

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

September 18, 2020

COPN Request No. VA-8517

Bon Secours DePaul Medical Center, LLC &
Hampton Roads Radiation Oncology Center, LLC
Norfolk, Virginia

Establish a specialized center for the provision of radiation therapy services including two linear accelerators, one CT scanner dedicated to treatment simulation modeling, brachytherapy services, and mobile PET/CT services.

Applicants

Bon Secours DePaul Medical Center, LLC

Bon Secours DePaul Medical Center (DePaul) is a general acute care hospital located in Norfolk, Virginia. DePaul is a 501(c)(3) not-for-profit, non-stock membership corporation. Bon Secours Hampton Roads Health System, Inc. (BSHR), also a 501 (c)(3), non-stock membership corporation, is the sole corporate parent member of DePaul. DePaul is located in PD 20 within Health Planning Region (HPR) V.

Hampton Roads Radiation Oncology Center, LLC

Hampton Roads Radiation Oncology Center, LLC (HRROC) is a limited liability company whose sole member is Ambulatory Ventures LLC. Ambulatory Ventures LLC is a wholly owned subsidiary of Bon Secours Mercy Health Innovations LLC.

Background

Stereotactic Radiosurgery services (SRS) and Stereotactic Body Radiotherapy (SRT) Services in PD 20

According to Virginia Health Information (VHI) data and DCOPN records, the linear accelerator inventory of PD 20 consists of seven linear accelerators without SRS/SRT capability and four linear accelerators with SRS/SRT capability, excluding Gamma Knives™ (**Table 1**).

Table 1. COPN Authorized Linear Accelerators (Excluding Gamma Knife) in PD 20

Facility	Lin. Acc. without SRS/SRT	Lin. Acc. with SRS/SRT	Total
Bon Secours DePaul Medical Center	1	1	2
Bon Secours Maryview Medical Center	1	0	1
Chesapeake Regional Medical Center*	1	1	2
Sentara Healthcare & Virginia Oncology Associates – Lake Wright (Sentara Cancer Center)**	1	1	2
Sentara Norfolk General Hospital	0	1	1
Sentara Obici Hospital	1	0	1
Sentara Virginia Beach General Hospital	1	0	1
Sentara Virginia Oncology Associates – Princess Anne	1	0	1
Total	7	4	11

Source: VHI (2018) and DCOPN Records

*Pursuant to COPN No. VA-0460, CRMC was approved to introduce SRS/SRT by replacing one linear accelerator without SRS/SRT capabilities with a new linear accelerator with SRS/SRT capabilities. The project was expected to be completed by March 2020.

** Pursuant to COPN No. VA-04667, Virginia Oncology Associates was approved to relocate its radiation therapy equipment to the Sentara Cancer Center and to add one linear accelerator with SRS/SRT capabilities. The project is expected to be completed in April 2021.

Computed Tomography Services in PD 20

According to 2018 VHI data, the most recent year for which such data is available, and DCOPN records, the computed tomography (CT) scanner inventory of PD 20 consists of 41 fixed site CT scanners and one mobile site CT scanner (**Table 2**). DCOPN notes that the proposed project includes a CT simulator used solely for the purposes of radiation therapy.

Table 2. COPN Authorized Computed Tomography Scanners in PD 20

Facility	Fixed CT Scanners	Mobile CT Scanners	Total
Atlantic Orthopaedic Specialists*	1	0	1
Bon Secours DePaul Medical Center	2	0	2
Bon Secours Maryview Medical Center	3	0	3
Bon Secours Harbor View Hospital	1	0	1
Chesapeake Regional Imaging - Kempsville	1	0	1
Chesapeake Regional Medical Center	4	0	4
Children's Hospital of The King's Daughters**	2	0	2
First Meridian d/b/a MRI & CT Diagnostics - Chesapeake	1	0	1
First Meridian d/b/a MRI & CT Diagnostics - Virginia Beach	1	0	1
Riverside Diagnostic Center - Smithfield	1	0	1
Sentara Advanced Imaging Center – Belle Harbour***	2	0	2

Facility	Fixed CT Scanners	Mobile CT Scanners	Total
Sentara Advanced Imaging Center - Greenbrier Healthplex	1	0	1
Sentara Advanced Imaging Center - Leigh	1	0	1
Sentara Advanced Imaging Center - Princess Anne	1	0	1
Sentara Advanced Imaging Center - St. Luke's	0	1	1
Sentara Advanced Imaging Center at First Colonial	1	0	1
Sentara Advanced Imaging Center-Fort Norfolk	1	0	1
Sentara Independence	1	0	1
Sentara Leigh Hospital	2	0	2
Sentara Norfolk General Hospital****	6	0	6
Sentara Obici Hospital	2	0	2
Sentara Princess Anne Hospital	2	0	2
Sentara Virginia Beach General Hospital	3	0	3
Southampton Memorial Hospital	1	0	1
Total	41	1	42

*One CT scanner added pursuant to COPN No. VA-04645 became operational June 2019.

** Second CT scanner added pursuant to COPN No. VA-04647 became operational December 2019.

***Second CT scanner added pursuant to COPN No. VA-04632, to be completed in late 2020.

****Sixth CT scanner added pursuant to COPN No. VA-04504 became operational January 2018.

Positron Emission Tomographic Services in PD 20

According to 2018 VHI data, the most recent year for which such data is available, and DCOPN records, the inventory of PET/CT scanners in PD 20 consists of three fixed PET/CT units and five mobile PET/CT sites (**Table 3**).

Table 3. COPN Authorized PET Mobile Sites and Fixed PET Units in PD 20

Facility	Fixed PET/CT Units	Mobile PET/CT Sites	Procedures
Bon Secours DePaul Medical Center	0	1	161
Bon Secours Maryview Medical Center	0	1	547
PET Institute of Hampton Roads*	1	0	620
Riverside Diagnostic Center – Smithfield	0	1	2
Sentara Norfolk General Hospital	0	1	4,853
TOTAL and Average	3¹	5²	6,183

Source: VHI (2018) and DCOPN records

*COPN No. VA-04668, issued on September 3, 2019, the cessation of PET services at the PET Institute of Hampton Roads and the surrender of PET Institute’s COPN No. VA-03490. The project is anticipated to be operational by February 2021.

¹ Though not included in the overall calculations for total procedures, this number includes the fixed-site PET/CT scanners added pursuant to COPN Nos. VA-04625 and 04668.

² Though not included in the overall calculations for total procedures, this number includes the mobile PET/CT service added pursuant to COPN No. VA-04648.

DCOPN notes that, while not included in the 2018 VHI data, DCOPN records indicate that, in addition to the one existing fixed PET/CT unit and three mobile PET/CT sites reported to VHI for 2018, an additional two fixed PET/CT units and one mobile PET/CT site have been added to the PD 20 inventory since 2018:

- COPN No. VA-04625 authorized the establishment of fixed-site PET/CT services at Sentara Leigh Hospital, together with the decommissioning of a nearby mobile PET/CT service site at Lake Wright. This project is expected to be operational by January 2021.
- COPN No. VA-04668 authorized the establishment of fixed PET/CT services at Chesapeake Regional Medical Center (CRMC), together with the cessation of PET services at the PET Institute of Hampton Roads and the cessation of mobile PET/CT services at CRMC. This project is expected to be operational by February 2021.
- COPN No. VA-04648 authorized the establishment of a mobile PET/CT site at CRMC, to become operational in November 2019. However, DCOPN notes that this certificate will ultimately be surrendered pursuant to COPN No. VA-04668.

DCOPN notes that the volumes for machines added to the PD 20 inventory subsequent to 2018 are not included in the number of total procedures shown in **Table 3**, as this data is not yet available from VHI.

Proposed Project

DePaul and HRROC propose to establish a specialized center for the provision of radiation therapy services, HRROC. HRROC will offer radiation therapy services on two linear accelerators (one of which will be capable of performing SRS and SRT), brachytherapy, CT simulation for radiation therapy treatment planning, and mobile PET/CT services. The services are already operational and offered by DePaul. All services will continue to be offered in the same space where they are currently offered, 155 Kingsley Lane, Suite 100, Norfolk, Virginia. If the Commissioner approves the proposed project, HRROC will commence offering these services and DePaul will discontinue the provision of these services. The applicant notes that it anticipates that HRROC will partner with area physicians and medical practice groups to offer radiation oncology and cancer services but will retain majority ownership.

The projected capital costs of the proposed project are \$4,639,413 approximately 1.1% of which are attributed to direct construction costs (**Table 4**). Capital costs will be funded through the capital contributions by the members of HRROC. Accordingly, there are no financing costs associated with this project. The applicant asserts that no renovations or space expansion are required for the proposed project. The applicant anticipates a target date of opening of 90 days after issuance of a COPN.

Table 4. Hampton Roads Radiation Oncology Center, LLC’s Projected Capital Costs

Direct Construction Costs	\$52,535
Site Acquisition Cost	\$4,561,087
Architectural and Engineering Fees	\$25,790
Other Consultant Fees	\$60,000
Total Capital Costs	\$4,639,413

Source: COPN Request No. VA-8517

Project Definitions

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part as the, “Establishment of a medical care facility...” A medical care facility, includes “[a]ny specialized center or clinic... developed for the provision of... computed tomography (CT) scanning... positron emission tomographic (PET) scanning, 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 project will provide or increase access to health care services for people in the area to be served, and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, HRROC’s radiation therapy services will be located in two spaces on the DePaul hospital campus: the ground floor of an existing medical office building located at 155 Kingsley Lane, Suite 100, Norfolk, Virginia, and the space occupied by the second linear accelerator inside the main hospital, located at 150 Kingsley Lane, Norfolk, Virginia. The DePaul campus is within one mile of I-64 and US Route 58. Additionally, the campus is served by public transportation.

The services that are the subject of the proposed project are already offered by the co-applicant, DePaul, and all services will be offered in the same space where they are currently offered. A mobile pad at the back of the building serves as the location for the mobile PET/CT services. If the State Health Commissioner (Commissioner) approves the proposed project, at such time that the project is completed, DePaul will cease offering the services that are the subject of COPN Request No. VA-8517 and the services will be offered by HRROC. Therefore, approval of the proposed project will not affect geographic access to radiation therapy services.

Population plays a major role in determining the need for radiation therapy services in a planning district. **Table 5** shows projected population growth in PD 20 through 2020.

Table 5. Population Projections for PD 20, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Isle of Wight	35,270	38,060	7.91%	0.75%	41,823	9.89%	0.95%
Southampton	18,570	17,739	-4.47%	-0.45%	17,711	-0.16%	-0.02%
Chesapeake	222,209	249,244	12.17%	1.13%	270,506	8.53%	0.82%
Franklin	8,582	8,268	-3.66%	-0.36%	8,140	-1.55%	-0.16%
Norfolk	242,803	246,881	1.68%	0.16%	249,889	1.22%	0.12%
Portsmouth	95,535	95,027	-0.53%	-0.05%	90,715	-4.54%	-0.46%
Suffolk	84,585	94,733	12.00%	1.11%	109,424	15.51%	1.45%
Virginia Beach	437,994	457,699	4.50%	0.43%	467,187	2.07%	0.21%
Total PD 20	1,145,548	1,207,652	5.42%	0.52%	1,255,394	3.95%	0.39%
PD 20 65+	124,196	167,891	35.18%	2.98%	222,845	32.73%	2.87%
Virginia	8,001,024	8,655,021	9.30%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations)

As depicted in **Table 5**, at an average annual growth rate of 0.52%, PD 20’s population growth rate is slightly below the state’s average annual growth rate of 0.77%. Overall, the planning district is projected to add an estimated 62,104 people in the 10-year period ending in 2020 – an average increase of 6,210 people annually and 47,742 in the 10-year period ending 2030 – an average increase of 4,774 people annually.

Regarding socioeconomic barriers to access to the applicant’s services, according to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR V facilities was 45.1% of all reported total gross patient revenues (**Table 6**). In that same year, DePaul, a co-applicant to COPN Request No. 8517, provided 7.62% of its gross patient revenue in the form of charity care. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition no less than the 5.1% HPR V average.

Table 6. HPR V Charity Care Contributions: 2018

2018 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	% of Gross Patient Revenue
Bon Secours DePaul Medical Center	\$698,996,618	\$53,230,518	7.62%
Sentara Careplex Hospital	\$889,460,665	\$64,660,889	7.27%
Riverside Tappahannock Hospital	\$162,491,011	\$11,307,825	6.96%
Riverside Regional Medical Center	\$1,861,151,990	\$126,769,911	6.81%
Bon Secours Maryview Medical Center	\$1,273,955,832	\$85,038,667	6.68%
Sentara Obici Hospital	\$825,126,790	\$54,851,619	6.65%
Riverside Walter Reed Hospital	\$252,673,741	\$16,571,599	6.56%
Sentara Virginia Beach General Hospital	\$1,210,282,480	\$67,107,518	5.54%
Riverside Doctors' Hospital Williamsburg	\$124,258,743	\$6,791,596	5.47%
Sentara Norfolk General Hospital	\$3,313,578,465	\$168,093,514	5.07%
Riverside Shore Memorial Hospital	\$235,708,877	\$11,934,270	5.06%
Sentara Leigh Hospital	\$1,182,257,169	\$55,810,160	4.72%
Bon Secours Mary Immaculate Hospital	\$675,071,989	\$29,896,497	4.43%
Sentara Princess Anne Hospital	\$967,617,447	\$38,069,270	3.93%
Sentara Williamsburg Regional Medical Center	\$659,049,590	\$24,789,255	3.76%
Chesapeake Regional Medical Center	\$900,598,911	\$15,330,992	1.70%
Hampton Roads Specialty Hospital	\$25,627,019	\$433,771	1.69%
Southampton Memorial Hospital	\$209,949,572	\$3,282,979	1.56%
Bon Secours Rappahannock General Hospital	\$71,220,177	\$1,107,592	1.56%
Children's Hospital of the King's Daughters	\$1,009,437,096	\$6,094,726	0.60%
Lake Taylor Transitional Care Hospital	\$46,761,019	\$0	0.00%
Hospital For Extended Recovery	\$25,515,975	-\$252,369	-0.99%
Total Facilities Reporting			22
Median			4.9%
Total \$ & Mean %	\$16,620,791,176	\$840,920,799	5.1%

Source: VHI (2018)

2. The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:

- (i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;**

DCOPN received 49 letters of support for the proposed project from members of the medical community and patients of DePaul. Collectively, these letters articulate numerous benefits of the project, such as:

- The excellence of the DePaul cancer program;
- The importance of radiation therapy in cancer treatment;
- The accessibility of the DePaul campus;
- The increase in demand for radiation therapy services;
- The lower cost of a non-hospital based cancer center.

Public Hearing

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8517 is not competing with another project in this batch cycle. DCOPN did not receive a request to conduct a public hearing.

(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

The status quo is a viable alternative to the proposed project. However, while the proposed project is not essential, allowing HRROC to operate the cancer treatment center services in a medical office building as a non-hospital facility means that the services provided will be billed and reimbursed at a lower rate than those provided in a hospital based setting. Furthermore, the proposed project is inventory neutral, as the services are already operational and offered by DePaul. Therefore, DCOPN concludes that the proposed project is more advantageous than the status quo.

(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 PD 20. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) any costs and benefits of the proposed project;

As demonstrated by **Table 4**, the projected capital costs of the proposed project are \$4,639,413, approximately 1.1% of which are attributed to direct construction costs. Capital costs will be funded through the capital contributions of the members of HRROC. Accordingly, there are no financing costs associated with this project. DCOPN concludes that when compared to similar radiation therapy projects these costs are modest. For example, COPN No. VA-04652 issued to Virginia Cancer Specialist, P.C. to relocate its radiation therapy services is anticipated to cost approximately \$12,112,000.

The applicant identified numerous benefits of the proposed project, including:

- The DePaul campus offers a modern, patient-friendly environment that is easily accessible to cancer patients and accompanying family members;
- All services are co-located in the same building, minimizing travel for treatment;
- DePaul’s state-of-the-art facilities and physicians offer a comprehensive cancer center with many treatment modalities to best meet the treatment needs of its patients;
- The proposed project is inventory neutral, as DePaul currently provides radiation therapy services and has provided such services for many years; and
- HRROC will operate as a non-hospital facility, which means that services provided to patients will be billed and reimbursed at a lower rate than those provided in a hospital-based setting.

(v) the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and

The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 3.4% in the first year of operations and 4.3% in the second year of operations (Table 7). DCOPN notes that, according to VHI data from 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR V facilities was 5.1% of all reported total gross patient revenues (Table 6). In that same year, DePaul provided 7.62% of its gross patient revenue in the form of charity care. Pursuant to Section 32.1 – 102.4 of the Code of Virginia, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition of no less than the 5.1% HPR V average.

Table 7. Hampton Road’s Radiation Oncology Center Pro Forma Income Statement

	Radiation Oncology		Mobile PET/CT	
	Year 1	Year 2	Year 1	Year 2
Outpatient Services Revenue	\$10,296,726	\$10,502,661	\$827,324	\$850,520
Contractuals	(\$7,792,924)	(\$7,854,259)	(\$581,058)	(\$589,695)
Charity Care	(\$350,089)	(\$451,614)	(\$28,129)	(\$36,572)
Bad Debt	(\$57,216)	(\$58,361)	(\$4,137)	(\$4,253)
Net Patient Services Revenue	\$2,096,497	\$2,138,427	\$214,000	\$220,000
Total Operating Expenses	\$1,928,775	\$1,967,350	\$176,550	\$181,500
EBIDA	\$167,722	\$171,077	\$37,450	\$38,500
Depreciation and Amortization Interest	\$140,000	\$140,000	N/A	N/A
Income from Operations	\$27,722	\$31,077	\$37,450	\$38,500

Source: COPN Request No. VA-8517

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

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 to determining a public need for the proposed projects.

3. The extent to which the application is consistent with the State Health Services Plan;

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for computed tomography (CT) imaging services. They are as follows:

Part II
Diagnostic Imaging Services
Article 1
Criteria and Standards for Computed Tomography

12VAC5-230-90. Travel time.

CT services should be available within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

The project does not include a diagnostic CT and will not improve access to diagnostic CT scanning services.

12VAC5-230-100. Need for new fixed site or mobile service.

- A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.**
- B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.**

The applicant is not seeking to establish new fixed site or mobile site for diagnostic CT services. As the CT simulator being requested will be used solely for simulation with radiation therapy treatment, this exemption from the utilization criteria is applicable to this project.

12VAC5-230-110. Expansion of fixed site service.

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

Not applicable. The applicant is not seeking to expand their CT services.

12VAC5-230-120. Adding or expanding mobile CT services.

- A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.**
- B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile CT scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.**

Not applicable to the proposed project. The applicant is not proposing to add or expand mobile CT services or to convert authorized mobile CT scanners to fixed site scanners.

12VAC5-230-130. Staffing.

CT services should be under the direction or supervision of one or more qualified physicians.

The applicant has provided assurances that its CT simulations services will be under the direction or supervision of one or more qualified physicians.

The SMFP contains standards and criteria for the establishment of PET/CT services. They are as follows:

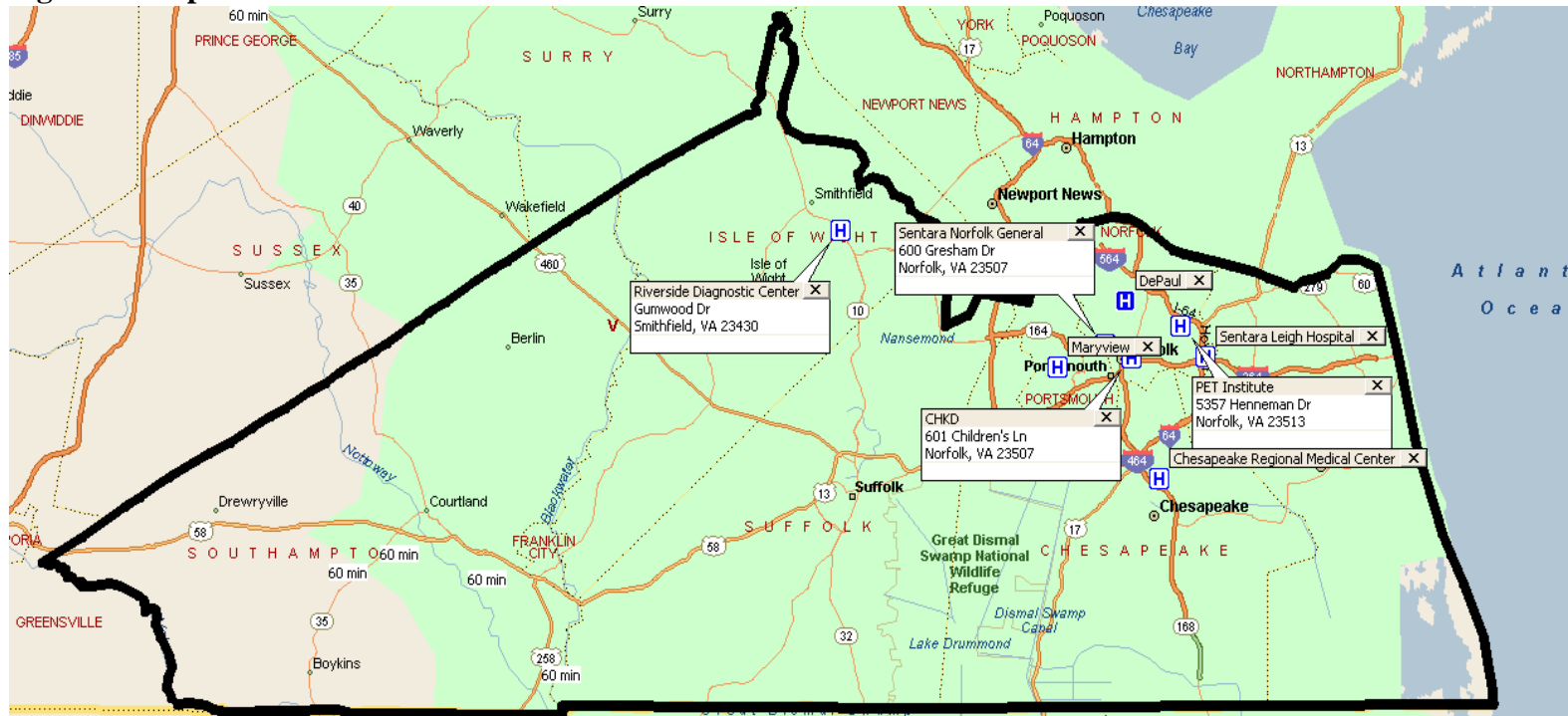
**Part II. Diagnostic Imaging Services
Article 4. Positron Emission Tomography**

12VAC5-230-200. Travel time.

PET services should be 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.

The heavy black line in **Figure 1** represents the boundary of PD 20. The blue “H” sign marks the location of DePaul. The white “H” signs mark the locations of all other existing fixed PET/CT and mobile PET/CT site services in PD 20. The green shaded area represents the area of PD 20 and surrounding areas that are within 60 minutes’ drive time of existing PET/CT services. Given the amount of shaded area, it is evident that PET/CT services currently exist within a 60-minute drive for at least 95% of the population of PD 20. Furthermore, DCOPN notes that the proposed project is inventory neutral and will not affect geographic access to PET/CT services.

Figure 1: Map of PET/CT Services in PD 20



Source: DCOPN Records

12VAC5-230-210. Need for New Fixed Site Service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

Not applicable. The applicant is not requesting to establish a fixed-site PET/CT service.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Not applicable. The applicant is not requesting to establish a fixed-site PET/CT service.

12VAC5-230-220. Expansion of Fixed Site Services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

Not applicable. The applicant is not requesting to expand a fixed-site PET/CT service.

12.VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

One measure of PET appropriate patients is the number of patients beginning a new course of radiation therapy at DePaul. The number of patients beginning a new course of radiation therapy is indicative of the need for cancer planning and staging utilizing PET/CT scanning for newly diagnosed and previously diagnosed cancer patients. According to VHI data for 2018, the most recent year for which data is available, DePaul began 180 new courses of radiation therapy in 2018. Furthermore, the applicant projects that it will perform 214 PET/CT scans in the first full year of operation of the proposed service and 220 PET/CT scans in the second full year of operation.

DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written, and should be treated as such:

“Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization.” (Source: Health Systems Agency of Norther Virginia Staff Report RE: COPN Request No. VA-8327, November 28, 2017).

Finally, DCOPN notes that the proposed mobile PET/CT service is inventory neutral as DePaul currently provides mobile PET/CT services, which have been operational for 10 years. If the Commissioner approves the proposed project, DePaul will discontinue the provision of mobile PET/CT services upon completion of the project.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

Not applicable. The applicant is not proposing to convert an authorized mobile PET or PET/CT scanner to a fixed-site PET/CT scanner.

12VAC5-230-240. Staffing.

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

The applicant has provided assurance that the proposed mobile PET/CT service will be under the direction of one or more qualified physicians. The applicant meets this standard.

The SMFP contains criteria/standards for radiation therapy services. They are as follows:

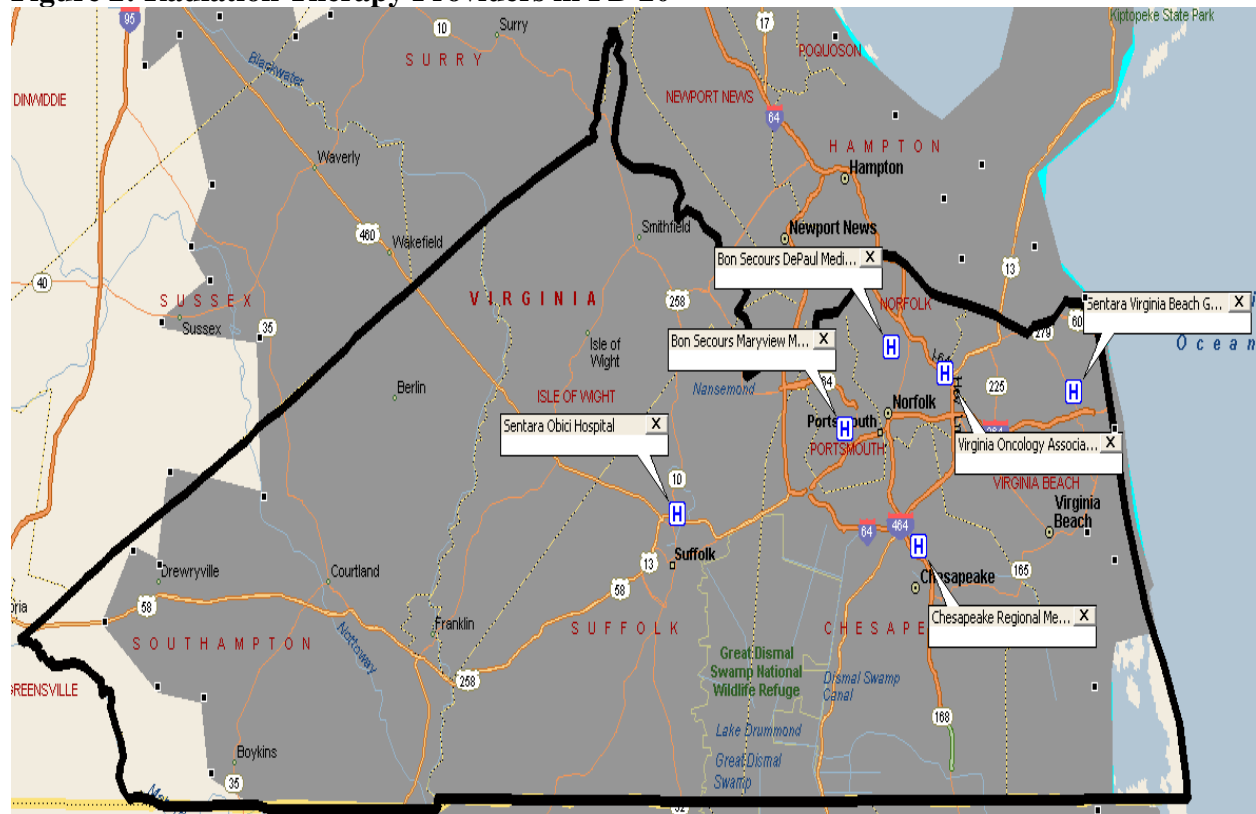
**Part III
Radiation Therapy Services
Article 1
Criteria and Standards for Radiation Therapy Services**

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.

The heavy dark line in **Figure 2** identifies the boundaries of PD 20. The grey shading illustrates the area that is within a 60-minute drive under normal driving conditions of all radiation therapy service providers. **Figure 2** clearly illustrates that radiation therapy services are already well within a one-hour drive under normal conditions for 95% of residents of the planning district.

Figure 2: Radiation Therapy Providers in PD 20



Source: DCOPN Records

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.**

The applicants are proposing to establish a specialized center for the provision of radiation therapy services, HRROC. However, the radiation therapy services are already operational and offered by DePaul. All services will continue to be offered in the same space where they are currently offered. If the Commissioner approves the proposed project, DePaul will discontinue the provision of radiation therapy services upon completion of the project. Approval of this project is inventory neutral and will not affect 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:

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

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.

Table 8 below shows the projected population and new cancer cases requiring radiation therapy in PD 20. Based on the SMFP methodology for determining need for linear accelerators in the planning district, there is a need for 11 linear accelerators in PD 20 through 2023. As there are 11 COPN approved linear accelerators in PD 20, there will be neither a need nor a surplus by 2023.

Table 8. Number of radiation therapy machines needed in PD 20

Locality	PD 20 Area 2023 Population	Cancer Incidence Rate (Per 100,000)	2023 Projected Cancer Cases	New Cancer Cases Requiring RT	Linear Accelerators Needed
Total PD 20	1,221,975	470.0	5,744	3,446	11

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations) and National Cancer Institute Incidence Rates Table (Latest Five-Year Average)

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.

While the establishment of HRROC is considered a new medical care facility under COPN, all of the proposed services are currently offered in the same location by DePaul. Approval of the proposed project is inventory neutral and would not affect the utilization of existing providers in the health planning district. The applicant projects that it will have 4,427 radiation therapy visits by the end of the second year of operations.

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.

Not applicable. The proposed project does not involve an expansion of a radiation therapy service.

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

DePaul participates in the Statewide Cancer Registry. According to the applicants, HRROC will also 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.

The applicant has provided assurances that their radiation therapy services will be under the direction or supervision of one or more qualified physicians.

The SMFP contains criteria/standards for stereotactic radiosurgery services. They are as follows:

Required Considerations Continued

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

Because this project represents an inventory neutral change in ownership of the radiation therapy, including CT simulation, and PET/CT services, with no change in the location the services are to be provided, DCOPN concludes that it is highly unlikely that approval of the project would affect the utilization or efficiency of other existing or COPN approved providers of radiation therapy services in HPR V or PD 20.

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

Because this project represents an inventory neutral change in ownership of the radiation therapy, including CT simulation, and PET/CT services, DCOPN concludes that it is highly unlikely that approval of the project would affect the utilization or efficiency of other existing or COPN approved providers of radiation therapy services in HPR V or PD 20.

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

As already discussed, DCOPN contends that the projected costs for the proposed project are modest when compared to previously authorized projects similar in scope. Furthermore, the Pro Forma Income Statement provided by the applicant projects a net profit of \$27,722 from radiation oncology and \$37,450 from PET/CT services in the first year of operation and of \$31,077 from radiation oncology and \$38,500 from PET/CT services in the second year of operation. The applicant will fund the proposed project through capital contributions of members of HRROC. Accordingly, there are no financing costs associated with this project.

The applicant does not anticipate needing to hire personnel to staff the proposed project, as the services are already provided in the same space by the co-applicant, DePaul.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care 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 health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

The proposal would introduce no new technology that would promote quality or cost effectiveness in the delivery of radiation therapy services. However, the proposed project does increase the potential for provision of services on an outpatient basis, offering considerably lower costs than those offered in a hospital setting.

In its application, submitted June 1, 2020, the applicant proposed to establish a specialized center for the provision of radiation therapy services, HRROC. HRROC seeks to offer radiation therapy services on two linear accelerators (one of which will be capable of performing SRS and SRT), brachytherapy, CT simulation for radiation therapy treatment planning, and mobile PET/CT services. The services are already operational and offered by DePaul. DCOPN notes that the addition of SRS/SRT is no longer subject to COPN review. Section 32.1 – 102.1:1 of the Code of Virginia directs, but a person is required to register medical equipment purchased for the provision of SRS/SRT:

Within thirty calendar days of becoming contractually obligated to acquire any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, or other specialized service designated by the Board by regulation, any person shall register such purchase with the Commissioner and the appropriate regional health planning agency.

Furthermore, Section 32.1 – 102.2 of the Code of Virginia allows the Commissioner to require the registrant to

- Provide a level of care in services or funds that matches the average percentage of indigent care provided in the appropriate health planning region and to participate in Medicaid at a reduced rate to indigents;
 - Obtain accreditation from a nationally recognized accrediting organization approved by the Board for the purpose of quality assurance, and
 - Report utilization and other data required by the Board to monitor and evaluate effects on health planning and availability of health care services in the Commonwealth.
- 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, and (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.**

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to establish a specialized center for the provision of radiation therapy services including two linear accelerators, one CT scanner dedicated to treatment simulation modeling, brachytherapy services as well as mobile PET/CT services is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. Notably, while the proposed project is inventory neutral because the proposed services are already in operation on the DePaul campus, allowing HRROC to operate the cancer treatment center services in a medical office building as a non-hospital facility means that the services provided will be billed and reimbursed at a lower rate than those provided in a hospital based setting.

Furthermore, there is no known opposition from other providers, health care professionals or community representatives in PD 20. Finally, DCOPN finds that the total capital and financing costs for the project of \$4,639,413 (**Table 4**) are modest and reasonable when compared to similar projects.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **conditional approval** of Bon Secours DePaul Medical Center, LLC and Hampton Roads Radiation Oncology Center, LLC's request to establish a specialized center for the provision of radiation therapy services including two linear accelerators, one CT scanner dedicated to treatment simulation modeling, brachytherapy services as well as mobile PET/CT services DCOPN's recommendation is based on the following findings.

1. The proposal project is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The proposed project is inventory neutral.
3. The proposed project is more advantageous than the status quo.
4. There is no known opposition to the project.
5. The capital costs are reasonable for the type of project.

DCOPN's recommendation is contingent upon Bon Secours DePaul Medical Center, LLC and Hampton Roads Radiation Oncology Center, LLC's agreement to the following charity care condition:

Bon Secours DePaul Medical Center, LLC and Hampton Roads Radiation Oncology Center, LLC will provide radiation therapy, including CT simulation, and PET/CT imaging 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 radiation therapy and PET/CT imaging services to medically underserved persons in an aggregate amount equal to at least 5.1% of Hampton Roads Radiation Oncology Center, LLC's total patient services revenue derived from radiation therapy and PET/CT imaging services provided at Hampton Roads Radiation Oncology Center, 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. Hampton Roads Radiation Oncology Center, LLC 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.

Hampton Roads Radiation Oncology Center, LLC will provide radiation therapy, including CT simulation, and PET/CT care 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 Hampton Roads Radiation Oncology Center, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.