

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

March 21, 2023

RE: COPN Request No. VA-8682

Maryview Hospital, LLC d/b/a

Bon Secours Maryview Medical Center

Virginia Beach, Virginia

Add One SRS Capable Linear Accelerator by Means of Relocation

Applicant

Maryview Hospital, LLC d/b/a Bon Secours Maryview Medical Center (“Maryview”) is a not-for-profit Limited Liability Company located at 3636 High Street, Portsmouth, Virginia 23707. Bon Secours Hampton Roads Health System LLC (“BSHR”) is the sole corporate member of Maryview. The Board of Directors for BSHR also serves as the Board of Directors for Maryview. BSHR and Maryview are both not-for-profit Virginia limited liability companies. The BSHR Board of Directors also serves as the Board of Directors of Maryview. Maryview owns 6 other companies, a minority ownership in 6 companies, and a majority ownership in Harbour View MOB 2, LLC (the entity from whom the proposed project is its leasing space).

The proposed project is to be located at Bon Secours Cancer Institute at Harbour View (“BSCI-HV”) at 7185 Harbour Towne Parkway, Suffolk, Virginia 23435. BSCI-HV is the name of the facility/suite in which Maryview operates outpatient radiologic services. BSCI-HV is situated in Planning District (“PD”) 20, located within Health Planning Region (“HPR”) V.

Background

Linear Accelerator

A linear accelerator (LINAC) uses microwave technology (similar to what is used for radar) to accelerate electrons in a part of the accelerator called the “wave guide”; these electrons then collide with a heavy metal target to produce high-energy x-rays.¹ These medical linear accelerators (LINAC) are most commonly used for external beam radiation treatments for patients with cancer; the beams can be targeted to destroy cancer cells while sparing the surrounding normal tissue from

¹ Radiological Society of North America (RSNA) and American College of Radiology (ACR). “Linear Accelerator.” Radiologyinfo.org. Accessed February 1, 2023.
<https://www.radiologyinfo.org/en/info/linac#:~:text=The%20linear%20accelerator%20uses%20microwave,high%20Denergy%20x%20Drays>.

direct contact with the beam.² Per the applicant, current radiotherapy delivery systems are image-guided, dual-energy, high-dose, multifunctional LINACs optimized for 3D conformal radiation therapy and stereostatic applications; stereostatic applications include single session radiosurgery, fractionated stereostatic radiation therapy, and intensity modulated radiosurgery.

Relevant Cancer Information

Radiation therapy is part of 40% of all cancer cures world-wide.³ Only 9 cents of every dollar spent on cancer treatment is spent on radiation therapy; the cost is relatively low due to the ambulatory nature of the treatment.⁴ Furthermore, radiation therapy can provide pain relief even in those that have incurable forms of cancer.

Virginia's four most frequently diagnosed cancers consist of breast, prostate, lung and bronchus, and colorectum cancers.⁵ Radiation types are dependent upon the location, size and type of cancer and is often conducted in conjunction with another treatment modality such as surgery or chemotherapy.⁶

Cancer incident rates can vary by racial, age, gender, and socioeconomic factors. Lifestyle habits, such as smoking and obesity, among others, can impact cancer likelihood. The American Cancer Society's Cancer Facts and Figures 2023 report provides the following information:

- 88% of people diagnosed with cancer are aged 50 and older, and 57% of them are aged 65 or older.
- Nationally, it is estimated that 41 out of 100 men and 39 out of 100 women will be develop cancer within their lifetimes.
- The 5-year relative survival rate for all cancers combined has increased since the early 1960s, from 39% to 69% in white people and 27% to 64% among black people.
- Lack of health insurance coverage is strongly associated with medical financial hardship and prevents many people from receiving optimal cancer care across the continuum, from prevention to early detection and treatment.
- According to National Health Interview Survey estimates, 17% of adults aged 65 and older were uninsured, with the highest prevalence being among Hispanic (34%), Native Hawaiian or Other Pacific Islander (31%), American Indian or Alaskan Native (29%), and black (19%) individuals. Furthermore, uninsured individuals and those from other marginalized populations are much more likely to be diagnosed with cancer at a late stage, when treatment is often more involved, costlier, and less successful.
- Breast cancer, a leading diagnosed cancer both nationally and within the Commonwealth, has an inequitable survival rate; for example, the 5-year survival rate is 9% lower for black women than white women.

² Radiological Society of North America (RSNA) and American College of Radiology (ACR). "Linear Accelerator." Radiologyinfo.org. Accessed February 1, 2023.

<https://www.radiologyinfo.org/en/info/linac#:~:text=The%20linear%20accelerator%20uses%20microwave,high%20Denergy%20x%20Drays>

³ <https://www.targetingcancer.com.au/about-radiation-oncology/benefits-and-effectiveness/>

⁴ <https://www.targetingcancer.com.au/about-radiation-oncology/benefits-and-effectiveness/>

⁵ <https://cancerstatisticscenter.cancer.org/#!/state/Virginia>

⁶ <https://www.oncologynurseadvisor.com/home/for-patients/fact-sheets/radiation-therapy-for-cancer-fact-sheet/2/>

- Prostate cancer, a leading cancer diagnosed in men both nationally and within the Commonwealth, has an incident rate more than 70% higher in black men than white men for reasons that remain unclear.

Consideration of the population and poverty rates is imperative to understanding the relative risk for the population the applicant serves, and ultimately can assist in understanding the need for the relocated LINAC to be approved.

Population Background Between 2020-2030, there is a projected decrease in population of 3.43%, but a projected increase in the age 65+ years cohort of 59.61% (much higher than both the state, district, and health planning region's 65+ cohort projections) (**Table 1**). The project proposes relocation of the LINAC, now owned by Maryview in a merger that occurred March 31, 2021, to its BSCI-HV location in Suffolk, Virginia. Suffolk's overall projected population growth from 2020-2030 is 8.33% while the PD is only 1.57%, the HPR is 0.37%, and the state of Virginia is 5.58%. While the overall population in Suffolk is projected to grow at a rate faster than that of the PD, HPR, and State, the 65+ cohort is projected to grow at a much slower rate of 6.71% compared to 20.32%, 21.65%, and 27.43% respectively.

The applicant reports that BSCI-HV and Maryview's primary service area mimics Maryview's Norfolk campus (where the proposed LINAC will be coming from), and encompasses Chesapeake, Portsmouth, and Suffolk, with a secondary service area of Isle of Wight, Norfolk, Southampton, and Franklin. Two of the secondary service areas, Norfolk, and Southampton, both have projected growth rates much higher than the PD, HPR, and State. The applicant expects the service areas to remain relatively the same with the relocation and expects the project to continue to benefit those already served and previously served by the applicant.

Although Suffolk is projected to see an 8.33% increase in population between 2020-2030, the population volume is projected to only be 102,571 in 2030, compared to Norfolk's 2030 estimated population of 229,864.

Table 1. PD 20 Population Data Contrasted with HPR V and State of Virginia Pop. Data

| Geographic Name | 2010 Census | 2020 Census | % Change 2010-2020 | 2030 Census | % Change 2020-2030 | 2020 65 + Census | 2030 65+ Census | % Change 65+ 2020-2030 |
|-----------------------|-------------|-------------|--------------------|-------------|--------------------|------------------|-----------------|------------------------|
| Newport News City | 180,966 | 186,014 | 2.79 | 189,026 | 1.62 | 21,090 | 30,113 | 42.78 |
| Norfolk City | 242,803 | 238,024 | (1.97) | 229,864 | (3.43) | 17,342 | 27,680 | 59.61 |
| Northampton County | 12,389 | 12,270 | (0.96) | 12,000 | (2.20) | 1,418 | 1,781 | 25.57 |
| Northumberland County | 12,330 | 11,798 | (4.31) | 11,185 | (5.19) | 2,135 | 2,417 | 13.20 |
| Poquoson City | 12,150 | 12,471 | 2.64 | 12,587 | 0.93 | 17,359 | 22,175 | 27.74 |
| Portsmouth City | 95,535 | 97,909 | 2.48 | 98,857 | 0.97 | 3,561 | 3,577 | 0.44 |
| Richmond County | 9,254 | 8,928 | (3.52) | 8,469 | (5.14) | 1,908 | 2,317 | 21.47 |
| Southampton County | 18,570 | 17,973 | (3.21) | 17,172 | (4.46) | 1,426 | 2,258 | 58.36 |
| Suffolk City | 84,585 | 94,685 | 11.94 | 102,571 | 8.33 | 671 | 716 | 6.71 |
| PD 20 Totals | 1,178,712 | 1,237,588 | 3.53 | 1,277,374 | 1.57 | 48,605 | 62,879 | 20.32 |
| HPR V Totals | 1,809,202 | 1,892,876 | 2.59 | 1,946,956 | 0.37 | 166,820 | 214,204 | 21.65 |
| Virginia | 8,001,024 | 8,646,905 | 8.07 | 9,129,002 | 5.58 | 1,352,448 | 1,723,382 | 27.43 |

Source: Data from Weldon Cooper Population Data, Chart Compiled by DCOPN

Illustrated in **Table 2**, both Suffolk (the locality which will have the most direct access to BSCI-HV) and the current service area have a higher proportion of black Americans within their population than when considering the entirety of the state. The service area as a whole has approximately twice the percentage of black Americans, who as described above, face disparity in terms of both diagnosis and treatment of cancers.

Table 2. Racial Demographics of Service Area Compared to the State of Virginia 2019

| Jurisdiction | White | Black | Asian | Other Races | Two or More Races |
|--------------------------------|--------------|--------------|-------|-------------|-------------------|
| Chesapeake City | 61.6% | 30.6% | 3.5% | 0.6% | 3.7% |
| Portsmouth City | 40.2% | 54.5% | 1.5% | 0.7% | 3.1% |
| Suffolk City | 52.1% | 42.6% | 1.9% | 0.5% | 2.9% |
| Isle of Wight County | 72.7% | 23.2% | 1.0% | 0.6% | 2.5% |
| Norfolk City | 49.3% | 42.1% | 3.8% | 0.9% | 3.9% |
| Southampton County | 62.3% | 34.7% | 0.5% | 0.6% | 1.9% |
| Franklin City | 38.9% | 57.5% | 1.0% | 0.5% | 2.2% |
| Average of Service Area | 53.9% | 40.8% | 1.9% | 0.6% | 17.9% |
| Virginia | 69.4% | 19.9% | 6.9% | 0.7% | 3.2% |

Source: Weldon-Cooper 2019 Population by Race

Furthermore, both Norfolk and Southampton (within the applicant’s service area) have significantly higher projected rates of growth in the 65+ years-old cohort than the PD, HPR, and State of Virginia. Norfolk City was in the PSA prior to the closure of DePaul, and has similar racial demographics as Suffolk City. As mentioned above, this population is much more at risk of needing radiation therapy services. Moreover, the poverty rate in the service area (SA) of the project is an average of 13.8% of the population, with an average of 12.3% and 15.0% in the Primary and Secondary SAs, respectively (**Table 3**). The service area rates of poverty are higher than that of Virginia as a whole at 10.7%. As discussed above, poverty has a negative impact on success of cancer treatment due to late diagnosis or not being diagnosed.

Table 3. Poverty Rates in Service Area Contrasted with Virginia

| Jurisdiction | Poverty Rate |
|----------------------|--------------|
| Chesapeake City | 9.0% |
| Portsmouth City | 17.2% |
| Suffolk City | 10.8% |
| Isle of Wight County | 9.2% |
| Norfolk City | 19.7% |
| Southampton County | 14.7% |
| Franklin City | 16.2% |
| Average of SA | 13.8% |
| Average of PSA | 12.3% |
| Average of SSA | 15.0% |
| Virginia | 10.7% |

Source: Index Mundi⁷

The PSA of the proposed LINAC located at the former DePaul campus included Norfolk, whose poverty rate is 19.7% compared to the proposed location's 10.8%.

Applicant Additional Background and Information

Bon Secours DePaul Medical Center, LLC (DePaul) merged with, and into, Maryview on March 31, 2021. With this transition, the applicant anticipated moving various existing equipment to other locations to better serve the needs of its patients. The project coincides with their vision- “[to be] inspired by God’s hope for the world, we will be a ministry where associates want to work, clinicians want to practice, people seek wellness, and communities thrive.” Their mission is to “extend the compassionate ministry of Jesus by improving the health and well-being of our communities and bring good help to those in need, especially people who are poor, dying, and underserved.”

DePaul ceased providing inpatient services on April 1, 2021, though radiation therapy services continued to be offered on the Norfolk campus by Maryview. At the end of August 2022, Maryview began consolidating its radiation oncology services to the Harbour View campus in anticipation of this COPN request.

Maryview is described by the applicant as the “flagship facility for Bon Secours Hampton Roads Health System.” BSCI-HV is operated under Maryview’s umbrella. BSCI-HV is located on Maryview’s existing comprehensive outpatient ambulatory campus. Maryview has developed this campus in response to the shift to ambulatory procedures and approach to health. They have chosen this location due to its ease of access, ease of parking, and the relative ease in which patients are able to navigate the campus. The campus is in a growing and developing area where the community at large regularly seeks dining, shopping, residence, medical needs, etc. opportunities.

Maryview consolidated its radiation oncology services in anticipation of this current COPN application, in addition to COPN application Request Number VA-8685 (also under review for this cycle) to relocate CT and MRI services to Virginia Beach from the DePaul campus. Previously, both LINACs were used at the DePaul campus to provide radiation therapy services to patients.

⁷ <https://www.indexmundi.com/facts/united-states/quick-facts/virginia/percent-of-people-of-all-ages-in-poverty#table>

Proposed Project

Maryview proposes to add one SRS capable linear accelerator at BSCI-HV by means of relocation of existing equipment. The applicant reports the project would be inventory neutral, but not location neutral. The existing equipment is currently located at Maryview's Norfolk Campus, formerly the Bon Secours DePaul Medical Center. The Norfolk Campus has 2 LINACs and a CT simulator, of which one LINAC would be relocated and the other LINAC and CT simulator would be relinquished, reducing the inventory in PD 20. Following relocation, the existing space at DePaul is being returned to the landlord, Bon Secours Mercy Health⁸. A new concrete vault is proposed to house the relocated LINAC along with approximately 2,200 square feet of new construction, approximately 1,417 square feet of which will be dedicated to the concrete vault. The project would reduce inventory, meaning the project is not inventory neutral.

The proposed target for opening is 24 months after the issuance of a COPN. Service provision will be available on an outpatient bases from 8:00 A.M. to 4:30 P.M. for 5 days each week.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as “[t]he addition by an existing medical care facility described in subsection A ([such as a] specialized center or clinic ...developed for the provision of ...radiation therapy...), of any new medical equipment for the provision of...radiation therapy...”

Required Considerations -- § 32.1-102.3, of the Code of Virginia

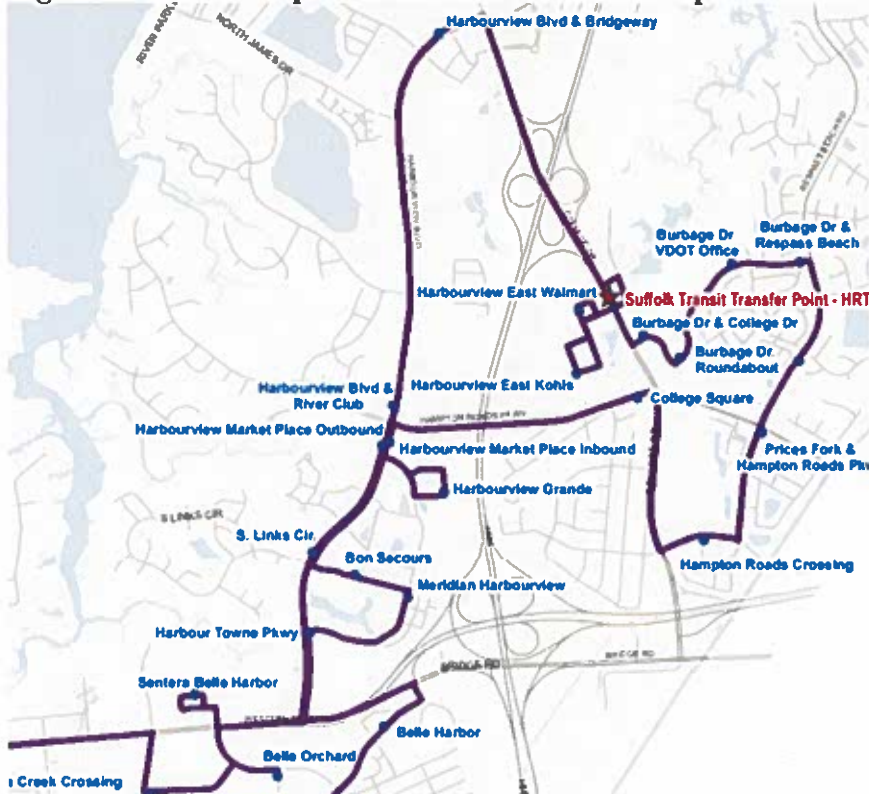
In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

- 1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

BSCI-HV is located near the intersection of two major transportation routes- US-17 and Interstate I-664. It is immediately accessible to I-664. US-17 is a four-lane divided highway which has existing turn lanes and traffic lights at the intersection of Harbour View Boulevard, allowing access from both east and west directions. BSCI-HV offers onsite parking. The applicant states public transportation does not yet service the BSCI-HV campus, but patients lacking transportation may access the campus by taxis, Uber, and LYFT services. DCOPN found that Suffolk Transit does stop at the Bon Secours Harbour View location via the Purple Route. The Suffolk Transit also connects to the Hampton Roads Transit system. The Purple Route has multiple stops around the Harbour View campus (**Figure 1**).

⁸ <https://www.pilotonline.com/inside-business/vp-nw-depaul-sale-0318-20220316-zjpk3pgtibgktpb2lh7454p7re-story.html>

Figure 1. Partial Purple Route Suffolk Transit Map



Source: Suffolk Transit suffolkva.gov

Additionally, the service area has proportionally higher rates of poverty and black Americans compared to the state as a whole, both demographics of which have higher incidences of needing cancer care, including radiation therapy. While the PD and HPR both have lower projected growth in the 65+ cohort between 2020-2030 than the state projection, there are localities within the service area, such as Norfolk and Southampton with 2.17 times and 2.13 times the projected growth of the state, respectively. Having access to another LINAC in this service area would likely benefit these populations.

2. **The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:**
 - (i) **The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.**

The applicant provided one letter of endorsement from a Bon Secours Board-certified radiation oncologist whose letter included the following:

- Their patients are looking for therapy services with excellent outcomes, improved access, and greater convenience to those services.
- The relocation of the LINAC from the DePaul campus to the Harbour View campus meets the needs of patients and is geographically better situated for the growing population throughout the region.

- The relocation is situated in close proximity to retail establishments, commercial developments, and restaurants, positioning the cancer center in the “hub of Suffolk as a prime location.”

Furthermore, the applicant provided 23 letters of support from within the Bon Secours system and 1 letter of support from outside of the Bon Secours system which collectively made the following assertions:

- There has been considerable growth in the Suffolk and Western Hampton Roads communities. Bon Secours continues to implement growth initiatives to meet the needs of the communities it serves.
- Bon Secours’s current project of expanding radiation therapy services will ensure that more cancer patients within the Western Hampton Roads community are continued to be served, in line with the Bon Secours mission to understand its patients’ needs and serve patients in a compassionate and caring manner.

All 24 letters were the same in content but offered support from individuals self-described as primary care physicians, surgeons, and physicians. No letters of opposition were received.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

The status quo is an option; however, timeliness and efficiency would be reasonably negatively affected. DePaul merged into Maryview in April of 2021. During the four months of data collected, the 2 LINACs at DePaul performed 981 outpatient treatment visits (**Table 5**). Maryview owned and operated one LINAC (one already being at BSCI-HV and acquired 2 additional LINAC units in the April 2021 merger, one of which remained operational and performed a total of 8,039 outpatient treatment visits in 2021 (**Table 5**). The applicant reports the oncology services at the former DePaul campus ended in August 2022, in anticipation of the COPN application currently being reviewed.

As Maryview is consolidating radiation therapy services at the BSCI-HV location, the need for a second LINAC is substantiated based upon the SMFP threshold of 8,000 treatment visits equating to a 100% utilization threshold; Maryview’s patient radiation services needs would reasonably be expected to be above 8,000.

The applicant proposes to expand radiation services at BSCI-HV through consolidation of existing equipment and reduction in total inventory. With the transition, the operational capacity of the BSCI-HV LINAC currently in use would continue to supersede the 100% utilization threshold and further climb as services are not being offered at the DePaul campus anymore. Additionally, expanding radiation services at an outpatient location, BSCI-HV, is more cost effective for patients than if the services were provided in a hospital setting.

While resuming radiologic services at the former DePaul campus would be the most ideal for those in the Norfolk area facing inequitable disparities in accessing healthcare, the services have been stopped as of August 2022. The former DePaul hospital is potentially being

converted into a 400-unit apartment complex, but this has not been established for certain as of a February 23, 2023, The Virginian-Pilot article.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6.

Currently there is no organization in HPR V designated by the Virginia Department of Health to serve as the Health Planning Agency for the eastern Virginia region. Therefore, this consideration is not applicable to the review of either proposed project.

(iv) Any costs and benefits of the project.

The total capital/financial costs of the project are estimated at \$3,282,607. There will also need to be two additional full-time radiation technicians hired by the applicant. A few benefits of the project are as follows:

- The location of the project and services rendered will be farther from both Sentara Norfolk General Hospital and Sentara Brock Cancer Center than the previous DePaul location, likely leading to a better distribution of patient pool for those providers.
- The project will allow for the reduction of an excess LINAC and CT simulator from the inventory.
- The project will allow for consolidation of resources, such as space, medical staffing, utilities, administrative staff, etc., to one location, further reducing costs beyond moving the services to a fully outpatient setting.
- The project will increase timely outpatient treatment for patients, reducing healthcare costs in comparison to the services' cost had they continued to be provided at DePaul with a hospital level of reimbursement.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

Maryview does not limit access of services to patients based upon economic factors such as ability to pay or any other socio-demographic reason such as residing outside of the region. BSCI-HV does not provide services to pediatric patients.

The average charity care contribution for HPR V using the most recent available data from 2020, was 2.5%. Although BSCI-HV is not listed during this timeframe, the DePaul Medical Center (where the LINAC is coming from) and Maryview Medical Center (BSCI-HV is operated under this hospital), contributed 3.51% and 1.92%, respectively (**Table 4**). Averaged, they provided charity care at a rate of 2.72%. If the Commissioner authorizes a COPN for this project, DCOPN would recommend a charity care contribution of at the regional average rate of at least 2.5% as a condition of the certificate.

The total capital costs expected for this project are \$3,282,607. These costs are reasonable compared to three other similar projects. The project is also estimated to be fiscally viable in both the short and long term, with expected excess revenues after expenses of \$3,986,917 for Year 1 \$4,021,473 for Year 2. The HPR V Charity Contribution average for 2020 was 2.5%; the applicant prepared its Pro Forma statement with 3.0% Charity Contribution anticipated.

The Division of Certificate of Public Need recommends the **conditional approval** of Maryview Hospital, LLC d/b/a Bon Secours Maryview Medical Center's COPN Request number VA-8682 to add a linear accelerator at Bon Secours Cancer Institute at Harbour View in Suffolk, Virginia for the following reasons:

1. The proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. There does not appear to be any less costly or more efficient alternative to the proposed project.
3. The expansion would ultimately result in a reduction of linear accelerator capacity in the PD.
4. The capital costs of the proposed project are reasonable.
5. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of radiation therapy services in PD 20.
6. The proposed project appears to be financially viable in the immediate and long-term.
7. There is no known opposition to the project.

Charity Conditions

DCOPN's recommendation is contingent upon Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center's agreement to the following charity care condition:

Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center will provide radiation therapy services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 2.5% of Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center's total patient services revenue derived from radiation therapy services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center will accept a revised percentage based on the regional average

after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center will provide radiation therapy services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Maryview Hospital, LLC, d/b/a Bon Secours Maryview Medical Center will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

Table 4. HPR V 2020 Charity Care Contribution

| Health Planning Region V | | | |
|---|-------------------------|------------------------------------|----------------------------------|
| 2020 Charity Care Contributions at or below 200% of Federal Poverty Level | | | |
| Hospital | Gross Patient Revenues | Adjusted Charity Care Contribution | Percent of Gross Patient Revenue |
| Riverside Tappahannock Hospital | \$165,747,566 | \$8,843,478 | 5.34% |
| Riverside Shore Memorial Hospital | \$247,007,286 | \$10,695,992 | 4.33% |
| Riverside Doctors' Hospital Williamsburg | \$149,491,510 | \$6,064,567 | 4.06% |
| Riverside Walter Reed Hospital | \$252,482,633 | \$9,401,927 | 3.72% |
| Bon Secours DePaul Medical Center | \$363,165,760 | \$12,756,832 | 3.51% |
| Sentara Careplex Hospital | \$909,090,883 | \$31,651,344 | 3.48% |
| Sentara Obici Hospital | \$914,294,131 | \$26,301,718 | 2.88% |
| Sentara Virginia Beach General Hospital | \$1,265,310,067 | \$36,146,887 | 2.86% |
| Sentara Norfolk General Hospital | \$3,753,299,758 | \$106,756,170 | 2.84% |
| Sentara Leigh Hospital | \$1,330,835,003 | \$34,335,012 | 2.58% |
| Riverside Regional Medical Center | \$2,191,107,102 | \$53,859,556 | 2.46% |
| Chesapeake Regional Medical Center | \$986,713,280 | \$21,292,946 | 2.16% |
| Hampton Roads Specialty Hospital | \$46,913,449 | \$1,010,073 | 2.15% |
| Sentara Princess Anne Hospital | \$1,032,703,976 | \$21,443,232 | 2.08% |
| Bon Secours Maryview Medical Center | \$1,148,940,309 | \$22,068,850 | 1.92% |
| Bon Secours Mary Immaculate Hospital | \$620,268,395 | \$11,887,663 | 1.92% |
| Sentara Williamsburg Regional Medical Center | \$655,360,428 | \$11,516,832 | 1.76% |
| Bon Secours Rappahannock General Hospital | \$70,546,600 | \$1,148,522 | 1.63% |
| Children's Hospital of the King's Daughters | \$1,120,616,182 | \$4,135,241 | 0.37% |
| Bon Secours Southampton Memorial Hospital | \$211,414,625 | \$460,731 | 0.22% |
| Lake Taylor Transitional Care Hospital | \$44,295,918 | \$0 | 0.00% |
| Hospital For Extended Recovery | \$30,370,572 | \$0 | 0.00% |
| Total Facilities Reporting | | | 22 |
| Median | | | 2.35% |
| Total \$ & Mean % | \$17,509,975,433 | \$431,777,573 | 2.5% |

Source: VHI Charity Care Data, 2020

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.

The applicant states:

“When maintenance, repairs, or downtime occurs, a linear accelerator can be out of service for several days, during which patients cannot continue receiving timely treatment. When a linear accelerator is replaced, the service can be down for much longer – several months (three or more months to replace the equipment).”

The applicant goes on to report that historically, Bon Secours’ patients were temporarily treated at other Bon Secours locations in order to ensure continuity and continuation of care. All other providers in the PD are able to do this, but Bon Secours would have to either transfer patient care to another provider mid-treatment or delay treatment in these circumstances without approval of this project. While the applicant does not address this, Bon Secours does not have any additional locations within the HPR providing radiation services as the DePaul location’s services have stopped as of August 2022. While maintenance and replacement of LINACs are relatively uncommon, DCOPN finds these circumstances worthy of the Commissioner’s attention.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

Part III. Radiation Therapy Services
Article 1. Radiation Therapy Services

12VAC5-230-280. Travel time.

Radiation therapy services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

Radiation therapy services are provided at multiple locations across PD 20 and are generally within 60 minutes driving time one way under normal conditions for 95% of the planning district population. The light green shaded area in **Figure 2** represents the area in PD 20 that is within a 60 minutes driving distance from radiation therapy services. Southampton County is a less populated area and is fairly rural. Looking at **Figure 2** it can be reasonably estimated that 95% of the population has access to radiation therapy services within PD 20.

Figure 2. PD 20 LINAC and Radiation Therapy Services Locations



Source: DCOPN generated using DCOPN inventory, Microsoft Streets& Trips, and Google Maps

12VAC5-230-290. Need for new service.

A. No new radiation therapy service should be approved unless:

1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and
2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.

B. The number of radiation therapy machines needed in a health planning district will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 60\%}{320}$$

where:

1. The population is projected to be at least 150,000 people three years from the current year as reported in the most current projections of a demographic entity as determined by the commissioner;
2. The cancer incidence rate as determined by data from the Statewide Cancer Registry;
3. 60% is the estimated number of new cancer cases in a health planning district that are treatable with radiation therapy; and
4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 procedures per case.

C. Proposals for new radiation therapy services located less than 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available shall demonstrate that the proposed new services will perform an average of 4,500 procedures annually by the second year of operation, without significantly reducing the utilization of existing services in the health planning district.

This provision is not applicable as the project is not proposing a new radiation therapy service, but rather the expansion (or addition) by relocation of existing radiation therapy services. Nevertheless, performing the calculation can give insight into PD20's radiation therapy needs. DCOPN performed the projections using Weldon-Cooper's 2020 population of 1,237,588, and the PD 20 cancer incidence rate of 530.0/100,000 people found on the State Cancer Profiles website as the Virginia State Registry webpage is under construction (Table 5).

Table 5. Cancer Incidence Rate PD 20 by Locality

| Geographic Name | 2020 Census | Cancer Incidence Rate/100K* |
|-----------------------------|------------------|-----------------------------|
| Newport News City | 186,014 | 431.9 |
| Norfolk City | 238,024 | 467.1 |
| Northampton County | 12,270 | 564.8 |
| Northumberland County | 11,798 | 383.0 |
| Poquoson City | 12,471 | 420.4 |
| Portsmouth City | 97,909 | 472.4 |
| Richmond County | 8,928 | 1,126.0 |
| Southampton County | 17,973 | 455.4 |
| Suffolk City | 94,685 | 449.2 |
| PD 20 Totals/Average | 1,237,588 | 530.0 |
| Virginia | 8,646,905 | 409.4 |

Source: Cancer Data from statecancerprofiles.cancer.gov; Population Data from Weldon-Cooper

*Age-adjusted incidence rate cases per 100,000, 95% Confidence Interval, Average rate from 2015-2019

$$\frac{1,237,588 \times 0.0053 \times 60\%}{320} = 12.3$$

The calculation yields 12.3, or 13 machines needed in the planning district. Moreover, the cancer incidence rate of PD 20 is approximately 129.5% of the incidence rate for the state of Virginia as a whole. The project proposes to move 1 of the 12 LINACs and to reduce the inventory by 1. As a result of the project, there would be 11 LINACS.

Utilizing the 2021 VHI data (59,256 treatments), the average utilization for 12 units would have been 4,938 treatments per unit. As some locations have different quantities of LINACs, the distribution would be appropriate per provider. Reducing one of the units from the total as one DePaul unit was not used for most of 2021, the average treatments per unit would have been 5,386. As the population grows, the reduction of one LINAC would allow for other providers to have the opportunity to expand their services or for an additional location to be established, creating greater competition.

12VAC5-230-300. Expansion of service.

Proposals to expand radiation therapy services should be approved only when all existing radiation therapy services operated by the applicant in the health planning district have performed an average of 8,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers.

There are currently twelve linear accelerators at eight different provider locations in PD 20 (**Table 6**). As presented in **Table 6**, in 2021, the twelve units performed a total of 59,256 treatment visits (excludes Gamma Knife and Superficial/Orthovoltage), for an average of 4,558 treatment visits per unit.

Considering utilization for each location (**Table 6**), BSCI-HV and Sentara Norfolk General Hospital are at or above the 100% SMFP utilization threshold. The reduction of one LINAC in PD 20 and the movement of the former DePaul location west to BSCI-HV would potentially allow for increased utilization of Chesapeake Regional Medical Center's radiology services, located approximately 25 minutes, or 15 miles south of the former DePaul Center for those who do not rely on public transportation. The public transportation time estimates between the former DePaul location and Chesapeake Regional Medical Center are between 1 hour and 45 minutes and 2 hours and 30 minutes.

Table 6. PD 20 Radiation Therapy Providers and Utilization

| Facility | LINACs Authorized | Treatment Visits | Utilization Per LINAC (%) |
|--|-------------------|------------------|---------------------------|
| Bon Secours Cancer Institute at Harbour View | 1 | 8,018 | 100.2 % |
| Chesapeake Regional Medical Center | 2 | 7,610 | 47.6 % |
| Hampton Roads Radiation Oncology Center* | 2 | 980 | 6.1 % |
| Sentara Norfolk General Hospital | 2** | 8,634 | 107.9 % |
| Sentara Obici Hospital | 1 | 7,247 | 90.6 % |
| Sentara Virginia Beach General Hospital | 1 | 7,923 | 99.0 % |
| Virginia Oncology Associates - Princess Anne | 1 | 3,879 | 48.5 % |
| Virginia Oncology Associates - Sentara Cancer Center | 2 | 12,171 | 76.1 % |
| PD 20 Totals | 12*** | 56,462**** | 58.8 %***** |

Source: VHI 2021 Data and DCOPN Inventory

*Also known as DePaul Medical Center and only contains data for 1 LINAC following the merger in April 2021.

**1 of the 2 is Gamma Knife and is not included in the inventory count for LINACs

***Excluding Gamma Knife

****4,706 per LINAC or 7059 per location on average

*****58.8% utilization per LINAC or 88.2% per location on average

Table 7 illustrates the data for the last five years of radiation therapy utilization at Bon Secours radiation therapy providers in Planning District 20. The data is presented with the specific site in which the visits took place. It is important to note that the COVID-19 pandemic negatively impacted health care utilization generally in 2020, resulting in artificially reduced radiation therapy services utilization.

Table 7. Bon Secours Radiation Therapy Services

| Historical Utilization for Bon Secours Radiation Therapy Services | | | | | | | | |
|---|--------------------------|--------|--------------|--------|-------------------------------------|--------|--------------|--------|
| | Maryview at Harbour View | | DePaul | | Maryview at Norfolk (former DePaul) | | TOTAL | |
| Year | New Patients | Visits | New Patients | Visits | New Patients | Visits | New Patients | Visits |
| 2017 | 222 | 4,403 | 211 | 3,961 | | | 433 | 8,364 |
| 2018 | 249 | 5,270 | 180 | 3,744 | | | 429 | 9,014 |
| 2019 | 284 | 6,508 | 223 | 4,212 | | | 507 | 10,720 |
| 2020 | 301 | 5,533 | 186 | 4,048 | | | 487 | 9,581 |
| 2021 | 334 | 6,542 | 52 | 980 | 82 | 1,497 | 468 | 9,019 |

Source: COPN Req. No. VA-8682 who sourced information from ALSD data for the respective years

Maryview proposes expansion of an existing radiation therapy service at BSCI-HV through the relocation of one of two linear accelerators from Maryview’s Norfolk campus, formerly Bon Secours DePaul Medical Center (“DePaul”).

As reflected in the 2021 procedural volumes included in **Table 7**, consolidation of Bon Secours’ radiation therapy services in PD 20 to the Harbour View campus necessitates relocation of a linear accelerator from Norfolk to bring the Harbour View complement to two linear accelerators

as Maryview's one LINAC would be operating at greater than 100% utilization per SMFP threshold of 8,000 procedures. Importantly, approval of this project will not add to the number of COPN-authorized linear accelerator units in the planning district. Instead, it will reduce the number of LINACs in the planning district by 1.

12VAC5-230-310. Statewide Cancer Registry.

Facilities with radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

BSCI-HV is a current participant in the Statewide Cancer Registry and provides assurances it will continue to participate in the Statewide Cancer Registry.

12VAC5-230-320. Staffing.

Radiation therapy services should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

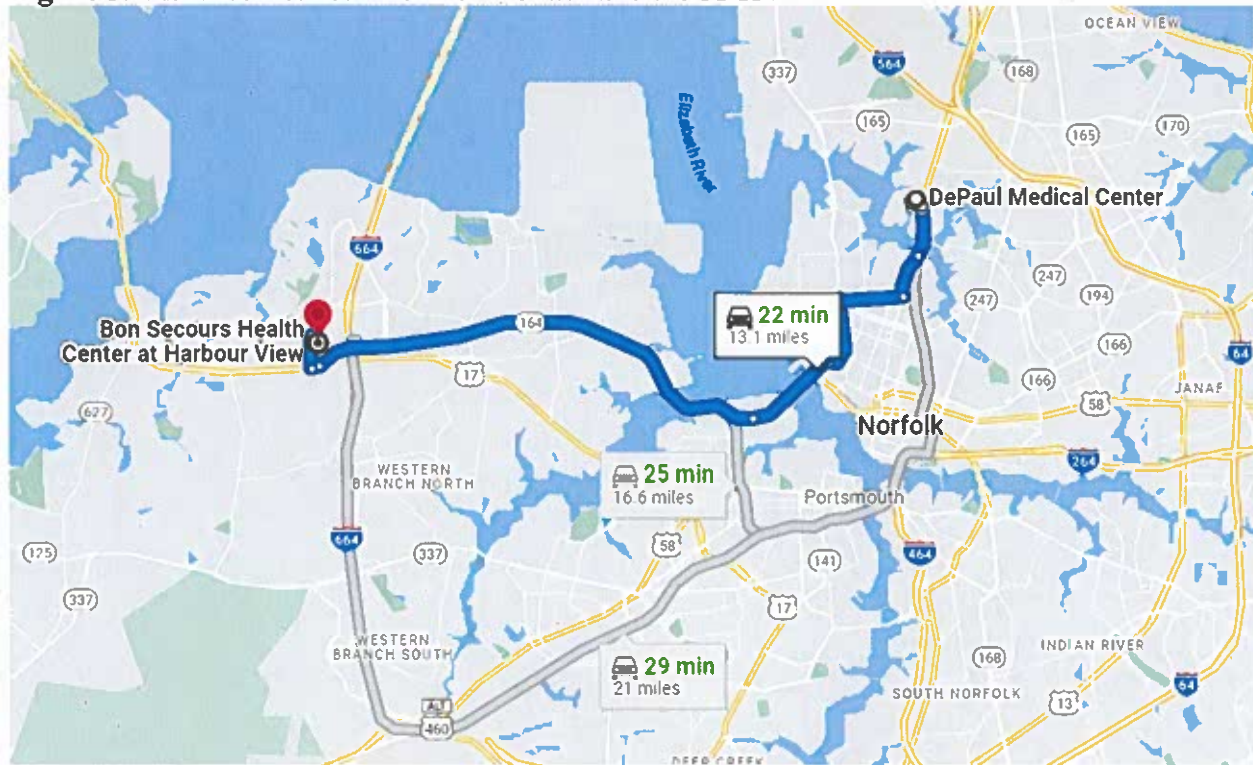
Maryview retains a Medical Director for Radiation Oncology Services, Dr. Michelle Nedelka; Dr. Nedelka maintains responsibility for remaining educated on best practices in innovations for radiation therapy, technological advancements, as well as trends that may affect quality of care. She is also responsible for oversight and revision of protocols and procedures to optimize patient outcomes. The applicant provided assurances that BSCI-HV radiation therapy services will continue to be under the direction or supervision of qualified physicians.

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

As calculated under the SMFP criteria, there is an estimated of a need for 13 machines in PD 20. The provider with the least utilization according to the 2021 VHI data is Chesapeake Regional Medical Center (CRMC). For patients not reliant on public transit, the ceasing of radiologic operation at the former DePaul site would potentially allow for an increase in CRMC's utilization, as CRMC is approximately 25 minutes driving-time south of the former DePaul location.

The project does not improve access to essential health care services for Norfolk. The applicant assumed the same patient populations will be supported through oncological services being consolidated to the BSCI-HV location, but the PSA for both are described as different within the application, reasonably so. At DePaul, Norfolk was listed as being within the PSA, while for BSCI-HV, Norfolk is listed as being within the secondary service area. **Figure 3**, below, illustrates the location change and the reasonable expectation that the patient population pool will be changed as a result.

Figure 3. Distance Between Former-DePaul and BSCI-HV



Source: Google Maps

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

With regard to continuity of care, BSCI-HV uses the EPIC electronic medical record interface which is also utilized throughout the Bon Secours Health System nationally. This allows Bon Secours Health System providers to all have access to the patients' medical records. Furthermore, there is no requirement for referrals to be made from Bon Secours physicians; BSCI-HV accepts referrals from any qualified physician. BSCI-HV is established with radiation services, so an expansion of these would increase efficiency for those in the area utilizing Bon Secours for their radiation therapy needs.

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.

The applicant anticipates the total capital cost of the project to be \$3,282,607 (Table 8). The entirety of the project is to be financed by accumulated reserves of Bon Secours Mercy Health. Consider relatively similar projects below:

- COPN VA-04679, issued October 14, 2019, authorized the University of Virginia Medical Center to add one MRI-equipped LINAC with SRS and SRT capabilities with an estimated capital cost of \$12,695,000 (\$14,855,698 in 2023)¹².
- COPN VA-04667, issued September 2, 2020, authorized Virginia Oncology Associates, P.C. to relocate an existing CT Simulator and radiation therapy equipment and the addition of one LINAC with SRS and SRT capabilities with an estimated capital cost of \$12,535,500 (\$14,279,906 in 2023).
- COPN VA-04652, issued April 8, 2019, authorized Virginia Cancer Specialists, P.C. to relocate an existing radiation oncology practice including 2 LINACs, one of which provides SRS and SRT services, a brachytherapy remote after loader, and a CT Simulator with an estimated capital cost of \$12,112,000 (\$14,173,471 in 2023).

Adjusting for inflation, Maryview’s proposal is 23.16% of the cost of the lowest priced project listed. While Maryview is only proposing a portion of the projects detailed above, the costs associated reflect a portion of the costs of the projects detailed above. DCOPN concludes the capital costs associated with the project are reasonable. While the applicant proposes to relocate existing equipment, no assurances were provided that a replacement would not occur immediately following the approval of the current project. If the applicant were to replace the equipment, the cost would increase. A LINAC replacement by Clinch Valley Medical Center (Registration VA-R-009-22) had a projected total capital cost of \$7,723,581. A LINAC replacement by Carilion Medical Center (Registration VA-R-001-21) had a projected total capital cost of \$4,044,314.

Table 8. Total Capital Costs Summary

| | |
|---|--------------------|
| Direct Construction Cost | \$2,145,685 |
| Equipment Not Included in Construction Contract | \$371,368 |
| Site Acquisition Costs | \$- |
| Site Preparation Costs | \$90,000 |
| Off-Site Costs | \$325,000 |
| Architectural and Engineering Fees | \$233,825 |
| Other Consultant Fees | \$116,729 |
| Taxes During Construction | \$- |
| A-HUD-232 Financing | \$- |
| B-Industrial Development Authority Revenue & General Revenue Bond Financing | \$- |
| C-Conventional Loan Financing | \$- |
| Total Capital Cost | \$3,282,607 |

Source: COPN Req. No. VA-8682

The expansion of radiation therapy services at BSCI-HV is expected to need the additional staffing of 2.0 full-time employees, specifically two radiation therapists. Bon Secours has partners with colleges, universities, and established allied health schools and programs, to include the allied health profession of radiation therapists. Bon Secours has used this newly trained pool of professionals to recruit new staff into the area.

¹² 2023 inflation rate adjusted figured determined using usinflationcalculator.com

The Bureau of Labor Statistics (BLS) projects the job outlook for radiation therapists to increase at 6% from 2021-2031 (as fast as the average of all jobs in the United States), with an estimated 800 positions to fill each year.¹³ In a meta-analysis of radiation therapist burnout in six different countries on multiple continents, it was found that the United States' radiation therapists alarmingly experienced the highest risk of developing burnout.¹⁴ In the Enrollment Snapshot for 2022 provided by the American Society of Radiologic Technologists (ASRT), there were 99 American Registry of Radiologic Technologists (ARRT) recognized programs in the US, 29.3% of which responded to the ASRT survey, had 1,208 estimated students for enrollment with a 9.2% attrition rate.¹⁵ There is an estimated 1,097 students who will graduate from these schools, which is more than the 800 positions BLS estimated to need to be filled.

Table 9. Pro Forma Income Estimate

| | Year 1 (2025) | Year 2 (2026) |
|--|--------------------|--------------------|
| Total Patient Revenue | \$51,734,813 | \$52,183,218 |
| Charity Deductions | \$(1,552,044) | \$(1,565,497) |
| Other Deductions | \$(40,296,134) | \$(40,645,397) |
| Net Operating Revenue | \$9,886,634 | \$9,972,325 |
| Total Operating Expenses after Depreciation and Amortization & Home Office Assessment | \$(5,899,717) | \$(5,950,852) |
| Recurring Operating Income | \$3,986,917 | \$4,021,473 |

Source: COPN Req. No. VA-8682

The applicant projects a profit of \$3,986,917 during the first year of operation, and \$4,021,473 during the second year of operation for BSCI-HV (the labeling was ambiguous and did not state whether the statement was in reference to the entirety of the radiation services at BSCI-HV, or the proposed LINAC alone) (Table 12). Maryview calculated these figures with an estimated “3.0% charity care contribution, 5% CDM [DCOPN assumes clinical data management] Increase for FY22, FY23, and FY24+FY25, [expenses are based on data from] FY21, [and] depreciation and amortization [was] based on FY21+ incremental capital over 25 years allocated to period”. As the project capital costs are estimated at \$3,282,607, DCOPN finds the project to be fiscally viable for both the short term and long term.

- The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of services on an outpatient basis; (iii) Any**

¹³ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Radiation Therapists, at <https://www.bls.gov/ooh/healthcare/radiation-therapists.htm> (visited March 03, 2023).

¹⁴ Guerra, Jéssica and Miguel Patricio. "Burnout in Radiation Therapists: Systematic Review with meta-analysis." *European Journal of Cancer Care* 28, no. 3 (2019): e12938-n/a.

¹⁵ https://www.asrt.org/docs/default-source/research/enrollment-snapshot/enrollment-snapshot-2022.pdf?sfvrsn=339d96d0_12

cooperative efforts to meet regional health care needs; (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining the extent to which the project provides improvements or innovations in the financing and delivery of health services.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

(i) The unique research, training, and clinical mission of the teaching hospital or medical school. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Bon Secours operates a school of nursing health professions and partners with colleges, universities, and established allied health professions. No other educational association was described in the application. DCOPN observed open radiology student positions listed on the Bon Secours Career website. Bon Secours operates a School of Health Sciences, including radiologic and diagnostic technician, with a 91% job placement rate located in Colonial Heights, Virginia; however, the information available does not state whether any of the graduates become employed within the Tidewater region.

DCOPN Staff Summary and Recommendations

In cancer incidence and treatment, there exists disparity in rates of being diagnosed with cancer, receiving treatment, and mortality. Two specific demographics, those in poverty and black Americans, have a disproportionately higher likelihood of having cancer, lower likelihood of receiving appropriate treatment, and higher mortality rates resulting from cancer. The average of DePaul's prior service area and Maryview's proposed service area for BSCI-HV have higher proportions of both of the aforementioned demographic groups than occurs statewide.

The support letters focused on increasing services for the Western Hampton Roads area, exposing Norfolk's population to a reduction in services. However, this reduction overall affords providers with utilization below the SMFP threshold to have a potential increase in patients but can further competition by leaving room for other providers to establish or expand services as the population continues to increase. Maryview's radiation therapy services are also currently providing over the 8,000-treatment threshold outlined in the SMFP. The SMFP calculation for number of radiation therapy machines in the PD resulted in a total of 13 machines; there are currently 12 and will be 11 after the project is completed. There does not appear for an adverse effect on patients' ability to receive timely access to care as many of the other locations in PD are at utilizations well below the SMFP threshold.