medical Capital) that is acceptable to the Department. [BFA]
8. Submission of an executed Restated Articles of Organization, acceptable to the Department. [CSL]
9. Submission of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
10. Submission of an amended and executed Certificate of Incorporation of Premier SC Holdings, Inc., acceptable to the Department. [CSL]

11. Submission of executed Bylaws of Premier SC Holdings, Inc., acceptable to the Department. [CSL]
12. Submission of an amended and executed Sublease Agreement, acceptable to the Department. [CSL]
13. Submission of an amended Master Lease, acceptable to the Department. [CSL]
14. Submission of landlord consent pursuant to Master Lease, acceptable to the Department. [CSL]
15. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
16. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **December 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and an expiration of the approval. It is the responsibility of the applicant to request prior approval for any extension to the project approval expiration date. [PMU]
2. Construction must start on or before **September 1, 2022**, and construction must be completed by **September 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. 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/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. [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 # 211151-B
W Medical, LLC d/b/a W Health Center

Program: Diagnostic and Treatment Center County: Kings
Purpose: Establishment and Construction Acknowledged: April 30, 2021

Executive Summary

Description

W Medical, LLC d/b/a W Health Center, a New York limited liability company, requests approval to establish and construct an Article 28 Diagnostic and Treatment Center (D&TC) at 70 Lee Avenue, Brooklyn, New York (Kings County). The D&TC will be certified for Medical Services - Primary Care, Medical Services - Other Medical Specialties, and Physical Therapy. More specifically, the D&TC will focus on Pediatrics, Infectious Diseases, Pulmonology, Orthopedics, Endocrinology, Cardiology and Physical Therapy. The primary service area is the Williamsburg section of Brooklyn with services available to all residents in Kings County.

The sole member of W Medical, LLC is Pinchas Halperin. The proposed Medical Director is Binyomin Nemon, DO, who is board-certified in Family Medicine. W Medical, LLC will be entering into a Transfer and Affiliation Agreement with Wyckoff Heights Medical Center, which is 1.1 miles away from the proposed center.

OPCHSM Recommendation

Contingent Approval

Need Summary

The D&TC will be in the Williamsburg area of Brooklyn, a designated Health Professional Shortage Area for primary care services. The applicant projects 7,540 visits in the first year and 9,553 in the third year with Medicaid at 68% and charity care at 2%.

Program Summary

The individual background review indicates the proposed member has met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

Total project costs of \$558,082 will be met via the proposed owner's equity. The proposed budget is as follows:

Table with 3 columns: Category, Year One, Year Three. Rows: Revenues (\$1,187,750 vs \$1,504,483), Expenses (\$1,115,257 vs \$1,365,227), Net Income (\$72,493 vs \$139,256).

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 (Department). 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 an executed building lease agreement, acceptable to the Department of Health. [BFA]
4. Submission of a photocopy of an amended and executed Restated Articles of Organization, acceptable to the Department. [CSL]
5. Submission of a photocopy of an executed Certificate of Assumed Name, acceptable to the Department. [CSL]
6. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
7. Submission of photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
8. Submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]

Approval conditional upon:

1. This project must be completed by **May 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **February 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The 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. [AER]

Council Action Date

February 20, 2022

Need and Program Analysis

Project Description

Proposed Operator	W Medical, LLC
To Be Known As	W Health Center
Site Address	70 Lee Avenue Brooklyn, New York 11211 (Kings County)
Services	Medical Services – Primary Care Medical Services-Other Medical Specialties Infectious Disease Pulmonology Orthopedics Endocrinology Cardiology Physical Therapy O/P
Hours of Operation	Monday through Friday 8:00 AM to 6:00 PM Sunday 8:30 AM to 6:00 PM as need dictates
Staffing (1st Year / 3rd Year)	7.25 FTEs / 9.05 FTEs
Medical Director(s)	Binyomin Nemon, D.O.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Expected to be provided by Wykoff Medical Center 1.1 miles / 7 minutes away

Background

The primary service area is the Williamsburg section of Brooklyn. The population of Kings County in 2010 was 2,504,700 and is estimated to grow to 2,810,876 by 2025, an increase of 12.2%. The U.S. Health Resources & Services Administration (HRSA) has designated Kings County as a Medically Underserved Area/Population and the Williamsburg section as a Health Professional Shortage Area for Primary Care services for Medicaid eligible. According to Data USA, in 2019, 93.7% of the population of Kings County has health coverage as follows:

Employer Plans	41.7%
Medicaid	33.2%
Medicare	8.0%
Non-Group Plans	10.5%
Military or VA	0.2%

The number of projected visits is 7,540 in Year One and 9,553 in Year Three. The applicant is committed to serving all persons in need without regard to ability to pay or source of payment and is projecting Medicaid utilization of 68% and charity care of 2%. The applicant intends to hire multicultural and bilingual staff to help meet the needs of the community.

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 Kings County is lower than the New York State rate.

Hospital Admissions per 100,000 Adults for Overall PQIs

2017 PQI Rates	Kings County	New York State
All PQIs	1,358	1,431

Character and Competence

The sole member of W Medical, LLC is Pinchas “David” Halpern.

Pinchas “David” Halperin describes himself as an Investor, Capitalist, Developer, and Philanthropist. He is the Director of Operations of Ahava Medical and Rehabilitation Center LLC and is an Investor in Diners NY LLC, a commercial bakery. He is an Investor in Divine Health LLC, a web-based store selling over-the-counter pharmacy products. He was the Founder and Principal of Certified Developers, a construction and real estate development company that specialized in consumer construction projects. He is the Owner of Home Meds Rx, a Residential and Long Term Care Pharmacy, and Rafieh Pharmacy. He is also the Owner and Operator of HPIM LLC, a commercial and residential real estate and investment company.

Dr. Binyomin Nemon is the proposed Medical Director. He is currently a Locum Tenens at various facilities in the Greater NYC area. Previously, he was the Primary Care/Adult Medicine Physician at the Damian Family Care Center, the Primary Care/Family Medicine Physician at Adaptation Medical, the Medical and Laboratory Director of Community Urgent Care, the Primary Care/Family Medicine Physician of Physician Medical Group, the Medical Director of Express Medical, the Medical Director of Bath Medical, the part-time Primary Care and Osteopathic Manipulative Treatment Physician at Care for You Medical P.C., a Family Practice and Urgent Care Physician at a private practice, a Medical Evaluator of Accident Victims for Enta Medical, an ER physician and the night coverage for the Michigan Department of Corrections for Emergency Medicine Consultants. He received his Doctor of Osteopathic Medicine degree from New York College of Osteopathic Medicine in New York and completed his residency in Family Practice at Mercy Hospital/University of Pittsburgh Medical Center and Family Practice Rural Track at Colorado Springs Osteopathic Foundation/Western University of Health Sciences. He is board-certified in Family Medicine.

Staff from the Department’s Division of Hospitals and Diagnostic & Treatment Centers (DHDTTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant’s ownership interest in other health care facilities. Licensed individuals were checked against the State’s Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the DHDTTC 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.

Pinchas Halperin disclosed a trademark infringement lawsuit filed November 16, 2020, which alleged acts of trademark infringement, passing off, violations of General Business Law, injury to business reputation, common law unfair competition, misappropriation, and unjust enrichment. The plaintiff alleged that his brand was used by several urgent care centers throughout NYC and specifically, Williamsburg, Brooklyn. Pinchas Halperin operated a new urgent care at the same location without changing the signage, making use of the Plaintiff’s name, brand, and trademark. Mr. Halperin generated substantial revenue from the unauthorized use and infringing use of the name and trademark. Moreover, it is alleged, the business was run poorly, injuring the Plaintiff’s brand. Kamin Health, a/k/a Williamsburg Urgent Care, was operated as a PC and managed under an MSO arrangement. A Stipulation of Settlement was filed on June 2, 2021.

Dr. Binyomin Nemon disclosed a complaint was filed in the Supreme Court in the State of New York County of Kings on April 9, 2010 against him and multiple other defendants. The allegation states the physicians were negligent in their treatment and diagnosis of the patient and prescribing and monitoring of the medication Ritalin. The patient alleges he was overprescribed the medication and the negligence caused his dependence on the medication. The case is ongoing but is in settlement negotiations.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3). Approval for this project will provide for access to a variety of medical services for residents in the Williamsburg section, and the surrounding communities, of Kings County.

Financial Analysis

Operating Budget

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

	Year One		Year Three	
	Per Visit	Total	Per Visit	Total
Revenues				
Medicare FFS	\$174.94	\$92,369	\$174.89	\$117,001
Medicare MC	\$160.04	\$156,839	\$159.95	\$198,662
Medicaid FFS	\$169.03	\$229,376	\$169.02	\$290,543
Medicaid MC	\$152.11	\$573,441	\$152.09	\$726,358
Private Pay	\$200.01	\$75,402	\$199.81	\$95,510
Commercial MC	\$160.01	<u>\$60,323</u>	\$159.85	<u>\$76,409</u>
Total Revenues		\$1,187,750		\$1,504,483
Expenses				
Operating	\$122.15	\$921,036	\$121.95	\$1,165,006
Capital	<u>\$25.76</u>	<u>\$194,221</u>	<u>\$20.96</u>	<u>\$200,221</u>
Total Expenses	\$147.91	\$1,115,257	\$421.91	\$1,365,227
Net Income/(Loss)		<u>\$72,493</u>		<u>\$139,256</u>
Utilization: (Visits)		7,540		9,553

The following is noted concerning the submitted budget:

- Revenues are based on current reimbursement methodologies for D&TCs.
- The Medicare Fee for Service rate was calculated based on 103% of the Medicaid FFS rate.
- The Medicaid Managed Care rate is calculated as 90% of the Medicaid FFS rate.
- Expenses are based on the historical experience of other comparable Article 28 D&TCs in the same geographic area.
- The proposed operators conservatively estimate an increase in the volume of visits from its inception through year three. Utilization assumptions are based on an initial 47.13% capacity for year one, with year three increasing to 59.70% of total capacity.

Utilization broken down by payor source during the first and third years is as follows:

Payor	Years One & Three
Medicare FFS	7.00%
Medicare MC	13.00%
Medicaid FFS	18.00%
Medicaid MC	50.00%
Private Pay	5.00%
Commercial FFS	5.00%
Charity Care	<u>2.00%</u>
Total	100.00%

Total Project Cost and Financing

Total project cost of \$558,082 is distributed as follows:

Renovation and Demolition	\$327,746
Design Contingency	\$16,387
Construction Contingency	\$16,387
Architect/Engineering Fees	\$31,000
Other Fees	\$65,000
Moveable Equipment	\$96,520
CON Fee	\$2,000
Additional Processing Fee	<u>\$3,042</u>
Total Project Cost	\$558,082

The proposed project will be funded via owners' equity.

Lease Rental Agreement

The applicant submitted a draft lease rental agreement for the site that is summarized in BFA Attachment B. The applicant submitted an affidavit indicating that the lease is a non-arm's length lease arrangement, as there is a common interest between the two parties. Letters from two New York licensed realtors have been provided attesting that the lease cost per square foot is at fair market value.

Capability and Feasibility

The total project cost of \$558,082 will be met via the proposed owner's equity. Working capital requirements are estimated at \$227,538, based on two months of third-year expenses. The proposed member will provide equity from their personal resources to meet the working capital requirements. BFA Attachment A is the personal net worth statement of the proposed owner of W Medical, LLC, which indicates the availability of sufficient funds for the project cost and working capital equity contributions. BFA Attachment C is the pro forma balance sheet of W Medical, LLC, which indicates a positive members equity position of \$783,620 as of the first day of operation.

The submitted budget indicates net incomes of \$72,493 and \$139,256 for the first and third years, respectively. Revenues are based on current reimbursement methodologies for D&TCs. The submitted budget appears reasonable.

Conclusion

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

Attachments

BHFP Attachment A	Map
BFA Attachment A	Personal Net Worth Statements of the sole owner of W Medical, LLC
BFA Attachment B	Lease Agreement Summary
BFA Attachment C	Pro Forma Balance Sheet of W Medical, LLC

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a diagnostic and treatment center to be located at 70 Lee 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:

211151 B

W Medical, LLC d/b/a W Health Center

APPROVAL CONTINGENT UPON:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health (Department). 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 an executed building lease agreement, acceptable to the Department of Health. [BFA]
4. Submission of a photocopy of an amended and executed Restated Articles of Organization, acceptable to the Department. [CSL]
5. Submission of a photocopy of an executed Certificate of Assumed Name, acceptable to the Department. [CSL]
6. Submission of a photocopy of an amended and executed Operating Agreement, acceptable to the Department. [CSL]
7. Submission of photocopy of an amended and executed Lease Agreement, acceptable to the Department. [CSL]
8. Submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **May 1, 2023**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for an extension to the project approval expiration date. [PMU]
2. Construction must start on or before **August 1, 2022**, and construction must be completed by **February 1, 2023**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The 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. [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 # 211226-E
Perry Avenue Family Medical, Inc.

Program: Diagnostic and Treatment Center **County:** Bronx
Purpose: Establishment **Acknowledged:** June 7, 2021

Executive Summary

Description

Perry Avenue Family Medical, Inc. d/b/a Perry Avenue Medical Center (Perry Avenue) an existing Article 28 Diagnostic and Treatment Center (D&TC) at 3071 Perry Avenue, Bronx (Bronx County), requests approval to transfer 100% ownership interest from four existing shareholders to two new shareholders.

The current and proposed ownership is as follows:

<u>Current Shareholders</u>	<u>%</u>
Kishore Ahuja MD	45.05%
Rita Ahuja, MD	45.05%
Kavita Ahuja	4.95%
Ashish Ahuja	<u>4.95%</u>
Total	100%

<u>Proposed Shareholders</u>	<u>%</u>
Aleksandr Babakhanov	85%
Gitel Stiel	<u>15%</u>
Total	100%

Kishore Ahuja, M.D. will continue to serve as the Medical Director, a position he has held for more than a decade. All other facets of existing services and operations will remain in place including the Transfer and Affiliation Agreement with Montefiore – Moses Division.

OPCHSM Recommendation

Contingent Approval

Need Summary

There are no changes to services as a result of this application. Perry Avenue is in a HRSA-designated Medically Underserved and a Primary Care Health Professional Shortage area.

The applicant projects 37,905 visits in the first year and 39,421 in the third year after the completion of the transfer, with Medicaid utilization of 71%.

Program Summary

The individual background review indicates the proposed new shareholders 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 total acquisition cost for 100% of the shares of Perry Avenue is \$5,500,000. Aleksandr Babakhanov provided a deposit for \$550,000, which is being held in escrow per an executed escrow agreement by Raymond Iryami Law Firm P.C. A letter of interest has been submitted by Flushing Bank for \$4,400,000 for a term of ten years and rate of 4.5%. The remaining \$550,000 will be paid via shareholders equity. The submitted budget is as follows:

<u>Budget</u>	<u>Year One</u>	<u>Year Three</u>
Revenues	\$4,696,983	\$4,884,863
Expenses	<u>\$4,597,565</u>	<u>\$4,711,462</u>
Gain/(Loss)	\$99,418	\$173,401

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 bank loan commitment, acceptable to the Department of Health. (BFA)
2. Submission of a photocopy of an amended and executed Certificate of Amendment of the Certificate of Incorporation of Perry Avenue Family Medical, Inc., acceptable to the Department of Health (Department). [CSL]
3. Submission of a photocopy of an amended and executed Lease Agreement between Perry Avenue Family Medical, Inc. and Cora Realty Co. LLC, acceptable to the Department. [CSL]
4. Submission of a photocopy of the consent of Cora Realty Co. LLC to the assignment of the Lease Agreement, acceptable to the Department. [CSL]
5. Submission of amended and executed stock transfer affidavits from each seller, acceptable to the Department. [CSL]
6. Submission of an executed stock transfer affidavit from Gitel Stiel, acceptable to the Department. [CSL]
7. Submission of an amended stock certificate, 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 the expiration of the approval. [PMU]

Council Action Date

February 10, 2022

Need and Program Analysis

Program Description

Perry Avenue began operations in November 2002 and provides a variety of medical services to the residents in Bronx County, including primary care, podiatry, optometry, physical therapy, and cardiology. The applicant indicates there will be no change in services as a result of this request. The applicant projects 37,905 visits in the first year and 39,421 in the third year after the completion of the transfer, with Medicaid utilization of 71%. The applicant states they are committed to serving all persons in need without regard to ability to pay or source of payment.

Background

The primary service area is the neighborhood of Williamsbridge in northern Bronx County. HRSA has designated Fordham a Health Professional Shortage Area (HPSA) for Medicaid eligible Primary Care Services and Bedford Park a Medically Underserved Area/Population.

According to Data USA, in 2019, 92.1% of the population of Bronx County had health coverage, broken down as follows:

Employee Plans	31.3%
Medicaid	42.3%
Medicare	6.97%
Non-group Plans	11%
Military or VA Plans	0.405%

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 2017 PQI rates for the overall PQI condition and shows that the PQI rate for Bronx County is significantly higher than the New York State rate.

Hospital Admissions per 100,000 Adults for Overall PQIs

2017 PQI Rates	Bronx County	New York State
All PQIs	2,191	1,431

Character and Competence

The table below details the proposed change in ownership:

Name	Current	Proposed
Kishore Ahuja MD	45.05%	0%
Rita Ahuja, MD	45.05%	0%
Kavita Ahuja	4.95%	0%
Ashish Ahuja	4.95%	0%
Alexsandr Babakhanov*	0.00%	85%
Gitel Stiel*	0.00%	15%
Total	100%	100%

**Subject to Character and Competence*

Alexsandr Babakhanov is a licensed pharmacist and has been employed at Mediserv Pharmacy for over five years, currently as the Staff Supervising Pharmacist. In this role, he is responsible for overseeing inventory, technicians, and the compounding pharmacists. He has also been employed as the Supervising Pharmacist of Orthoserve, Inc for over four years where he is responsible for managing the pharmaceutical team. He was previously employed at ProHealth Pharmacy, as a freelance Pharmacist, performing the duties of a pharmacist at sites to cover staffing as needed, and at Prime Made Pharmacy. He received his pharmacy degree from Long Island University Brooklyn Campus.

Gitel Stiel has been an Administrator at Ahava Medical and Rehabilitation Center for over 13 years where her responsibilities include hiring and scheduling for the facility of approximately 250 employees; preparation and submission of application and supporting documents for new facility licenses and license renewals; staff training and review on regulatory compliance, improved patient care, and compliance with company policy and procedure; developing and updating the policy and procedure manual for the divisions of the company; and decisions regarding equipment and supply purchases, including implementing cost-saving measures.

Staff from the Department's Division of Hospitals and Diagnostic & Treatment Centers (DHDTTC) reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the State's Office of Medicaid Management, Office of Professional Medical Conduct, and Education Department databases, as well as, the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Alexsandr Babakhanov disclosed being charged with Criminal Possession of a Controlled Substance in the Seventh Degree, a Class A misdemeanor. On May 28, 2014, he was in the possession of the controlled substances Codeine, Fentanyl, Oxycodone, and Oxymorphone. On June 2, 2015, he was convicted and entered a plea of guilty to the crime. The State Education Department Office of Professional Discipline stayed a two-year suspension on his license. He was placed on probation for a period from July 31, 2018 to July 30, 2020.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3). There will be no changes in services as a result of this application.

Financial Analysis

Operating Budget

The applicant has submitted an operating budget, in 2022 dollars, for the current year (2019), and the first- and third-year after the change in ownership interest, summarized as follows:

	<u>Current Year (2019)</u>		<u>Year One (2022)</u>		<u>Year Three (2024)</u>	
	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>	<u>Per Visit</u>	<u>Total</u>
<u>Revenues</u>						
Commercial FFS	\$124.99	\$1,124,298	\$124.99	\$1,169,297	\$124.99	\$4,589,322
Medicare FFS	76.63	120,083	76.63	124,886	70.63	129,882
Medicaid FFS	164.16	153,161	164.16	159,287	164.16	165,659
Medicaid MC	<u>124.99</u>	<u>3,118,788</u>	<u>124.99</u>	<u>3,243,512</u>	<u>124.99</u>	<u>3,373,234</u>
Total Revenue		\$4,516,330		\$4,696,983		\$4,884,863
<u>Expenses</u>						
Operating	\$116.76	\$4,255,387	\$86.70	\$3,286,499	\$85.98	\$3,389,806
Capital	<u>5.61</u>	<u>204,637</u>	<u>34.59</u>	<u>1,311,066</u>	<u>33.52</u>	<u>1,321,656</u>
Total Expenses	\$122.37	\$4,460,024	\$121.29	\$4,597,565	\$119.50	\$4,711,462
Net Income/(Loss)		<u>\$56,306</u>		<u>\$99,418</u>		<u>\$173,401</u>
Visits		36,447		37,905		39,421
Cost Per Visit		\$122.37		\$121.29		\$119.50

Utilization by payor for the current year and after the change in shareholders is as follows:

Payor	Current Year (2019)		Year One		Year Three	
	Visits	%	Visits	%	Visits	%
Commercial MC	8995	24.68%	9,355	24.68%	9,729	24.68%
Medicare FFS	1,567	4.3%	1,630	4.3%	1,695	4.3%
Medicaid FFS	933	2.6%	970	2.6%	1,009	2.6%
Medicaid MC	<u>24,952</u>	<u>68.46%</u>	<u>25,950</u>	<u>68.46%</u>	<u>26,988</u>	<u>68.46%</u>
Total	36,447	100%	37,905	100%	39,421	100%

The following is noted concerning the submitted budget:

- Revenues, expenses, and utilization assumptions are based on current reimbursement rates and historical experience of the D&TC.
- The practice had positive net income in 2018 and 2019. The company recorded a net loss of \$156,438 in 2020 due to a 25% decline in utilization resulting from the COVID-19 pandemic.
- Capital expense increases in years One and Three are due to interest payments on the loan payment according to the submitted budgets.

Agreements and Contracts

BFA Attachment B contains summaries of the following agreements:

- An executed Stock Purchase Agreement to acquire the operations of Perry Avenue Medical, Inc., to be effectuated upon PHHPC approval.
- An executed existing building lease. The agreement is an arm's length arrangement, as the landlord and tenant do not have any relationship.

Capability and Feasibility

The total purchase price for the 100% transfer of the 200 shares is \$5,500,000, which is to be funded via equity and a loan upon PHHPC approval, as follows:

Escrow Deposit	\$550,000
Bank Loan	\$4,400,000
Members Equity	<u>\$550,000</u>
Total	\$5,500,000

Alexsandr Babakhanov and Gitel Stiel are purchasing 85% and 15% shareholders' interest respectively, to be funded by a loan of \$4,400,000 and equity of \$1,100,000; \$935,000 from Alexsandr Babakhanov via the \$550,000 deposited in escrow held by Raymond Iryami Law Firm P.C. and \$385,000 in equity at the time of closing and \$165,000 from Gitel Stiel at the time of closing. A letter of interest from Flushing Bank has been submitted for \$4,400,000 for ten years at a 4.5% interest rate for a ten-year term. BFA Attachment A is the net-worth statement for the two proposed shareholders, which show sufficient equity to fund the equity portion acquisition.

The working capital requirement is estimated at \$766,261, based on two months of projected first-year expenses, and will be paid out of existing operations. BFA Attachment C is the Perry Avenue Family Medical Center's internal financial statements as of July 31, 2021, and demonstrates that there are sufficient resources for the equity requirement.

The submitted budget projects a net income of \$99,418 and \$173,401 during the first and third years, respectively. Revenues are based on current reimbursement rates; Medicare and Medicaid reflect prevailing reimbursement methodologies. The submitted budget appears reasonable.

BFA Attachment C is the internal financial statements from January 1, 2021 through July 31, 2021. As shown, the facility had positive working capital and positive net asset positions and achieved a net ordinary income before other expenses and officer's and relative salary of \$1,335,982.

BFA Attachment D is the D&TC's certified 2020 financial statement. As shown, the facility had a negative working capital position and positive net asset position. The facility incurred a net loss of \$156,438, for

which the applicant states the reason was as a result of decreased utilization caused by the COVID-19 pandemic. With reduced staffing and precautionary safety measures taken, the facility was not equipped to resume the pre-pandemic level of utilization.

BFA Attachment E is the D&TC's certified 2019 financial statement. As shown, the facility had a positive working capital position and a positive stockholder's equity position and achieved a net profit of \$56,371.

Conclusion

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

Attachments

- | | |
|------------------|--|
| BFA Attachment A | Shareholders' Net Worth Statement |
| BFA Attachment B | Agreements and Contracts |
| BFA Attachment C | Perry Avenue Family Medical Center - Internal Financial Statement 1/1/2021 through 7/31/2021 |
| BFA Attachment D | Perry Avenue Family Medical Center - Certified Financial Statement, 12/31/2020 |
| BFA Attachment E | Perry Avenue Family Medical Center – Certified Financial Statement, 12/31/2019 |

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 10th day of February 2022, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 100 percent ownership from the existing members to two new members at 85 percent and 15 percent respectively, 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:

211226 E

Perry Avenue Family Medical Inc.

APPROVAL CONTINGENT UPON:

1. Submission of an executed bank loan commitment, acceptable to the Department of Health. (BFA)
2. Submission of a photocopy of an amended and executed Certificate of Amendment of the Certificate of Incorporation of Perry Avenue Family Medical, Inc., acceptable to the Department of Health (Department). [CSL]
3. Submission of a photocopy of an amended and executed Lease Agreement between Perry Avenue Family Medical, Inc. and Cora Realty Co. LLC, acceptable to the Department. [CSL]
4. Submission of a photocopy of the consent of Cora Realty Co. LLC to the assignment of the Lease Agreement, acceptable to the Department. [CSL]
5. Submission of amended and executed stock transfer affidavits from each seller, acceptable to the Department. [CSL]
6. Submission of an executed stock transfer affidavit from Gitel Stiel, acceptable to the Department. [CSL]
7. Submission of an amended stock certificate, 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 the 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*.