April 19, 2018

PROJECT REVIEW COMMITTEE MEETING

DISTRICT OF COLUMBIA GOVERNMENT
DEPARTMENT OF HEALTH
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
899 North Capitol Street, N.E.
Sixth Floor
Washington, D.C. 20002

PROJECT REVIEW COMMITTEE MEETING

Date: April 19, 2018
Time: 6:00 p.m.
Place: 899 North Capitol Street, N.E.
6th Floor, Conf. Rm. 6002
Washington, D.C. 20002

AGENDA

I. Call to Order

II. Quorum Declaration

III. Action on PRC Minutes March 15, 2018

IV. Chairperson's Report

V. Staff Report

- **MedStar Medical Group II, LLC – Establishment of Otolaryngology and Audiology Services - Certificate of Need Registration No. 18-2-3**

  Public Comment

- **Sibley Memorial Hospital – Fifth Year Renewal of the Certificate of Need for the Establishment of Proton Therapy Services - Certificate of Need Registration No. 17-3-2**

VI. Unfinished Business

VII. New Business

VIII. Public Comment

IX. Adjournment

PROJECT REVIEW COMMITTEE MINUTES

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

PROJECT REVIEW COMMITTEE MEETING MINUTES

March 15, 2018

MEMBERS PRESENT:	**MEMBERS ABSENT:**
Zinethia Clemmons	Steven Nash
Brenda Kelly	Chioma Nwachukwu
Goulda Downer, Ph.D.	Sandy Allen
Jacqueline Bowens	Stephen Neuman
Robert Brandon, Esq.	Barbara Ormond
	Marc Rankin, M.D.

STAFF PRESENT:

Amha Selassie
John Clark
Thomas McQueen
Dana L. Mitchener

GUEST LIST:	**ORGANIZATION:**
Dr. Olu Ezeani	Ergo Solutions
Andrea Brown	BridgePoint Healthcare
Swenda Moreh	BridgePoint Healthcare
Sammin Washington	BridgePoint Healthcare
Calvin Smith	BridgePoint Healthcare
Marc Ferrel	BridgePoint Healthcare
Courtland Wyatt	Ergo Solutions
Michael Davis	Plant the Seed Youth Treatment Services
Bill Quirk	Children's National
Dave Waye	Children's National

Dontrell Smith	ANC 7E06
Cliff Barnes	EBG
G. Brown	Ergo Solutions
Sekou Murphy	Bread for the City
Danina Lee	Plant the Seed Youth Treatment Services
D. Davis	Plant the Seed Youth Treatment Services
Toya Davis	Plant the Seed Youth Treatment Services
Catherine E. Davis	Plant the Seed Youth Treatment Services
Teerah Goodman	
Sara Tewolde	Public

I. Call to Order

Chairperson Robert Brandon called the Project Review Committee meeting to order.

II. Quorum Declaration

There was a quorum.

III. Action on PRC Minutes of February 22, 2018

The minutes were approved.

IV. Chairperson's Report

There was no Chairperson's report.

V. Staff Report

A. DCA Hadley SNF, LLC d/b/a BridgePoint Sub-Acute and Rehabilitation National Harbor – Addition of 32 Skilled Nursing Beds - Certificate of Need Registration No. 17-8-6

Presentation by Staff

Mr. Thomas McQueen, the lead analyst for the project stated that the applicant, DCA Hadley SNF LLC, d/b/a BridgePoint Sub-Acute and Rehabilitation National Harbor, states that BridgePoint Healthcare is a diversified provider of post-acute care in settings ranging from long-term acute-care hospitals to skilled nursing facilities.

Mr. McQueen stated that BridgePoint has three locations that include two in Washington, DC, BridgePoint Hospital National Harbor, and BridgePoint Hospital Capitol Hill and one in New Orleans, BridgePoint Continuing Care Hospital.

Mr. McQueen then said that according to the Applicant, in 2014, BridgePoint purchased Specialty Hospitals of Washington which at the time operated the only two long-term care acute hospitals in the greater metropolitan area and also the areas only to skilled nursing facilities, licensed for residents requiring ventilators and other complex health conditions.

According to Mr. McQueen, BridgePoint acquired Capitol Hill Hospital with 117 skilled nursing beds and 60 long-term care acute hospital beds, and Hadley Hospital with 62 skilled nursing beds and 82 long-term care acute hospital beds.

Mr. McQueen stated that the Applicant is now seeking a certificate of need to add 32 skilled nursing beds at BridgePoint National Harbor. BridgePoint National Harbor currently has a 62-bed licensed skilled nursing facility that is co-located with an 82-bed

LTACH. BridgePoint National Harbor is currently one of two facilities in the District designed by the Department of Health to care for patients with a mechanical ventilator.

Mr. McQueen maintained that according to the applicant, the additional beds will be located on the first and second floor of the facility. The first floor section was previously used as a physician medical office suite and is currently unoccupied. The second floor is currently housing administrative, respiratory and rehabilitation offices which will be relocated throughout the facility.

Mr. McQueen stated that according to the Applicant, each floor will have eight double-occupancy rooms totaling 16 beds, a nurse station, a day room, two showers, and other utility ancillary rooms as required by regulations. Additionally, BridgePoint National Harbor will renovate the front yard of the facility to provide a scenic and useable courtyard for the benefit of residents and their visitors.

Mr. McQueen then said that the capital expenditure associated with this project is $5,319,999. The Applicant stated that the services should be operational by August of 2019.

According to Mr. McQueen, after a careful review of the information, staff has determined that the Applicant has demonstrated the need for the proposed services. In general, there is an adequate supply of post-acute care services. However, there are gaps to accessing particular services.

Mr. McQueen stated that the Applicant has provided information from the Department of Health Care Finance that identifies that there is a gap in services for skilled nursing patients and skilled nursing facilities in the District. This is suggested by the number of DC Medicaid patients receiving services at skilled nursing facilities outside the District, 288.

Additionally, Mr. McQueen stated, BridgePoint has demonstrated that it is the only provider of vent services in the District and one of four providers to serve the bariatric population. Staff also notes that in December of 2016, Washington Home, a 122-bed DC skilled nursing facility, closed its facility.

Mr. McQueen stated that as a result, staff recommends approval of the certificate of need to DC Hadley SNF LLC d/b/a BridgePoint Sub-Acute and Rehabilitation National Harbor for the additional 32 skilled nursing beds.

Presentation by the Applicant

Marc Ferrell, President and CEO of BridgePoint Healthcare, stated that currently, BridgePoint operates 142 long-term acute care hospital beds and 178 skilled nursing beds in the District of Columbia. He has been involved in the acquisition of these facilities since early 2014 and remain as the President and CEO of the company.

According to Mr. Ferrell, the facility was days away from closing. They received an emergency approval by the city council to approve the sale of the buildings, and an emergency certificate of need. There were plans to send the patients who were on tracheostomy tubes and ventilators to Maryland, Virginia and Pennsylvania. Those plans were made by the Department of Health and the Department of Health Care Finance.

Mr. Ferrell maintained that the first year, they were able to stabilize their workforce. They spent their capital budget dealing with items such as heating, ventilation, air conditioning, hot water boilers, and leaking roofs. The buildings were in disrepair and it took them quite a bit of time to resolve those issues.

He then said that in the second year, they continued their investment into the facilities and redid the entire IT infrastructure from the street to every patient room in terms of

rewiring, wireless internet to implement electronic medical records in the skilled nursing units.

He then said that in the third year, the facility received a 5-star rating from CMS that's attributable to all the hard work of the staff, physicians and team that have worked tirelessly to make a difference in the facility.

According to Mr. Ferrell, currently, the sub-acute and rehabilitation has 62 total beds. They had 21,614 patient days, an average daily census of 59.2. Out of the 62 beds, almost 83 percent of the population was Medicaid and they had a 96 percent occupancy rate, not including bed hold days. So our occupancy availability of beds was actually -- our occupancy was actually higher.

Mr. Ferrell stated that the hospital has 82 beds, 18,202 patient days. In 2017, close to a 50 average daily census with 17 percent Medicaid and 85 percent other with a 61 percent occupancy.

Mr. Ferrell maintained that the facility currently has a ventilator capacity of 17 patients and they run very close to 17 patients per day. There's approximately a three- to four-week waiting list for a patient on mechanical ventilator in the District of Columbia with Medicaid to find a bed in one of their facilities. And that's the primary goal of why they're here today, to help deal with that shortage.

Mr. Ferrell stated that currently there are 288 Medicaid skilled nursing beneficiaries or D.C. residents residing out of the District. Most of them are in Maryland and Virginia because they cannot find a bed in D.C. to care for them.

Mr. Ferrell then said that approximately 25 of those patients are on mechanical ventilation and a smaller number who are on kidney dialysis and ventilator support as that dual service is not currently offered in Washington, D.C.

Mr. Ferrell stated that their plan is to use the first and second floor of the attached medical office building and gut the entire premises and build, from the walls in, 32 skilled nursing beds. These beds would then be specifically dedicated to patients on mechanical ventilation. The rooms would be of adequate size, electrical, oxygen, suction, and lighting. They will be state-of-the-art rooms for these residents.

Mr. Ferrell stated that as soon as construction is complete and the beds are licensed, they will then ask the Department of Health to approve an increase from their current 17-bed capacity for ventilator care up to 32 beds.

Mr. Ferrell maintained that this will also help reduce the out-of-state skilled nursing placements and to allow the 32 D.C. residents the opportunity to come back into the District.

Discussion

Ms. Bowens wanted to know what BridgePoint's long-term strategy in terms of referrals.

Mr. Ferrell stated that they have two contracts, one with the MedStar system and one with the Inova system whereby any patients that they have that are considered unfunded patients, they contract with BridgePoint and they take care of the ventilator patient in one of their beds.

Mr. Ferrell maintained that they do have a preference to take and accept patients from inside the District first.

Ms. Clemmons wanted to know if there will be displacement of patients during the renovations.

Mr. Ferrell said no, that they'll be able to do everything parallel because the area that will be under construction is not being utilized for patient care. It is being utilized for

ancillary services, rehab, respiratory. But they'll be relocated to another space before that begins.

Dr. Downer wanted to know what their opinion is as to why they are the only provider of ventilator services in the District that serves a bariatric population.

Mr. Ferrell stated that he's a respiratory therapist by training and has worked in the sub-acute skilled nursing LTC arena for the last 20 years. To some folks, it's really intimidating to offer this type of a program.

According to Mr. Ferrell, this program goes hand in hand with their specialty hospital side. So they've taken a critically ill patient, rehabilitate them and can move them into their skilled nursing unit.

Mr. Ferrell then said that a couple other things that make them unique is, these are hospital-based skilled nursing facilities. So, if a patient is on their skilled nursing unit and they have a major medical problem, there are physicians on the hospital side 24 hours a day, seven days a week, 365 days a year that will respond to that emergency. In any other freestanding nursing home setting, you would have to call 911 and send the patient out.

So, they have a low return to acute rate because of that. And they can get x-ray, laboratory, and clinical services done immediately that other skilled nursing facilities would wait for. They also have in-wall oxygen, suction and air that a lot of skilled nursing facilities don't have.

According to Mr. Ferrell, the risk is very high. It can be very expensive to provide this equipment.

Mr. Brandon wanted to know about the hospital patient census and the capacity rate.

Mr. Ferrell stated that Medicare handed them their largest change in the 20 years he's been there with patient criteria to the specialty hospitals. They will only allow them now to take patients that have been in an ICU for three days or more or on a ventilator. And so they've wiped out a large population of patients that before they would pay for. And that was effective early January 2016.

Mr. Ferrell maintained that their secondary plan, if this does not change within the next 12 months, they will probably come back looking to convert 35 of those beds to skilled nursing and further help with that 288 patients outside of the District.

Ms. Clemmons wanted to know what percentage of their population come from Ward 8.

Mr. Ferrell stated that their number one referring source is UMC. They received 271 admissions in 2017. Compared to Washington Hospital Center, 171.

Mr. Ferrell maintained that they have a very good working relationship with UMC. Any of their patients that need short-term acute hospitalization go to UMC, so they have a transfer agreement with them.

Ms. Downer wanted to know if they have a relationship with Howard University.

Mr. Ferrell stated that Howard is probably the fourth largest referral source that they have. They don't have an official affiliation with Howard other than a transfer agreement between their two facilities.

Mr. Brandon wanted to know what facilities do they have for dialysis and what's the utilization.

Mr. Ferrell stated that they have a dialysis provider who comes into the building and provides dialysis to the hospital patients and they pay them so many dollars per treatment.

Vote

The PRC agreed to accept staff's recommendation to approve the project.

B. Plant the Seed Youth Treatment Services, LLC – Establishment of a 15-Bed In-Patient Residential Substance Abuse Treatment Program for Youth Certificate of Need Registration No. 17-7-5

Mr. John Clark, the lead analyst for the project, stated that Plant the Seed Youth Treatment Services (PTS) was established in 2017 with an administrative and drug treatment staff who have more than two years of experience in the District and other agencies which provides drug treatment services. The staff have been client directors, nurses, clinical care coordinators, psychiatrists, psychologists, social workers and drug treatment counselors.

Mr. Clark stated that PTS is proposing a 15-bed inpatient substance abuse treatment program for youth aged 13 through 20. It will contain nine bedrooms and six and a half bathrooms. It will be located within the Marshall Heights community in Ward 7. The site is bordered by Benning Road, Southern Avenue, and East Capitol Street. It's easily accessible by public and private transportation and it's near the Benning Road metro station.

According to Mr. Clark, the D.C. Department of Behavioral Health (DBH) has determined that the American Society of Addiction and Medicine's level three treatment regimen is the appropriate level of care for a significant number of youth in the District who are in need of drug treatment services.

Mr. Clark stated that in support of DBH's determination of need for youth residential treatment, the Applicant cites national statistics which rank the District as either second or third highest of all the large urban areas for certain categories of illicit drug use among youth.

Mr. Clark then said that having a crisis which is heightened by CDC findings during 2013 that 41 percent of juvenile rescues in the District tested positive for marijuana. The 2010 census reported that one in every five District residents is an adolescent between 10 and 24 years old with 53 percent of that population being children, youth, and young adults in Wards 7 and 8.

According to Mr. Clark, a level three treatment regimen which DBH prescribes and which the Applicant proposes to offer includes 25 hours of treatment services per week for a period of up to 28 days, a 24-hour supportive treatment environment in which to initiate and continue the individual recovery process, at least 20 hours of additional complex treatment services, and have the ability to accommodate patients who have co-occurring or severe social interpersonal impairments caused by substance abuse and/or interaction with the criminal justice system.

Mr. Clark stated that since the nearest treatment facility is located in Baltimore, DBH has been forced to place District youth in a facility which prevents parents from participating in the treatment cycle and limits access to coordinated local after-release treatment from inpatient treatment through local outpatient services.

Mr. Clark maintained that through a coordination with the school system for age-appropriate education services, PTS maintains affiliated provider agreements with court services, the family division, juvenile probation, child and family services, outpatient treatment services, Sasha Bruce Youthwork, prevention centers in all wards and Psychiatric Institute of Washington.

Mr. Clark stated that during preparation of the application, PTS states that it presented its proposal to the ANC 7E for consideration in its October 2017 meeting. In an email dated January 23, 2018, the ANC informed SHPDA that at its January 28, 2018 meeting that it had unanimously voted not to support the proposed project.

According to Mr. Clark, the Zoning Board recommended, along with the D.C. Office of Planning, that the application be approved because it would not cause either congestion or traffic delays.

Mr. Clark stated that as a result of this combination of circumstances, the SHPDA has recommended approval of the application because it is the only location in the city that will provide inpatient care.

Presentation by the Applicant

Mr. Mike Davis, CEO for Plant the Seed Youth Treatment Services, stated that they are proposing a 15-bed inpatient residential treatment program for youth. This proposed program is located at 5212 Astor Place, S.E. DCRA designated them not as a community-based institutional facility but designated them as a healthcare facility. So, they're providing a healthcare service to the community.

Mr. Davis stated that he's director of an adult residential treatment program. He has a view of what the city faces in terms of drug and alcohol use and the problem that it faces which transcends to youth also. He maintains that treatment works, and he sees it work over and over again in the adult community. He believes that it would work in the youth community, providing they have this level of care.

According to Mr. Davis, they're not trying to add an additional program into that community. What they're trying to do is replace an educational program that had dissolved at that location.

Mr. Davis stated that they want to provide a solution to a glaring problem, and that problem is that the youth in D.C. are having a difficult time with drug and alcohol use. And inpatient care is essential for services to be complete and for the D.C. residents to receive a system of care for their youth. And they want to be able to provide and be a part of a linkage to that system of care.

Ms. Catherine Davis, Administrator, stated that nationally, the National Institute of Drug Abuse has found that 41 percent of arrestees that are youth test positive for marijuana.

Ms. Davis stated that 53 percent of D.C. children, youth, and young adults live in Wards 7 and 8. One in every five D.C. residents is an adolescent between the ages of 10 and 24. The poverty level data shows that consistently more children live in poverty in the District of Columbia compared to the rest of the nation, particularly in Wards 7 and 8.

According to Ms. Davis, the rate of youth placed in juvenile detention and correctional facilities is also consistently higher than the national average. In 2010, residential placements were twice as high as the nation.

Ms. Davis then said that among high school students, the following rates are consistently higher than the national average. For those using marijuana for the first time before the age of 13 is 11 percent. Having used marijuana during their lifetime is 43 percent. Having used marijuana during the last 30 days is 26 percent and had a least one drink of alcohol or more - one or more days of their lives is 65 percent. And these rates are consistently higher than the national average

Ms. Davis stated that there are only four outpatient services servicing youth in D.C. - one in Ward 1, one in Ward 4, one in Ward 6, and one in Ward 8. There are no residential services addressing the crisis of substance abuse in D.C. There are also no outpatient services for youth in Ward 7 which is the ward they're proposing to open this residential service.

Mr. Davis stated that in a substance abuse inpatient treatment clinical environment, you have an assessment diagnostic done by a licensed practitioner. You have a substance abuse counseling done by certified addictions counselors who are certified by the District of Columbia who use a personalized approach.

Mr. Davis maintained that clinical care coordination is done to ensure that the individual has a continuity of care plan that puts them back in the community and the resources and services that are in the community are readily available to them.

Mr. Davis then said that there is case management that supports the clinical care coordination and crisis intervention not just for the individual client but also for the family.

Mr. Davis maintained that they have a 24-hour surveillance that's both through audio-visual cameras on the outside. At no time are they left unsupervised. They have clinical staff during the daytime, and professional monitoring staff in the afternoon. Overnight would be ratioed according to the regulations with the District of Columbia Chapter 63 which says that there should be at least three supervised adults who are paid staff overnight while the residents are in quarters.

Discussion

Mr. Brandon wanted to know who owns the house and will they be leasing the property.

Mr. Davis stated that the house is owned by Godwin and Joyce Ukwuani. They live right next door. It's an adjoining property. He built a 6,800 square foot residence and having two adjoining residences. They're leasing 3,400 of that and Mr. Ukwuani has 3,400 that's his home.

Mr. Brandon wanted to know a little bit about the services that Mr. Davis is providing in the adult population and if he is doing any outpatient youth drug and alcohol counseling now.

Mr. Davis stated that he is and he's a clinical supervisor for a youth program for the agency that he works for.

Mr. Davis maintained that he also works as a consultant at Hillcrest Services with the largest youth outpatient program in D.C. that provides youth services, both mental health and substance use disorder. He was a consultant for them for over a year.

Mr. Brandon wanted to know what his role will be at this facility.

Mr. Davis stated that he's the CEO and a licensed practitioner. There will be other practitioners and he would also give his professional insight as a practitioner. But primarily, he would be the CEO to make sure that the culture of the program fits under Department of Behavioral Health and that they're compliant and making and meeting the regulations.

Ms. Bowens wanted to know if they would be licensed by the Department of Behavioral Health.

Mr. Davis stated that they would be licensed by the Department of Behavioral Health to provide addiction and substance abuse resources.

Ms. Bowens wanted to know his opinion as to why there's no existing facility to address the issues plaguing the youth.

Mr. Davis believes that there was a sense of denial within the community of Washington, D.C. that the issue wasn't really an issue. And now that it's become an issue that they see or recognize and so he believes that the District of Columbia is doing the right thing in saying, they need to provide this service for their own youth in our own city at this time.

Ms. Bowens wanted to know beyond marijuana, what are the drugs of choice that you're seeing and preparing for with this group of kids that they're going to be bringing in.

Mr. Davis stated that K-2 which is a synthetic drug and is a generic drug for marijuana. This drug is potentially dangerous. They're seeing youth OD'ing. They're coming into the hospitals unconscious, and with bizarre behaviors because of this synthetic drug.

Dr. Davis then said that Molly is a drug that's putting youth at high risk because of its sensitivity to sexual problems. A lot of youth participate in a lot of sexual activity or are promiscuous and using unprotected sex. And they would also provide sex education to inform them about HIV, the different choices that are being made in terms of being sexually responsible.

Ms. Bowens wanted to know what their strategic plan is with respect to being financially sustainable.

Mr. Davis stated that they will be reimbursed through Medicaid and through DBH.

Ms. Kelly wanted to know how the youth will be referred to them.

Mr. Davis stated through court services, walk-ins, DBH, child family services, outpatient programs and schools. The Board of Education may identify a child in school who's having a problem with drugs and alcohol. Every arm that touches a youth in D.C. would have the opportunity to participate in this residence program.

Ms. Kelly wanted to know how they will determine a child is having a problem with drugs and will they be treating specific modalities and how will they handle the wide variety of youth that might come into the center from various places

Mr. Davis stated through individualized treatment planning.

Ms. Kelly wanted to know what they meant by the zoning board approval was suspended.

Mr. Davis stated the zoning board approved the increase from six residents because they could only provide six in the residence in terms of occupancy. They approved that to 15. So when you talk about space, accommodations, structural accommodations, the zoning board said that not only can they do 6, they can do 15.

Mr. Davis then said that the zoning board suspended the approval until March 21st to give the ANC an opportunity to speak at that time.

The PRC had concerns with regards to blend of all the varieties of addictions in the same environment, will prescribers for medications for treatment be onsite and how will current illnesses be handled.

Mr. Davis stated that they have a contractual nurse that comes in and would provide that.

Ms. Clemmons wanted to what model they are using and what guarantees of success are they predicting.

Mr. Davis stated that the Department of Behavioral Health has laid out a plan in terms of how a program should operate from what's needed infrastructurally and what's needed evidence-based-wise and we're providing services that are clinically appropriate and that they're going to be provided by those who are certified under the District of Columbia.

Dr. Downer wanted to know if they have a disaster emergency plan.

Mr. Davis that they have a disaster emergency plan that's located in their policy.

Ms. Downer wanted to know if they had a plan for the residents after they finish the program.

Ms. Davis stated that they are interested in having a mentorship program so that each individual that leaves the program will have a mentor assigned to them and they have continuity of care.

Continuity of care with other agencies, to meet the needs of the individuals will be established through the course of the treatment.

Mr. Dontrell Smith stated that he is Commissioner of 7E-06 where the facility is potentially being located.

According to Mr. Smith, the reason why this was suspended in regards to the Office of Zoning was the initial hearing for zoning was in January. And on the record the next scheduled hearing was set for March 21st, but they moved it up to February 21st without notification.

So, because the ANC was not properly informed of the change of the date, so therefore, on the record, they have retracted their statement from the date of February 21st off the record and they're going to re-hear the whole statement because the ANC as well as no one from the community was present because of the error on their part.

Mr. Davis stated he has also provided the resolution that was submitted to the Office of Zoning in regards to the application for the increased occupancy from 6 to 15.

Mr. Davis stated that after talking to the Applicant, and going out and talking to the community, the ANC as a whole commission do not support it.

Mr. Brandon wanted to know if Marshall Heights would get party status.

Mr. Smith stated that they had before the initial application which was in January. They weren't able to. But they said due to the case, they will be able to speak at the next

zoning hearing. So Marshall Heights said the association is also in line with this process of not having Plant the Seed facility within this area.

Mr. Brandon stated that he has more questions and maybe they should get more information on the program.

Ms. Bowens stated that she believes that there is a need and this type of service don't exist. She maintains that as much as she believes this is important, she is concerned about setting up something for failure because they don't have enough information about the model.

Mr. Brandon stated that he would suggest that they defer for two months so that they will have information about zoning so the community can have more input.

He then said that they can get more information from the Department of Behavioral Health about what they believe is the right program for residential facility for youth and then get more information from the Applicant.

Vote

The PRC agreed to defer the vote until May until they receive additional information.

VI. Unfinished Business

There was no unfinished business.

VII. New Business

There was no new business.

VIII. Public Comment

There was no public comment.

IX. Plan Development and Implementation Committee Report

The Committee talked about meeting to discuss some priority areas to get started on implementation of the Plan.

X. Adjournment

The meeting was adjourned at 8:29 p.m.

STAFF REPORT I

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

899 North Capitol Street, N.E.

Sixth Floor

Washington, D.C. 20002

ANALYSIS OF NEW CERTIFICATE OF NEED APPLICATION
BASIC PROJECT AND REVIEW INFORMATION

Project Data

Registration Number	18-2-3
Applicant:	MedStar Medical Group II, LLC
Project Title:	Establishment of Otolaryngology and Audiology Services
Address:	2440 M Street, N.W. Washington, DC 20037
Project Representative:	Francisco Semiao
Proposed Capital Expenditure:	$272,802.67
Proposed Completion Date:	Soon After CON Approval

Review Data

Date for Project Review Committee Action:	April 19, 2018
Date for SHCC Action:	May 10, 2018
Estimated SHPDA Decision Date:	May 20, 2018
Lead SHPDA Analyst:	Thomas McQueen

Description of the Applicant and the Proposed Project:

MedStar Health, Inc. established the MedStar Medical Group II, LLC (MMG) as the parent company for primary care facilities and specialty services. MMG is a wholly owned subsidiary within the MedStar Health System. The Applicant maintains that the MMG provides conventional primary care and specialty services limited to medical consultation, general non-invasive examination and minor treatment to all people. The strategic plan for MMG is to expand the primary and specialty care base in the District and to deliver high quality, cost-efficient medical care.

The Applicant is now seeking a certificate of need for the establishment of Otolaryngology and Audiology services. The Applicant states that MMG has entered into an agreement with Dr. Catherin Picken to transition her Otolaryngology and Audiology practice, Washington ENT, into an employed model within MMG. The current private practice is located at 2440 M Street NW, in suite 620 and 606 that encompasses approximately 3,200 sq. ft. The Applicant maintains that all of the employed staff would become employed associates of MMG and MMG will assume the responsibility of the building leases that have two years remaining on the leases.

According to the Applicant, the Washington ENT Group Medical Office offers a full array of ear, nose and throat services to help patients stay healthy. The Applicant maintains that Otolaryngologists diagnose and manage diseases of the ears, nose, sinuses, larynx (voice box), mouth, and throat, as well as structures of the neck and face:

- The ears - hearing loss affects one in ten North Americans. Otolaryngologists are trained in both the medical and surgical treatment of hearing loss, ear infections, balance disorders, ear noise (tinnitus), and some cranial nerve disorders. Otolaryngologists also manage congenital (birth) disorders of the outer and inner ear.

- The nose - about 35 million people develop chronic sinusitis each year, making it one of the most common health complaints in America. Care of the nasal cavity and sinuses is one of the primary skills of otolaryngologists. Problems in the nasal area include allergies, smell disorders, polyps, and nasal obstruction due to a deviated septum.

- The throat - communicating (speech and singing) and eating a meal all involve this vital area. Specific to otolaryngologists is expertise in managing diseases of the throat, larynx (voice box), and the upper aero-digestive tract or esophagus, including voice and swallowing disorders.

- The head and neck - this area of the body includes the important functions of sight, smell, hearing, and the appearance of the face. In the head and neck area, otolaryngologists are trained to treat infections, benign (non-cancerous) and malignant (cancerous) tumors, facial trauma, and deformities of the face. They perform both cosmetic plastic and reconstructive surgery.

- Pediatrics - children face many of the same health problems that adults do, however symptoms may show themselves differently and treatment methods that work well in adults may not be appropriate for children.

The Applicant states that Audiology is a branch of science that studies hearing, balance, and related disorders. Audiologists treat those with hearing loss and proactively prevent related damage employing various testing strategies (e.g. hearing tests, otoacoustic emission measurements, videonystagmography, and electrophysiologic tests). Audiology aims to determine whether someone can hear within the normal range, and if not, which portions of hearing (high, middle, or low frequencies) are affected, to what degree, and where the lesion causing the hearing loss is found. The Applicant maintains that in addition to testing hearing, audiologists can also work with a wide range of clientele in rehabilitation (individuals with tinnitus, auditory processing disorders,

cochlear implant users and/or hearing aid users), from pediatric populations to the elderly and may perform assessment of tinnitus and the vestibular system.

The capital expenditure associated with this project is $272,802.67 and the project is scheduled to be operational soon after certificate of need approval.

Need:

According to the Applicant, the proposed project will offer a cost effective way to expand a busy, high quality otolaryngology and audiology practice to more DC residents and workers. The Applicant states that there is a shortage of otolaryngology and audiology services and limitations in access to those that are available in the District. The Applicant maintains that a recent study by the DC Board of Medicine showed that even though there are many physicians in the DC area, a large number of specialists are not in private practice, taking new patients and/or accepting insurance reimbursement. The Applicant further states that MMG is a leader in establishing a network of physicians that provide high quality care in convenient settings, without exclusivity regarding insurance.

The Applicant states that the service area of the practice includes two MedStar primary care offices: MedStar Health at Lafayette Centre and MedStar Medical Group at Adams Morgan. The Applicant further states that the service area is defined as the downtown community. The practice's patients are split between downtown residents and commuters to downtown area employers. The service area has the following zip codes: 20001, 20003, 20004, 20005, 20006, 20009, 20036 and 20037. The population includes 174,000 residents and approximately 291,000 commuters. The Applicant maintains that the establishment of otolaryngology and audiology services would provide greater access for the current primary care patients, including the patients covered by Medicaid and pediatric patients. According to the Applicant, MedStar currently does not have an otolaryngologist in the community and more importantly one that accepts pediatric patients in the service area.

The Applicant maintains that currently Dr. Picken's practice does not accept patients with Medicaid coverage. The Applicant states that after the practice acquisition, Dr. Picken will accept adult and pediatric patients and the insurances accepted by MMG, including contracted Medicaid MCOs. According to the Applicant, in fiscal year 2017 MedStar Health at Lafayette Centre had 7,289 primary care patients and approximately 7% were contracted with Medicaid MCO coverage. MedStar Medical Group at Adams Morgan had 2,442 primary care patients and approximately 21% were contracted with Medicaid MCO coverage. The Applicant further states that the percentage of patients contracted with Medicaid MCO for both MedStar practices have increased in fiscal year 2018 from the percentages in fiscal year 2017.

The Applicant states that MedStar Health at Lafayette Centre and MedStar Medical Group at Adams Morgan patients that are in need of an otolaryngologist are referred to either MedStar Washington Hospital Center or MedStar Georgetown University Hospital. However, nearly half (44%) of the households in the service area are without a vehicle. Whereas, 2440 M St., N.W. is accessible walking distance from Lafayette Centre (.3 miles) and MedStar Medical Group at Adams Morgan (1 mile).

After a review of the information, staff has determined that the Applicant has demonstrated the need for the proposed services. The Applicant has shown that the service is currently operational and that it will be more accessible to the Medicaid population after the services are under the MMG umbrella. Additionally, the Applicant has stated that the otolaryngology and audiology services will be the only ENT services operated by MMG in the service area.

Accessibility:

The Applicant states that the office is located in a business area and near a residential area, on a major bus and metro line, with public parking immediately available on either side of the building. The office will be open from 7:30 am to 5:00 pm, 5 days a week. The Applicant maintains the MMG provides its services without regard to race, color,

national origin or creed and makes its facility accessible to the disabled. MMG is in compliance with applicable regulations in regards to providing access for the handicapped and disabled. The Applicant further states that their intent is to offer medical services with no barriers, and that the facility will accept most health insurance, including Medicare and Medicaid and will use the Federal Sliding Fee schedule for those without insurance.

According to the Applicant, MMG will not, and does not, turn patients away based on insurance status. The financial assistance policies will be consistent with current MedStar practices for all services. Additionally, MedStar's code of conduct states that MedStar does not tolerate any type of discrimination against its patients.

Staff has, therefore, determined that the Applicant is consistent with the criteria and standards for accessibility of care.

Quality:

The Applicant states that the proposed services will incorporate MedStar's standards of quality by use of MedStar's policies and procedures related to patient privacy, staffing, quality assurance and peer review. The Applicant maintains that MedStar's Quality & Safety Director will manage the tracking of quality metrics and improvement efforts and report to the MedStar Ambulatory Services Medical Director, who will report results to the MedStar Quality, Safety, and Patient Affairs Committee. The Quality Safety and Patient Affairs Committee is a subcommittee of the MedStar Board that is managing an ongoing effort to standardize clinical policies and procedures across the MedStar Health System sites in order to ensure consistent care.

According to the Applicant the proposed service will benefit from the incorporation with the MedStar IT infrastructure. This includes for example the transition to the new electronic medical record system, billing systems, and quality metrics. Additionally, the proposed service will have access to multiple clinical studies through the MedStar

Health Research Institute. The Applicant maintains that currently MedStar has 23 practices in the Metro DC area that are Level 3 NCQA medical homes, and ten more are in the application process. Additionally, as part of MedStar Health, this office has access to clinical and quality support functions such as the performance improvement and risk management departments.

The Applicant states that all MedStar Health physicians must maintain their CME credits needed for relicensing. Medical Assistants are tested upon hiring including a written test and skills testing in the SIM lab. Employees are re-tested yearly on their skills and every employee of MedStar has to complete yearly modules in the Simulation Training & Education Lab (SiTEL) dealing with infection control, compliance, HIPPA, OSHA, fire safety, etc.

The Applicant maintains that Dr. Catherin Picken, the leader of the practice, has lived and worked in Washington, DC for over 30 years. She graduated summa cum laude from Knox College in Galesburg Illinois, and then graduated from Northwestern University Medical School. She completed her internship and two years of residency in General Surgery at Northwestern before becoming a clinical surgical fellow at the NIH National Heart, Lung and Blood institute in Bethesda, Maryland. After selecting Head and Neck Surgery as her career choice, she completed four more years of residency in Otolaryngology-Head and Neck Surgery at Georgetown University Medical Center.

The Applicant states that during her early career, she served as Chief, Division of Otolaryngology-Head and Neck Surgery at the Veteran's Administration Medical Center in Washington, DC for four years before joining the Department of Otolaryngology-Head and Neck surgery at Georgetown full time. She was with Georgetown University for over 10 years prior to entering private practice. According to the Applicant, Dr. Picken received numerous awards while at Georgetown, including teaching awards, a Special Citation for Clinical Excellence, and recognition in the hospital's Gallery of Service Excellence every year since it was instituted. She has been cited in Washingtonian magazine's "Top Doctors" in every edition since 1996, Who's Who, Best Doctors in

America, Checkbook Magazine, and in the new "Super Doctors of Washington DC" published in the Washington Post. She has also served on the Board of Directors of Georgetown University Hospital.

According to the Applicant, Dr. Picken has gained recognition in the community for her experience and expertise in nasal and sinus problems including polyps, tumors and complex revision sinus procedures; evaluation and treatment of sleep disorders; and management and surgery of head and neck tumors including salivary gland tumors, thyroid and parathyroid tumors, cervical lymph node tumors, and oral and throat and voice box tumors.

Based on the above considerations, staff has determined that MMG has met the criteria and standards for the quality of care.

Continuity:

The Applicant maintains that MedStar Health is a vertically integrated health care system with access to a comprehensive range of health care providers and services. Services include hospital services, specialized tertiary services, acute and outpatient rehabilitation, home health, long term care and ambulatory care.

Collaboration within the system fosters a team approach among primary care, diagnostics and specialty care that enhances a patient's continuity of care. The Applicant states that for patients needing additional diagnostics or specialist consultations, referrals will be ordered by a physician, which is electronically generated from the electronic medical record and either given to the patient or faxed directly to the specialist or the diagnostic center, or both. These services will be chosen by the physicians based on their quality, availability and patient preferences, either within the MedStar system or to another available specialist or center.

According to the Applicant, MedStar has implemented a system-wide electronic health record (EHR) in its ambulatory care centers. This one-patient-one-chart model insures that patient problems, medications, allergies, immunizations, results and other clinical information are available at any point of entry. Clinical information from MedStar hospitals, including discharge summaries and operative reports, are available through MedStar's Health Information Exchange and are seamlessly viewed in the physician practices via the EHR. This system is designed to reduce unnecessary duplication of services and to provide the clinical information necessary to manage the patient's care in the most quality driven and expeditious manner possible.

The Applicant states that when MMG establishes the proposed services patients and payers will be notified of the change. MMG will transition the private practice's computers and contracts to meet MedStar's specifications. This transition will be seamless for patients, with no change in physician, staff or location. Minor changes in processes may be evident; for example, bills will come from MedStar rather than the physician. For patients needing hospitalization, Dr. Picken currently admits to hospitalists at MedStar Georgetown University Hospital, and Sibley Memorial Hospital.

Based on the above information, the staff concludes that MMG is consistent with the criteria and standards of continuity of care.

Acceptability:

The Applicant maintains that MMG is committed to providing quality healthcare, which is fully satisfactory to patients, their families and physicians. MMG recognizes and supports the Patient's Bill of Rights, as established by the MedStar Health's policies and procedures. Patients will receive copy of this document. Patients will also be given the HIPPA notice of privacy practices policy upon admission. A MedStar Health's Compliance Department is available to respond to customer grievances whenever possible. When a customer complaint is received, it is investigated immediately.

Remedial action is taken as appropriate and the affected parties are informed of the resolution.

According to the Applicant, MMG has informed Advisory Neighborhood Commission 2-A (ANC) but the SHPDA has not received any correspondence from the commission regarding their comments.

Staff has, therefore determined that MMG is consistent with the criteria and standards for the acceptability of care.

Financial Feasibility:

The capital expenditure associated with this project is $272,802.67. The cost of establish the practice will be funded from internal MedStar Health's funds. The Applicant states that the role of the corporate structure is to help develop and approve the budget, guarantee financial support, and provide infrastructure that would allow the facility to take advantage of economies of scale.

The Applicant states that the charges for patient services will be based on the evaluation and management codes common for ENT services. The average charge per visit is estimated at $421.97 per visit. An initial review of the Applicant's financial statements shows that it has the funds to finance the project and an analysis of its financial projections also shows that the project should generate more revenues than expenses.

Staff has, therefore, determined that the Applicant is consistent with the criteria and standards of financial feasibility.

Preliminary Staff Recommendations to the SHPDA Director:

After a careful review of the application, staff has determined that the Applicant has demonstrated the need for the Otolaryngology and Audiology services.

The Applicant has shown that the service is currently operational and that it will be more accessible to the Medicaid population after the services are under the MMG umbrella. Additionally, the Applicant has stated that the Otolaryngology and Audiology services will be the only ENT services in the service area operated by MMG.

As a result, staff recommends approval of the certificate of need for MedStar Medical Group II, LLC for the establishment of Otolaryngology and Audiology services at 2440 M Street, N.W.

STAFF REPORT II

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

899 North Capitol Street, N.E.

Sixth Floor

Washington, D.C. 20002

ANALYSIS OF NEW CERTIFICATE OF NEED APPLICATION
BASIC PROJECT AND REVIEW INFORMATION

Project Data

Registration Number	**17-3-2**
Applicant:	**Sibley Memorial Hospital**
Project Title:	**Fifth Year Renewal of the Certificate of Need for the Establishment of Proton Therapy Services**
Address:	**5255 Loughboro Road, N.W. Washington, DC 20016**
Project Representative:	**Anne Langley**
Proposed Capital Expenditure:	**$157,392,791**
Proposed Completion Date:	**September 2019**

Review Data

Date for Project Review Committee Action:	**April 19, 2018**
Date for SHCC Action:	**May 10, 2018**
Estimated SHPDA Decision Date:	**May 20, 2018**
Lead SHPDA Analyst:	**Thomas McQueen**

Description of the Applicant and the Proposed Project:

Sibley Memorial Hospital (Sibley) is a non-profit, full-service, acute care community hospital serving the Washington, D.C. area for nearly 130 years. The Applicant states that Sibley provides specialty services that include childbirth, obstetrics, orthopedics, rehabilitative medicine, and cancer treatment. In 2010, Sibley became a member of the Johns Hopkins Health System. The Applicant maintains that over the past decade, Sibley has undertaken significant campus improvements including the construction of the Medical Office Building (2010), Parking Garage (2010), Cancer Center (2012), Patient Tower (New Sibley) (2016), and the soon to be opened Proton Therapy Services which have strengthened Sibley's ability to serve the needs of patients, staff, and the greater community.

The Applicant is seeking a certificate of need for a fifth year renewal of the certificate of need for the establishment of Proton Therapy Services. The Applicant was awarded a certificate of need in May of 2013 (CON Registration Number 12-3-10), to establish the Sibley Proton Center on the Sibley campus. The Applicant states that due to the complexity of constructing and making operational a proton therapy center, and due to additional delays beyond the control of Sibley, the time for project completion will exceed five years. Therefore, Sibley now seeks a renewal CON to allow for equipment installation, commissioning and other final stages of implementation to begin proton therapy treatment.

The Applicant states that delays to the project arose when the initial vendor for the proton therapy equipment Sumitomo was unable to meet timelines prescribed by the Applicant. When the time came to create a contractual relationship for the purchase of the equipment, the Applicant maintains that Sumitomo was unable to fulfill the needs of the Applicant in the timeframe required. The Applicant concludes that this presented a significant delay for the project timeline. According to the Applicant, the treatment rooms now will be equipped with the most advanced proton therapy equipment provided by

Hitachi, and the equipment will include integrated cone beam image guidance, robotic positioning, pencil beam scanning, treatment gating, and continuous dose delivery. The Applicant states that Hitachi has developed these advanced technologies to work synergistically and to aid the Radiation Oncologist and clinical care team in maximizing the assurance of tumor positioning, maximizing the control of tumor motion, and maximizing the avoidance of health tissue toxicity.

The Applicant maintains that when Sibley Memorial Hospital and Johns Hopkins Medicine finalized their strategic partnership in November 2010, they agreed to prioritize the growth and enhancement of several clinical services and programs at Sibley. The enhancement of oncology services in the District was specifically identified as a high priority. The Applicant states that strategic planning around oncology services focused on growth in new oncology services at Sibley and the integration of existing oncology programs with the Sidney Kimmel Comprehensive Cancer Center (SKCCC) at Johns Hopkins. The SKCCC was established in 1973 and received the National Cancer institute designation as a Comprehensive Cancer Center in the same year. The Applicant further states that the SKCCC is consistently ranked as a top ten cancer center in the United States by the US News and World Report.

According to the Applicant, since 2010, Sibley and SKCCC leadership have partnered in the pursuit to expand and transform the Sibley oncology program and bring the resources of a leading academic cancer center to the District at Sibley. This program represents the first significant expansion of the SKCCC outside of Baltimore. The Applicant states that Sibley and the SKCCC have achieved the following accomplishments since 2010:

Infrastructure Integration and Development:

- Sibley's radiation oncology capital reinvestment strategy fully integrates equipment, operating systems, and treatment planning with SKCCC;

- The Sibley radiation oncology physician practice is fully integrated with the SKCCC faculty;

- SKCCC medical oncology is established at Sibley and has grown to include a 30,000 square foot clinic that includes 34 infusion rooms, 20 exam and consult rooms, and an independent infusion pharmacy;

- The Sibley pathology physician practice and clinical operations are fully integrated with Johns Hopkins/SKCCC;

- The Sibley radiology practice is fully integrated with Johns Hopkins/SKCCC;

- Sibley integrated its Electronic Medical Record system with the Johns Hopkins Medicine investment in EPIC. This includes integration with the SKCCC implementation of EPIC Beacon, which is the medical oncology management module within EPIC; and

- In collaboration with SKCCC, Sibley has developed a dedicated oncology inpatient unit.

Clinical Program Development:

- In collaboration with the SKCCC and Children's' National Medical Center, Sibley has developed, staffed and implemented a pediatric radiation oncology program. This is Sibley's first licensed specialty pediatric service. The first patient was treated in August 2016;

- Sibley established and operates an oncology clinic for residents of Wards 7 and 8, to improve detection and early intervention and to address social determinants of health that impede patients' ability to pursue and successfully complete a course of care. The clinic was established as a collaboration with United Medical Center ("UMC") and Howard University Hospital;

- In 2017, several JHSOM oncology recruitments were completed to build the multidisciplinary thoracic oncology team at Sibley. This team is directly collaborating with the established Johns Hopkins Thoracic Cancer Center of Excellence at Johns Hopkins Bayview Medical Center to develop integrated clinical care, research, and teaching programs at Sibley for the thoracic cancer population in Washington, D.C., and the region;

- In July of 2017, in collaboration with SKCCC, Sibley implemented a Hematologic Oncology program where over 40 patients have been treated;

- Sibley has established its oncology clinical trial department with the SKCCC. Since 2012, over 450 Sibley patients have been enrolled in clinical trials;

- Sibley and Johns Hopkins Health System ("JHHS") are fully contracted with and enrolled in all Washington, D.C. managed Medicaid programs including: Trusted, AmeriHealth, and Amerigroup D.C. Sibley is able to care for all Medicaid-enrolled District residents;

- Sibley and SKCCC have established comprehensive multidisciplinary services in breast cancer, gynecologic cancers, prostate cancer, gastrointestinal cancers, and thoracic cancers;

- Sibley and SKCCC have developed and implemented an advanced brachytherapy service for gynecologic cancers with plans to expand services to include MRI guided procedures;

- Sibley radiation oncology was awarded accreditation by the American Society for Radiation Oncology ("ASTRO") Accreditation Program for Excellence (APEX®); and

- Oncology support services have been established at Sibley including survivorship, integrative health, oncology-dedicated social work, and a patient transportation program.

According to the Applicant, the Sibley Proton Center is a central component of the expansion of oncology care in the District of Columbia and the further integration of Sibley and JHM. As an academic proton therapy program and facility, the Sibley Proton Center will not only be a local resource for the District, but it will also be the only Johns Hopkins Medicine Proton Center, caring for patients from across the region and the globe, providing training opportunities for faculty, fellows, residents, and other clinical staff, advancing the science of proton therapy through basic science, clinical trials, registries, and more. The Sibley Proton Center will expand opportunities for researchers at SKCC to conduct cutting-edge research, helping to answer critical questions and shape future advancements in oncology care.

The Sibley Proton Center is located on the northwest corner of Sibley's property. The Applicant states that the construction of the Sibley Proton Center started in the summer of 2016. To support the size and weight of the 84,000 square foot building, equipment, and shielding, Sibley had to drill 115 structural support foundations that are between three to five feet in diameter and are placed on bed rock that is 45 feet below grade. Twenty-eight thousand cubic yards of concrete were poured in the construction of the building, which is approximately 3,100 cement truckloads. According to the Applicant, the Sibley Proton Center is now weather tight and has full building support infrastructure in place, including, but not limited to, HVAC, full and permanent power with PEPCO, full water infrastructure and supply, and all medical gasses.

The Sibley Proton Center is a three-story building that includes the infrastructure that supports the proton therapy equipment, clinical treatment space, clinical consultation and follow-up space, CT and MR simulation imaging, patient support spaces, resident teaching spaces, administrative spaces, translational research space, and vendor space. The Applicant maintains that the three proton therapy clinical treatment rooms

will each house a 360 degree rotational gantry within a treatment vault that is forty feet wide, forty feet deep, and fifty feet tall. The shielding for these rooms, including the fixed beam treatment room and the accelerator room, ranges from three (3) to six (6) foot concrete. The Applicant states that the building layout includes.

Ground Floor:

- Ambulance and patient access;
- Staff access;
- Staff lounge;
- Building support services and storage;
- Translational research;
- IT offices; and
- Hitachi storage.

First Floor:

- Main entrance for patients from the parking garage and from Sibley Hospital;
- Hospital access bridge;
- Main waiting room and check in;
- Proton therapy accelerator, beam line, treatment vaults, and treatment rooms;
- Pediatric clinical space including waiting room, changing rooms, exam and consultation rooms, anesthesia preparation and recovery, nursing stations, one treatment room, resident teaching, and physician offices;
- Adult clinical space including waiting rooms, changing rooms, anesthesia and recovery space, exam rooms, nursing station, resident teaching, and two treatment rooms;
- Research treatment room and supporting research space; and
- Hitachi control room and engineer offices.

Second Floor:

- Waiting room and check in;
- Adult exam and consult rooms;
- CT and MR Simulation;
- Anesthesia preparation and recovery;
- Nursing station;
- Dosimetry and Medical Physics;
- Physician and nursing offices;
- Resident teaching; and
- Proton equipment power supply.

Roof:

- Green roof;
- Mechanical infrastructure; and
- Equipment crane system.

The Applicant states that Sibley Proton Center building has been deemed ready for equipment, and equipment installation has begun. The proton therapy equipment began shipping from Japan by boat to the Port of Baltimore in November 2017. According to the Applicant, full equipment installation will be complete by August 2018 and Hitachi will begin commissioning the proton therapy equipment in September 2018. The Applicant further states that the equipment will be turned over to Johns Hopkins medical physicists in June 2019 for clinical commissioning and Sibley expects to treat the first patient in September 2019.

According to the Applicant, Proton Therapy minimizes exposure of healthy tissues to significant amounts of radiation and the collateral damage associated with such exposure. The challenge of conventional radiation therapy is that it delivers a dose of radiation through streams of energy called photons which are created when electrons interact with one another. The Applicant states that radiation oncology clinicians are able to deliver a photon beam that travels through a patient and delivers a radiation

dose to the tissue (healthy and cancerous) with which it interacts. The radiation oncologist uses multiple beams that intersect at the site of the tumor in order to deliver the maximum dose possible to the tumor. The Applicant maintains that despite efforts to minimize the incidental dose of radiation delivered to healthy tissue, damage is still done to healthy tissue, and depending on the type of patient and the location of the tumor, the damage could have clinically significant impact. Patients that have the highest risk of clinically significant impact are pediatric patients and adult patients that are being treated at or near critical organs, such as the brain, the spine, the neck, or the lung.

The Applicant maintains that the choice between defeating cancer through the use of conventional radiation and succumbing to it is usually clear for clinicians and patients. Radiation therapy can be a very difficult choice, given the potential for significant collateral damage and associated risks. The Applicant states that current work in radiation therapy research and development is focused on achieving the same high rates of success in treating cancer while minimizing or eliminating the damage to healthy tissue and associated negative effects.

According to the Applicant, value in proton therapy is derived from the ability to control dose distribution, and to do so better than conventional radiation therapies allow. This enhanced dose control improves cancer targeting and improves the ability to spare healthy tissues and reduce toxicities and their side effects. The advantage of proton physics is ideal for the pediatric cancer population, particularly since many of the patients have a long life expectancy. Clinical value of proton therapy over conventional radiation therapy is also applicable to diseases where sparing surrounding healthy tissue is critical, such as intracranial, spine, neck, abdominal, and lung tumors.

The Applicant maintains that while there has been both clinical and biologic research with proton therapy in the United States over the past 20 years, the research has not kept pace with its clinical implementation. The Applicant states that this proposal to develop the Sibley Proton Center is specifically formulated and dedicated to address

this deficiency. The focus on research as a component of the work at the Sibley Proton Center is vital to the success of the facility. The Sibley Proton Center will house an entire treatment room dedicated exclusively to research. The Applicant further states that although proton therapy has been performed for decades, and it is effective and safe to treat cancer patients with it, providers have not reached its optimal use. The research room has been constructed to advance the understanding and use of proton technology. According to the Applicant, research will focus on the molecular underpinnings of proton therapy and concentrate on how cells (cancer cells and normal cells) actually respond to proton therapy in ways that no one has actually studied before. Additionally, research will also focus on the development of new agents, and on how to integrate new drugs, immunotherapies, and signal transduction agents, with proton therapy. The Applicant maintains that the molecular radiation research is critical to the advancement of the use of proton therapy because there has been little of such research and very few institutions anywhere in the world have made comparable investments in faculty, infrastructure and in continuing support of research.

According to the Applicant, every patient treated with proton therapy will be considered for enrollment in a clinical trial. The protocols developed for the Sibley Proton Center will initially seek to answer questions of comparative efficacy to provide a data-driven understanding of whether proton therapy provides better outcomes than conventional therapies. Another important field of research will be to study and understand the effectiveness of combination therapies, which use proton therapy in combination with radio sensitizers, chemotherapy, and conventional radiation protocols. The Applicant states that with the JHM expertise in laboratory-based biologic studies of cancer development pathways and cellular repair pathways, the Sibley Proton Center and JHM will have the opportunity to be the global leader in the study of the cellular response to proton therapy. The Applicant projects that this research will be critical to transform the clinical application of proton therapy, where, in theory, shorter courses of treatments using proton therapy may be comparatively more effective than longer conventional therapies, thus potentially changing the cost position of proton therapy to the cheaper clinical option.

The capital expenditure associated with this project is $157,392,791. The cost of the construction of the building is $74,682,464, the purchase price of the equipment is $68,660,243, the pre-site development cost is $5,552,657, the financing cost is $4,800,000, the cost of training staff and working capital is $2,089,542, and the contingency cost is $1,607,884.The project is scheduled to be operational by September 2019.

Need:

The Applicant maintains that in 2013, after extensive review and broad input, SHPDA found that Sibley had demonstrated sufficient need and awarded Sibley a Certificate of Need ("CON") for the construction of a proton facility. In addition, in 2014, SHPDA found that Sibley had demonstrated sufficient need and awarded Sibley a CON for the establishment of pediatric radiation oncology services, including one proton treatment room specifically for pediatric patients. The Applicant states that since then, the following has occurred:

1. The number of current and projected future cancer patients in the Sibley Proton Center service area, which comprise the pool of patients from which proton therapy candidates are drawn, has increased compared to the projections from 2012;

2. Proton equipment and treatment planning technology have advanced to include integrated image guidance, pencil beam scanning, and respiratory motion management. These advanced technologies are being introduced more broadly in the market and will allow for better tumor targeting and better healthy tissue sparing when implemented at Sibley;

3. The clinical and scientific evidence concerning the medical necessity of proton therapy has advanced; there is now stronger evidence that proton therapy achieves better outcomes for certain populations and tumor types; and

4. The proton therapy resources and capacity available to serve patients has grown but is still inadequate to meet the needs of the population identified in the Sibley Proton Center service area, including nationally and internationally.

According to the Applicant, the service area definitions for the Sibley Proton Center remain the same as those described in the previously approved CON. The Sibley Proton Center will serve three distinct markets: the Regional Service Area, the Other Domestic Service Area, and the International Service Area.

The Applicant states that the Regional Service Area (RSA) is defined as all counties within a 100 mile radius of Sibley Memorial Hospital. The population of the RSA is approximately 15 million people. Sibley estimates that about 70% of the Sibley proton therapy patients will be generated from this RSA. The Other Domestic Service Area (ODSA) is defined as all other market areas in the United States that are not included in the RSA. 20% of the proton therapy patients at the Sibley facility are expected to come from the ODSA. The International Service Area (ISA) is defined as all markets outside of the United States. 10% of the Sibley Proton Center patients are expected to originate from the ISA.

Regional Service Area Need Analysis

The Applicant maintains that the Sibley Proton Center will provide proton therapy services to pediatric and adult cancer patients in this RSA that includes Washington, D.C., Northern Virginia, Central Maryland, Southern Pennsylvania, Delaware, and small portions of West Virginia and New Jersey. The 2019 projected total population for the RSA increased by 7% compared to Sibley's earlier proton CON application which included 2010 population data. The Applicant states that the RSA need analysis uses the model documented by The Health Care Advisory Board, a global research, technology and consulting firm that provides guidance and insights regarding the most challenging trends facing the health care industry. In 2012, the Advisory Board published a report entitled "Proton Beam Therapy — Energizing Technologies and Market Opportunities" ("the Advisory Board Report"). According to the Applicant, in this

report, the Advisory Board published a planning model that uses population data and NCI SEER incidence data to project patient-based demand for cancer services, for radiation therapy services, for proton therapy services, and for the full scale proton center capacity needed to serve the population.

The Applicant states that the Advisory Board model was used to project the number of full scale proton centers needed in the region. At that time, the Advisory Board specified full scale centers as having between three and five treatment rooms. Treatment room capacity per facility can vary from a single room to five rooms. Due to this variability in proton center treatment room capacity, Sibley determined that the better measure of proton therapy capacity is treatment rooms rather than proton centers. The Applicant further states that when the Advisory Board published its report, the average number of treatment rooms per clinically active full scale proton therapy center was 4 rooms, so Sibley used this average to convert Full Scale Proton Centers Needed as reported in the model to the Number of Treatment Rooms Needed as indicated below. The RSA grew by approximately 1 million people from 2010 to 2019 and the projected number of treatment rooms rose from 16.1 to 17.26.

State	2010 Population	Total Cancer Incidence Rate	Projected New Cancer Patients	Projected Radiation Patients	Projected Proton Eligible Patients	Number of Treatment Rooms Needed
Washington DC	704,713	477.0	3,361	1,681	252	0.84
Delaware	979,922	495.3	4,854	2,427	364	1.212
Maryland	6,069,546	447.3	27,146	13,575	2,036	6.788
New Jersey	217,805	478.4	1,042	521	78	0.26
Pennsylvania	2,603,229	484.5	12,613	6,307	946	3.152
Virginia	4,504,164	418.1	18,832	9,416	1,412	4.708
West Virginia	256,287	468.8	1,201	601	90	0.3
Total RSA	**15,335,666**	**450.3**	**69,052**	**34,528**	**5,178**	**17.26**

According to the Applicant, the basics of the model are as follows:

1. Projecting Cancer Patients: The projected number of new cancer patients is calculated by applying the NCI Surveillance, Epidemiology, and End Results ("SEER") incidence rates to the corresponding RSA population data. The NCI publishes SEER cancer incidence rate per 100,000 population on an annual basis. The RSA cancer incidence rate of 450.3/100,000 is applied to the RSA population of 15,335,666, resulting in a projected 69,052 new cancer patients.

2. Projecting Radiation Patients: The Advisory Board model assumes that 50% of cancer patients require radiation therapy. This ratio was applied to the calculated 69,052 new cancer cases resulting in 34,528 new radiation cases. The Advisory Board projection for radiation therapy utilization is quite conservative. Data from the American Society for Radiation Oncology (ASTRO) indicates that radiation therapy utilization is 66% of new cancer patients, and information from NCI suggests that it is 60%.

3. Projecting Proton Eligible Patients: The Advisory Board model applies a 15% rate to determine the number of radiation therapy patients that would be eligible for proton therapy. This rate is consistent with a widely reported study conducted in Sweden (the Swedish Study). According to the Swedish Study, 15% of the radiation oncology patients in Sweden are eligible for proton therapy; this study was more recently cited in the Annals of Internal Medicine, in an article entitled, "Systematic review: charged-particle radiation therapy for cancer." Using the 15% rate, the number of Proton Eligible Patients in the Advisory Board model is 5,178. This projection of Proton Eligible Patients could range up to 6,836 using the ASTRO radiation therapy utilization rate.

4. Projecting Full Scale Centers: The Advisory Board model assumes that a single full scale center has the capacity to treat 1,200 patients annually. Applying this assumption to the projected 5,178 proton eligible patients, results in the need for 4.32 full scale centers.

5. Projecting Treatment Rooms: Applying the ratio of four treatment rooms per full scale center, the model projects a need for 17 treatment rooms. Using the ASTRO utilization assumption once again, the projection for proton treatment rooms needed increases to nearly 23 rooms.

The Applicant states that the actual and planned treatment room capacity in the RSA has increased since the original Sibley Proton CON was approved. The projections also show that despite the additional capacity developed or planned since 2012, there will continue to be significant need for proton therapy in excess of the capacity available. According to the Applicant, since 2012, the Maryland Proton Treatment Center started operations in Baltimore. In D.C., Sibley was approved for the utilization of three clinical treatment rooms, and Georgetown was approved for one treatment room. In Virginia, INOVA was recently approved for a two treatment room facility. As shown in the table below, these centers, all of which are in various stages of planning, construction, and clinical use equate to a capacity of 11 treatment rooms. The Applicant maintains that based on the conservative Advisory Board model projected need of 17 rooms, there continues to be excess need in the market. The Applicant further states that when applying the ASTRO radiation therapy utilization to the Advisory Board model, the projected need for treatment rooms is double the actual and planned capacity in the RSA.

Projected Proton Treatment Rooms Needed			
		Advisory Board Model	Advisory Board Model with ASTRO Assumptions
RSA Proton Therapy Provider	**Proton Center Status**	**Treatment rooms**	**Treatment Rooms**
Maryland Proton Treatment Center	Treating	5	5
Sibley Proton Center	CON Approval, Under Construction	3	3
Georgetown	CON Approval, Under Construction	1	1
Inova	CON Approval	2	2

Total Actual and Planned RSA Treatment Room Capacity	11	11
Treatment Rooms Needed	17	22
Additional Treatment Rooms Needed	6	11

The Applicant states that ASTRO more significantly identifies types of patients who will benefit from proton therapy at a higher value than conventional photon based therapies as Group 1 Medical Necessity patients. ASTRO does this by classifying tumor types for which proton therapy should be considered medically necessary based on published clinical data and on the healthy tissue sparing ability of protons. Additionally, ASTRO defines a second set of patients for whom proton therapy is recommended. These patients are labeled Group 2, Coverage with Evidence Development ("CED") patients. The table below provides a comparative review by tumor type of ASTRO's recommendations for proton therapy in 2012 and 2017. According to the Applicant, ASTRO has advanced its position from being one of general optimism to one of general inclusion.

Comparison of Astro Publications		
Site Specific Tumor Indication	**2012 ASTRO Emerging Technology Committee indication**	**2017 ASTRO Model Policy Proton Beam Therapy Indication**
Pediatric	Need for CNS: Insufficient evidence for off trial use on Non-CNS solid tumors	Group 1 Medical Necessity
Head & Neck	Need for Ocular: Insufficient evidence for off trial use on general head and neck tumors	Group 1 Medical Necessity & Group 2 CED
Central Nervous System (CNS)	Need for base of skull tumors; Insufficient evidence for off trial use on general Non-CNS tumors	Group 1 Medical Necessity
Pancreas	Insufficient evidence for off trial use	Group 2 CED
Thoracic	Insufficient evidence for off trial use	Group 2 CED
Liver	Evidence supports use	Group 1 Medical Necessity & Group 2 CED
Sarcoma	Not Reviewed	Group 1 Medical Necessity

Prostate	Evidence supports use	Group 2 CED
Breast	Not Reviewed	Group 2 CED
Gastrointestinal	Insufficient evidence for off trial use	Group 2 CED
Lymphomas	Not Reviewed	Group 2 CED
Gynecologic	Not Reviewed	Group 2 CED
Reirradiation	Not Reviewed	Group 1 Medical Necessity & Group 2 CED

In summary, the Applicant requests a fifth year renewal of the certificate of need because:

1. Construction of the Sibley Proton Center is complete. The equipment has been purchased from Hitachi, and installation began in February 2018. The entire budget for the project is committed and encumbered. Recruitment has been initiated for key leadership and medical physics positions.

2. The Sibley Proton Center has the resources and is well-positioned to build and develop a world class academic proton therapy program that will excel in all three domains of the Johns Hopkins Tripartite Mission: clinical care, training, and research.

3. The Sibley Proton Center includes sufficient capacity to care for pediatric patients, specifically-indicated adult tumors (head, neck, spine, etc.), and patients in clinical trials, as well as to enable access to the equipment for training and cutting edge translational research.

4. Children of Washington, D.C. now have access to comprehensive, coordinated pediatric radiation oncology through the partnership of Sibley, Children's National, and JHU. The partners are collaborating on clinical trial research and the development of transformative proton therapy protocols.

5. Sibley, Johns Hopkins, Children's National, and other strategic partners, all with an established history of providing oncology leadership and oncology care to the patients of Washington, D.C., of the Sibley Proton Center's Regional Service Area, and of Out of Region Domestic and International populations, are committed and have the resources to complete the Proton Center in Washington, D.C.

The Applicant states that the development of the Sibley Proton Center consists of two significant cost components making up the budget of $157.4M: the construction of the building and the acquisition of the proton therapy equipment. These two capital items represent 87% of the total cost of the project. The Applicant maintains that a competitive bidding process was completed for each of these components to ensure that the most cost-effective contractors were selected. The construction bidding process was split into two parts, a competitive design bid and a competitive construction bid. According to the Applicant, the construction of the building is complete and the equipment has been purchased, therefore if the project did not receive a renewal of the certificate of need for the project, Sibley would lose significant financial resources with the proposed project.

Based on the information in the record, staff has determined, that the Applicant has demonstrated the need for the renewal of the certificate of need for the establishment of proton therapy services. Given the incidence and prevalence of cancer in the District, it is important to have options of treatment modalities. The Applicant has demonstrated that proton therapy minimizes exposure of healthy tissues to significant amounts of radiation and the collateral damage associated with such exposure over conventional radiation. The Applicant has also demonstrated that through the evolution of ASTRO's proton therapy assessment, research continues to advance and expand the need for proton therapy across a broader range of tumor types. The SHPDA staff has concluded that the Applicant has justified the renewal of the certificate of need based on the following:

1. The Sibley Proton Therapy Center building is complete;
2. The equipment has been purchased and instillation has begun; and

3. Some staff have been recruited and trained in the provision of proton therapy services.

Accessibility:

Sibley Memorial Hospital is located in the far northwest corner of the District. The Applicant states that Sibley is well served by Metrobus and Ride-On. Additionally, a shuttle bus runs from the Tenleytown Metro Station on the Red Line, to Sibley providing service to employees, visitors, patients, and community members. The Applicant maintains that over the past few years, Sibley has made efforts to develop new strategies that will improve the vehicular and transit accessibility of Sibley, while minimizing impacts on the surrounding community. These strategies include:

1. Shuttle bus service to Tenleytown Metro station;
2. Programs for employees to incentivize transit use and carpools; and
3. Priority parking for low-emitting and alternative fuel vehicles.

According to the Applicant, based on the volume projection, the Sibley Proton Center is planning staffing and operations to accommodate 13-hour treatment days Monday through Friday. Additional capacity will be available with weekend and extended weekday hours as demand grows.

The Applicant maintains that the Proton Center will not affect Sibley Memorial Hospital's long-standing commitment to provide services regardless of a patient's culture or economic conditions. All patient areas of the Hospital are fully accessible to individuals with vision and mobility impairments, and this will be true of the new Proton Center as well. The Applicant states that Sibley Memorial Hospital does not discriminate against any individual on the basis of race, religion, sex, sexual preference, or handicap. The Applicant further states that Sibley makes all of its services available regardless of a patient's ability to pay, source of payment, or the institutional affiliation of the patient's physician.

The Applicant states that Proton therapy is usually performed as an outpatient service and patients are typically referred from a medical oncologist or a surgical oncologist to a radiation oncologist. If it is determined that the patient requires radiation therapy as part of the treatment plan, then the radiation oncologist will determine if proton therapy is the best modality of care for the patient's diagnosis. If proton therapy is determined to be the best course of care for the patient, then the patient is referred to the proton center.

According to the Applicant, patients can be referred from within any of the Johns Hopkins facilities, from partners such as Children's National and Unity, and from other health care systems or individual providers in the RSA, the ODSA, and the ISA. There will be a single access point to the Sibley Proton Center. The Applicant states that patient records will be coordinated by the Proton Center staff and patients requiring additional support services, the Proton Center staff will work with each patient to navigate them to the appropriate care location.

Staff has, therefore, determined that the Applicant is consistent with the criteria and standards for accessibility of care.

Quality:

The Applicant states that Sibley is committed to providing quality care. Sibley has a formal Patient Safety and Quality Coordination Department that is responsible for occurrence reporting system, root cause analyses, failure modes and effects analysis, infection control, invasive procedure review, and utilization review. The Applicant maintains that the quality and safety program for radiation oncology is fully integrated across Johns Hopkins Medicine and is led by Dr. Jean Wright at Sibley. This integrated quality and safety program is formalized through the implementation of the Johns Hopkins Medical Physics Quality Management Program and the Department's Policies and Procedures at Sibley. The Applicant further states that Sibley is duly licensed by the government of the District of Columbia as an acute care hospital. The Hospital is also accredited by the Joint Commission and has achieved APEX accreditation from

ASTRO. The Applicant believes that these approvals indicate that quality of care is provided throughout the entire hospital.

According to the Applicant, the Radiation Oncology programs across Johns Hopkins Medicine are integrated, and that integration will extend to the Sibley Proton Center. The goals of integration are to enhance the quality of the Sibley Radiation Oncology program through:

1. Standardization of radiation equipment, radiation oncology-specific information systems (operating and treatment planning systems), and the electronic medical record (EPIC). This integration enhances communications and collaborations in multidisciplinary patient care;

2. Patient access to advanced treatment modalities, such stereotactic radiation therapy, brachytherapy, and proton therapy, and access to innovative clinical trials, including combination trials with surgical oncology, medical oncology, and immunotherapy;

3. Standardization of the Department's quality and safety procedures, protocols, initiatives, and research;

4. Expansion and development of training programs, such as the radiation oncology residency program, the medical physics residency program, the collaborative medical physics training program with Howard University, and the development of the Sibley Proton Center as a Training Center; and

5. Expansion of the Department Molecular Radiation Sciences translational research division, specifically in the development and utilization of the Sibley Proton Center's research vault.

The Applicant states that the medical staff of Sibley is organized into clinical departments and is led by a Chairman who is a member of the Executive Committee of

the medical staff. Each Chair holds monthly meetings where utilization review and medical audits are presented. Statistics and unusual cases are presented. Re-admissions are discussed, as well as cases with length of stay concerns. Some clinical sections have specific meetings in which 2-4 cases are presented in depth and discussed. The Chair of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine, Dr. Ted DeWeese, will be the Medical Director for the Sibley Proton Center. The Medical Director will report through the Medical Staff structure at Sibley.

The Applicant maintains that under the direction of the Medical Director of the Sibley Proton Center, several peer review programs will be implemented to ensure the highest quality of care for patients. These peer review programs will benchmark the established peer review programs of the Johns Hopkins SKCCC, and many of these programs are currently implemented within the Sibley Radiation Oncology Department. For example, multidisciplinary faculty teams practicing at Sibley actively participate in tumor boards, multidisciplinary clinics, and new patient peer review held through the SKCCC. The Applicant states that In these peer review settings, Sibley faculty participate in case discussions and patient assessments, and they also present cases from Sibley for a broader SKCCC peer review.

According to the Applicant, staff for the Proton Center will be recruited, trained, and managed to ensure the highest level of safety and quality for patients. All physician and advanced practice providers at the Sibley Proton Center will receive malpractice coverage through The Johns Hopkins University The Applicant maintains that all Radiation Oncology faculty must participate in and complete continuing education in order to maintain their licensure. In addition, medical physicists, medical dosimetrists, radiation therapists, nurse practitioners, and nurses are required to engage in continuing education in order to maintain their licensure and/or certification. The Applicant states that all professional staff are required to participate in continuing education in order to meet and exceed the highest standards of quality. Continuing education activities include seminars and other specialized training. Technical staff also

receive regular in-service training. Training for the nursing and technical staff is coordinated by a Clinical Nurse Specialist. Clinical staff participate in applicable education programs as well as annual competency assessments and necessary equipment-specific competency training. The Applicant further states that clinical staff are trained in Basic Life Safety and infant CPR in addition to adult CPR, which is included in the Hospital wide training program.

Based on the above considerations, staff has determined that Sibley has met the criteria and standards for the quality of care.

Continuity:

According to the Applicant, Sibley has established transfer agreements with most of the hospitals in the Washington metropolitan area for regular patient transfers. Appropriate transportation arrangements are made in accordance with the patient's physical and mental condition, and may be provided by the metropolitan Police Department, the District of Columbia Fire Department, rescue squads, private ambulance companies, or by other means. A standardized transfer form, utilized by all metropolitan area hospitals, is completed by the appropriate personnel prior to the patient's discharge or transfer to another facility. The Applicant states that all of these established agreements and practices will serve proton therapy patients as well.

The Applicant states that due to the highly specialized nature and limited regional availability of proton therapy, Sibley expects referrals from a wide range of hospitals and providers. According to the Applicant, maintaining continuity of care as much as possible will be a high priority, including ensuring communication and collaboration with referring entities. Johns Hopkins has implemented EPIC as the electronic medical record across the Johns Hopkins Health System, which facilitates continuity of care within the system. The Applicant further states that handoffs currently occur with patients from Children's National who are receiving pediatric radiation oncology services at Sibley. This program has allowed Sibley to test communication and other systems designed to preserve continuity of care through handoffs, with excellent results. The

Applicant maintains that regardless of referral source, effective transfers with excellent communication are essential to high quality care, and they are of the highest priority to Sibley. Referrals to other providers, when necessary, will be made based on quality, value, and patient preference. In addition, Johns Hopkins Health System and Sibley Memorial Hospital have referral agreements throughout the D.C. Region to connect patients with appropriate services, and include provisions for linkages to primary, secondary, and tertiary levels of care as needed.

Based on the above information, the staff concludes that Sibley is consistent with the criteria and standards of continuity of care.

Acceptability:

The Applicant states that Sibley Memorial Hospital is committed to providing quality health care that is fully satisfactory to patients, their families, and physicians. Sibley recognizes and supports the Patients' Bill of Rights as established by the American Hospital Association. The Applicant maintains that Sibley has a policy for investigating and responding to inquiries, concerns and problems. Hospital officials are available to respond to customer grievances whenever possible. When a customer complaint is received, it is investigated immediately, remedial action is taken as appropriate, and the affected parties are informed of the resolution.

The Applicant maintains that the SKCCC at Sibley believes that the more patients know about their cancer and its treatment, the more equipped they are to actively participate in their care. The Sibley Center for Patient and Family Services offers a variety of resources to assist patients and families during treatment. The Applicant states that at Sibley, every new patient receives a Patient and Family Resource Guide, a customized notebook, complete with handouts addressing that individual patient's needs. The handouts include information on the disease, treatment, coping with side effects, the psychological impact of cancer, exercise, and what to do when treatment is over. Patients are provided with information on nutrition, pain and palliative care, spiritual and

pastoral care, navigation and social work services, support groups, transportation resources, among many other support services. Patient materials also include information on how to file a grievance, how to contact providers after hours, and how family members and caregivers can participate in care planning. The Applicant further states that all Johns Hopkins Medicine entities:

- Provide free aids and services to people with disabilities to communicate effectively, such as qualified sign language interpreters; written information in other formats (large print, audio, accessible electronic formats, other formats); and

- Provide free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages.

According to the Applicant, Sibley has informed the Advisory Neighborhood Commission (ANC) regarding the proposed project, however, the SHPDA has not received any correspondence from the ANC regarding this project. Sibley has received letters of support in connection with the proposed project from Johns Hopkins All Children's Hospital, Children's National, and Howard University. The Applicant has also reached a collaborative care agreement with unity Health care regarding a cancer care program.

By a letter, of March 27, 2018, MedStar Health, Inc. (MedStar) raised concerns about the viability of additional proton therapy capacity that would be created by the Sibley Proton Therapy Center. Since the Certificate of Need was first approved a substantial number of regional proton therapy services have become operational or been planned.

- In 2015, the Maryland Proton Treatment Center opened in Baltimore with five vaults;
- MedStar Georgetown University Hospital is set to open in April of 2018 with one vault; and

- Inova Hospital has been approved to open a two-vault proton therapy center in Fairfax Virginia, likely to be operational within the next few years.

MedStar states that the addition of 4 vaults at Sibley would oversaturate the market for Washington, D.C. metropolitan area. Proton Centers in the region are struggling to find sufficient demand for their services. MedStar maintains that the Maryland Center fell short of projected patient volumes, seeing only 668 patients in its first year of operation and therefore the facility had to convert from a for-profit entity to a non-profit entity to free up cash while it ramps up to attract patients. Additionally, the Hampton University Proton Therapy Institute has fallen far below expectations, averaging a little more than one-tenth of initial projections between 2010 and 2015 and requiring the center to rely on state support.

According to MedStar, there have been closures of Proton therapy Centers due to lack of patients. In 2014 the proton therapy center at Indiana University closed, in part because it was only treating about 200 patients a year, far below the projected 850. In 2017 the Scripps Proton Therapy Center in San Diego declared chapter 11 bankruptcy after patient volumes failed to meet expectations. MedStar states that Proton Therapy Centers in Georgia and Oklahoma are struggling with similar challenges.

The Applicant states that there were conditions placed on the original certificate of need to establish a cancer clinic in an underserved area of the District and to ensure that underserved, uninsured, under insured, and minority patients have access to proton therapy treatment. According to the Applicant, Sibley has done the following:

- With partners United Medical Center and Howard University Hospital, Sibley established a Collaborative Oncology Clinic ("Sibley Oncology Clinic"), located at UMC Medical Center in Ward 8 on January 12, 2015. The Sibley Oncology Clinic serves as a cancer medical home for patients, ensuring that patients get all necessary care in a timely manner, and with every supports necessary to ensure treatment adherence and an optimal patient experience. The Sibley Oncology

Clinic is located at UMC, in the Medical Office Building adjacent to the hospital and is operated by Sibley. The clinic has its own waiting room, three exam rooms, a physician work area and a reception desk. Sibley leases the space for the Sibley Oncology Clinic from UMC;

- Sibley is collaborating with Unity to explore opportunities to establish a new cancer service ("Cancer Service") within Unity's soon to be constructed Medical and Dental Health Center located within the So Others Might Eat Conway Center near the Benning Road Metro station in Ward 7. The Cancer Service will provide care navigation and coordination services. Unity's new facility will serve as the home base for a Sibley Nurse Navigator who will deploy a place based model of care by traveling to Unity's five additional health centers located throughout Wards 7 and 8. Sibley's Nurse Navigator will provide direct services and coordinate care for patients who have a suspicious finding or a cancer diagnosis as they seek specialty oncology care at Sibley; and

- Sibley has contracts with all of the Medicaid Managed Care Organizations to serve Medicaid beneficiaries.

Staff has, therefore determined that Sibley is consistent with the criteria and standards for the acceptability of care.

Financial Feasibility:

The capital expenditure associated with this project is $157,392,791. The cost of the construction of the building is $74,682,464, the purchase price of the equipment is $68,660,243, the pre-site development cost is $5,552,657, the financing cost is $4,800,000, the cost of training staff and working capital is $2,089,542, and the contingency cost is $1,607,884.The original CON had a capital expenditure of $129,900,000, as a result the capital expenditure has increased by approximately $27 million.

The Applicant states that the main reason for the increase in capital expenditure is due to the increase in the size of the Proton Center building from 49,000 sf to 84,000 sf and the increased size and shielding needed in the treatment rooms. According to the Applicant, the size and specifications of the new equipment made it necessary to increase the size of the gantries and increase the amount of shielding needed. Additionally, the weight of the building increased, therefore the foundation was improved to support the weight of the building and equipment.

The Applicant states that the sources of funds for the project are as follows:

Source	**Amount**	**Responsible Party**
Sibley Cash	$50,395,306	Sibley
Philanthropy	$20,000,000	Sibley and JHHS
Bonds (debt)	$60,000,000	Sibley and JHHS
Johns Hopkins Health System	$25,000,000	JHHS
Land Equity	$1,997,485	Sibley
Total	**$157,392,791**	Sibley and JHHS

The Applicant states that Sibley has made a significant contribution from its own cash. According to the Applicant, Sibley continues to have full fiscal control of its assets and the investments pursued with those assets. The Applicant further states that Johns Hopkins Health System (JHHS) has made a significant contribution from its cash assets to the project as well. The cash and land equity investments contributed by both Sibley and JHHS account for nearly 50% of the total project funding. Philanthropy and Debt account for the balance of the funding on the project. The Applicant maintains that these collaborative funding mechanisms between Sibley and JHHS are strong examples of how Sibley joining Johns Hopkins has added value to the financing strategies for this project.

According to the Applicant, through Sibley's affiliation with the JHHS, Sibley became a member of the Johns Hopkins Health System Obligated Group. All debt of the Obligated

Group is secured by the full financial strength of its members. As a result, the Applicant maintains that JHHS is one of the few organizations in the country to hold ratings in the "AA" category by all three major bond rating agencies (AA- by S&P and Fitch and Aa3 by Moody's). Through their inclusion as an Obligated Group member, Sibley has a broader access to capital in the debt market, and Sibley is able to realize a significantly lower cost of capital than they could achieve on their own. The Applicant states that while Sibley is responsible to JHHS for the payments on the debt, JHHS is ultimately responsible to the lender.

The Applicant maintains that in 2015, Sibley conducted an in-depth analysis and validation of the Sibley Proton Center business plan. As part of this process, Sibley engaged Arthur D. Little (ADL), a global management consulting firm, to provide an independent, third party assessment of the plan. The Applicant states that ADL found that public payors in the region currently provide coverage for proton therapy, but private payors are more restrictive. ADL also found that historical experience at other proton centers shows strong success rates for proton therapy coverage approval, though the approval process may be more resource-intensive (e.g. single case agreements).

The Applicant states that the payment mechanisms for the delivery of services have not changed substantially to effect the financial viability of the project. The Applicant has also stated that Sibley and JHHS have committed the financial resources to completing the project and that this will be the only Proton Center for all of JHHS. Staff has, therefore, determined that the Applicant is consistent with the criteria and standards of financial feasibility.

Preliminary Staff Recommendations to the SHPDA Director:

After a careful review of the application, staff has determined that the Applicant has demonstrated the need for the renewal of the certificate of need for the establishment of proton therapy services. Given the incidence and prevalence of cancer in the District, it

is important to have options of treatment modalities. The Applicant has demonstrated that proton therapy minimizes exposure of healthy tissues to significant amounts of radiation and the collateral damage associated with such exposure over conventional radiation. The Applicant has also demonstrated that through the evolution of ASTRO's proton therapy assessment, research continues to advance and expand the need for proton therapy across a broader range of tumor types. The SHPDA staff has concluded that the Applicant has justified the renewal of the certificate of need based on the following:

1. The Sibley Proton Therapy center building is complete;
2. The equipment has been purchased and instillation has begun;
3. Some staff have been recruited and trained in the provision of proton therapy services;
4. The Applicant states that the payment mechanisms for the delivery of services have not changed substantially to effect the financial viability of the project:
5. Sibley and JHHS have committed the financial resources to completing the project; and
6. Sibley will house the only Proton Center for the Johns Hopkins Health System.

Staff has also determined that as a condition of certificate of need approval the following conditions which were attached to the original CON remain in place:

- Given the incidence and prevalence of cancer in the District of Columbia and given the health disparities in the District, the Applicant must, in consultation with the Department of Health, establish, operate and maintain a new full time cancer screening and treatment clinic in one of the underserved areas of the District in Ward 5 or 8, particularly to prevent and treat the most common cancers — breast, lung, prostate and colorectal;

- In order to ensure that underserved, uninsured, under insured, and minority patients have access to proton therapy treatment, the Applicant must enter into

clear arrangements with the D.C. Primary Care Association, clinics, hospitals, and other entities that serve these patients and establish mechanisms to facilitate access to the proton therapy services; and

- Provide to SHPDA annually information on the proton therapy utilization and on the operations of the cancer screening and treatment clinic, including the number of patients served, the diagnosis, source of payment, source of referral, as well as the race, age, sex, ward, and zip code of the patients.

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