

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2021

COPN Request No. VA-8510

HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital

Henrico County, Virginia

Convert Mobile PET/CT Service to Fixed-Site Service at Henrico Doctors' Hospital-Forest

Applicant

HCA Health Services of Virginia, Inc. ("HCA Virginia") is a for-profit, Virginia stock corporation. HCA Healthcare Inc., headquartered in Nashville, Tennessee, is the ultimate corporate parent of HCA Virginia. Henrico Doctors' Hospital ("HDH") is an affiliate of HCA Virginia. Henrico Doctors' Hospital-Forest ("HDH-Forest") is a campus of HDH and is located in Henrico County, Health Planning Region (HPR) IV, Planning District (PD) 15.

Background

HDH is a 340-bed, tertiary-care hospital located in Henrico County. As a tertiary-care hospital, HDH provides an extensive array of diagnostic, medical, and surgical services to the population of Central Virginia.

According to 2018 Virginia Health Information (VHI) data, the most recent year for which such data is available, there was one fixed-site PET scanner in operation in PD 15. This machine, located at VCU Medical Center, performed 1,739 procedures in 2018. Additionally, there were six operational mobile sites in PD 15. Collectively, machines located at mobile sites performed 3,569 procedures in 2020. The collective PD 15 PET inventory (both mobile and fixed) performed 5,308 procedures in 2020.

DCOPN notes that subsequent to 2018, Bon Secours Health System eliminated its mobile service (which served three Bon Secours locations) and established a fixed-site service at Reynolds Crossing in its place. Additionally, Virginia Cardiovascular Specialists established a fixed-site PET service. With regard to mobile PET services, a site was added at West Creek Medical Center. As of the date of this report, PD 15 has three fixed-site PET scanners and four mobile sites, totaling seven operational PET services.

Table 1. PD 15 COPN Authorized PET Mobile Sites and Fixed PET Units: 2018

| Fixed PET Units | | | |
|---|----------------------|-------------|--------------------------|
| Facility | # of Units | Type | Procedures |
| Bon Secours Imaging Center at Reynolds Crossing | 1 | PET/CT | 1,595 ¹ |
| Virginia Cardiovascular Specialists | 1 | PET only | -- |
| VCU Health System | 1 | PET only | 1,739 |
| TOTAL | 3 | | 1,739² |
| Mobile PET Sites | | | |
| Facility | # of Sites | Type | Procedures |
| Henrico Doctors' Hospital—Parham | 1 | PET only | 2 |
| Henrico Doctors' Hospital—Forest | 1 | PET/CT | 829 |
| Johnston-Willis Hospital | 1 | PET/CT | 1,143 |
| West Creek Medical Center | 1 | PET/CT | -- |
| TOTAL | 4 | -- | 3,569³ |
| GRAND TOTAL | 7⁴ | -- | 5,308 |

Source: VHI (2018) and DCOPN records

The applicant stated that for 2019, the mobile service at HDH-Forest performed 1,035 procedures, a 79.7% increase from 2014 (**Table 2**)⁵. While DCOPN cannot quantifiably confirm the applicant's data, it does note that the number of procedures performed at HDH-Forest has increased steadily in recent years – 44% from 2014 to 2018. Furthermore, the applicant has projected that by the second year of operation, the fixed-site service, if approved, will perform approximately 1,430 procedures. Due to the consistent increase in procedures over the past several years, DCOPN contends that the applicant's projections are reasonable.

Table 2. Historic HDH—Forest Mobile PET Inventory and Procedures: 2018-2014

| Year | Procedures |
|--------------------|-------------------|
| Year 2 (Projected) | 1,430 |
| Year 1 (Projected) | 1,232 |
| 2019 | 1,035 |
| 2018 | 829 |
| 2017 | 732 |
| 2016 | 689 |
| 2015 | 592 |
| 2014 | 576 |

Source: VHI (2014-2018) and COPN Request No. VA-8510

¹ COPN No. VA-04619 authorized the conversion of Bon Secours Health System's mobile unit, which serviced three Bon Secours mobile sites, (Memorial Regional, St. Francis, and St. Mary's) to a fixed-site service located at Reynolds Crossing. Accordingly, DCOPN has listed the 2018 VHI procedures data for those three mobile sites with Reynolds Crossing. This data has been included in the calculations for mobile PET/CT scanners under the SMFP and also included in the calculations for collective mobile procedures in Table 1.

² This number reflects only those procedures performed on fixed-site units in 2018.

³ Includes procedures performed at then-existing Bon Secours mobile sites, which were subsequently converted to one fixed-site service.

⁴ This number reflects additions to the PD 15 PET inventory that took place after 2018.

⁵ While DCOPN cannot quantifiably confirm this data, it notes that the applicant is required to release such data to VHI, and therefore has included it in the analysis for this project.

Proposed Project

HDH proposes to convert the current mobile service at HDH-Forest to a fixed-site service. To accommodate the requested fixed scanner, the applicant intends to renovate existing space within the imaging department adjacent to the MRI, CT, and nuclear medicine departments. The applicant states that the fixed PET/CT scanner will support its oncology and cardiac services, while improving patient care. The applicant additionally states that approval of the proposed project would help to address long wait times, scheduling complications, and delays in diagnosis and treatment for its patients. The applicant states that the addition of a fixed-site scanner is more cost-effective than continuing to pay rent for a mobile unit. The applicant has provided assurances that the CT modality of the requested scanner will be used only in conjunction with the PET modality.

The applicant anticipates construction for the proposed project to commence within 15 months of COPN issuance and to be completed within 28 months of COPN issuance. The applicant anticipates a target date of opening within 29 months of COPN issuance. If approved, schedule allowances may need to be made in order to accommodate the applicant’s response to the COVID-19 pandemic.

The projected capital costs for the proposed project total \$3,979,077 (**Table 3**), the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project.

Table 3. Projected Capital Costs

| | |
|---|-------------|
| Direct Construction Costs | \$1,708,204 |
| Equipment Not Included in Construction Contract | \$2,082,478 |
| Architectural and Engineering Fees | \$188,395 |
| Total Capital Costs | \$3,979,077 |

Source: COPN Request No. VA-8510

The proposed project, if approved, would add one fixed-site PET/CT scanner to the PD 15 inventory, however the overall impact on the PD 15 inventory would be neutral.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “Introduction into an existing medical care facility described in subsection A of any new...computed tomographic (CT) scanning...positron emission tomographic (PET) scanning...equipment for the provision of such service.” A medical care facility is defined, in part, as “Any facility licensed as a hospital, as defined in § 32.1-123.”

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;

HDH-Forest is located in Henrico County close to the region’s two main Interstate highways, I-64 and I-95, and is easily accessible to the populations both within HPR IV and outside the region to the west and north. Additionally, HDH-Forest is accessible from Richmond via public bus lines. As will be discussed in more detail later in this staff analysis report, DCOPN concludes that at least 95% of the population of PD 15 is within 60 minutes’ drive time, one way, under normal driving condition of existing PET/CT services. Furthermore, the applicant is a current provider of this service. Accordingly, DCOPN concludes that the proposed project would not improve geographic access to inpatient bed services in any meaningful way.

Regarding socioeconomic barriers to access to services, the applicant has provided assurances that it would accept all patients in need of PET/CT services without regard to ability to pay or payment source. Additionally, the Pro Forma Income Statement provided by the applicant proffered a charity care condition equal to 3.0% of gross patient services revenue (reflected in the “Deductions from Revenue”) line (**Table 4**). While this amount is lower than the 3.7% HPR IV average, it is higher than the 2.17% contribution made by HDH in 2018 (**Table 5**). Furthermore, DCOPN notes that pursuant to the recent change to §32.1-102.4B of the Code of Virginia, DCOPN is now required to place a charity care condition on all applicants seeking a COPN. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition consistent with the 3.7% HPR IV average. DCOPN notes that its recommendation includes a provision allowing for the reassessment of the charity rate when more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

Table 4. HDH-Forest Pro Forma Income Statement

| | Year 1 | Year 2 |
|-------------------------------|--------------------|--------------------|
| Gross Patient Service Revenue | \$16,071,440 | \$19,400,810 |
| Deductions from Revenue | \$12,077,296 | \$14,671,800 |
| Net Revenue | \$3,994,144 | \$4,729,010 |
| Total Expenses | \$2,076,000 | \$2,328,000 |
| Net Income | \$1,918,144 | \$2,401,010 |

Source: COPN Request No. VA-8510

Table 5. HPR IV Charity Care Contributions: 2018

| Hospital | Gross Patient Revenues | Adjusted Charity Care Contribution | Percent of Gross Patient Revenue |
|--|-------------------------|------------------------------------|----------------------------------|
| Bon Secours Richmond Community Hospital | \$674,969,731 | \$42,666,943 | 6.32% |
| VCU Health System | \$5,621,665,960 | \$352,825,510 | 6.28% |
| Southside Community Hospital | \$293,702,705 | \$14,237,351 | 4.85% |
| Bon Secours St. Francis Medical Center | \$970,223,902 | \$43,084,096 | 4.44% |
| Bon Secours Memorial Regional Medical Center | \$1,552,613,092 | \$68,611,063 | 4.42% |
| Bon Secours St. Mary's Hospital | \$2,176,359,866 | \$77,859,815 | 3.58% |
| Sentara Halifax Regional Hospital | \$294,576,590 | \$9,953,244 | 3.38% |
| Southside Regional Medical Center | \$1,956,522,794 | \$63,281,154 | 3.23% |
| VCU Community Memorial Hospital | \$260,605,004 | \$7,269,351 | 2.79% |
| CJW Medical Center | \$6,586,796,429 | \$176,068,998 | 2.67% |
| Henrico Doctors' Hospital | \$4,501,141,313 | \$97,784,217 | 2.17% |
| Southern Virginia Regional Medical Center | \$208,002,057 | \$4,386,121 | 2.11% |
| John Randolph Medical Center | \$839,825,455 | \$17,429,142 | 2.08% |
| Vibra Hospital of Richmond LLC | \$120,847,463 | \$0 | 0.00% |
| Cumberland Hospital for Children and Adolescents | \$60,602,814 | \$0 | 0.00% |
| Total Facilities | | | 15 |
| Median | | | 3.2% |
| Total \$ & Mean % | \$26,118,455,175 | \$975,457,005 | 3.7% |

Source: VHI (2018)

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, three localities in PD 15 had poverty rates higher than the 10.7% statewide average (**Table 6**). Henrico County had a poverty rate of 8.7%.

Table 6. Statewide and PD 15 Poverty Rates

| Locality | Poverty Rate |
|---------------|--------------|
| Virginia | 10.7% |
| Charles City | 12.5% |
| Chesterfield | 6.6% |
| Goochland | 6.2% |
| Hanover | 5.1% |
| Henrico | 8.7% |
| New Kent | 5.0% |
| Powhatan | 12.5% |
| Richmond City | 23.2% |

Source: U.S. Census Data (census.gov)

The most recent Weldon-Cooper data projects a total PD 15 population of 1,219,936 persons by 2030 (**Table 7**). This represents an approximate 21.7% increase in total population from 2010-2030. Comparatively, Weldon-Cooper projects the population of Virginia as a whole to increase by only 16.6% for the same period. With regard to Henrico County specifically, Weldon-Cooper projects a total population increase of approximately 18.4% from 2010-2030. With regard to the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase (**Table 8**). Specifically, Weldon-Cooper projects an increase of approximately 92.5% among PD 15's

collective 65 and older age cohort, while an increase of approximately 79.3% is expected among this cohort in Henrico County. This is important as this age group uses medical care resources, including PET/CT services, at a rate much higher than the rest of the population.

Table 7. Statewide and PD 15 Total Population Projections: 2010-2030

| Locality | 2010 | 2020 | % Change | 2030 | % Change | 2010-2030 % Change |
|--------------------|------------------|------------------|--------------|------------------|-------------|--------------------|
| Virginia | 8,001,024 | 8,655,021 | 8.2% | 9,331,666 | 7.8% | 16.6% |
| Charles City | 7,256 | 6,982 | (3.8%) | 6,941 | (0.6%) | (4.3%) |
| Chesterfield | 316,236 | 353,841 | 11.9% | 396,647 | 12.1% | 25.4% |
| Goochland | 21,717 | 23,547 | 8.4% | 26,702 | 13.4% | 23.0% |
| Hanover | 99,863 | 109,244 | 9.4% | 119,360 | 9.3% | 19.5% |
| Henrico | 306,935 | 332,103 | 8.2% | 363,259 | 9.4% | 18.4% |
| New Kent | 18,429 | 23,474 | 27.4% | 28,104 | 19.7% | 52.5% |
| Powhatan | 28,046 | 29,909 | 6.6% | 33,440 | 11.8% | 19.2% |
| Richmond City | 204,214 | 232,533 | 13.9% | 245,483 | 5.6% | 20.2% |
| TOTAL PD 15 | 1,002,696 | 1,111,633 | 10.9% | 1,219,936 | 9.7% | 21.7% |

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

Table 8. PD 15 Population Projections for 65+ Age Cohort, 2010-2030

| Locality | 2010 | 2020 | % Change | 2030 | % Change | 2010-2030 % Change |
|--------------------|----------------|----------------|--------------|----------------|--------------|--------------------|
| Charles City | 1,214 | 1,773 | 46.1% | 2,189 | 23.4% | 80.3% |
| Chesterfield | 32,878 | 55,297 | 68.2% | 72,476 | 31.1% | 120.4% |
| Goochland | 3,237 | 5,420 | 67.4% | 7,421 | 36.9% | 129.3% |
| Hanover | 13,104 | 19,807 | 51.2% | 27,456 | 38.6% | 109.5% |
| Henrico | 37,924 | 53,255 | 40.4% | 68,003 | 27.7% | 79.3% |
| New Kent | 2,226 | 4,303 | 93.3% | 6,663 | 54.8% | 199.3% |
| Powhatan | 3,407 | 6,041 | 77.3% | 8,552 | 41.5% | 151.0% |
| Richmond City | 22,619 | 26,352 | 16.5% | 31,657 | 20.1% | 40.0% |
| TOTAL PD 15 | 116,609 | 172,249 | 47.7% | 224,417 | 30.3% | 92.5% |

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

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;**

The applicant provided numerous letters of support for the proposed project. Collectively, these letters addressed the following:

- Using a mobile PET/CT unit to conduct studies inevitably leads to undesirable delays in treatment because the mobile unit is often unavailable when a patient is determined to need imaging.
- PET/CT imaging is a lengthy procedure, and the limited operational schedule of a mobile unit may not allow patients to undergo imaging when they need it.
- The patients of HDH will directly benefit from a fixed PET/CT scanner because a fixed unit's 24/7 availability will eliminate the logistical hurdles posed by a mobile unit's limited schedule.
- The proper management of each cancer patient depends on prompt and accurate diagnosis and evaluation, for which a PET/CT is the gold standard.
- A PET/CT scan sets the bar for accuracy and detail in diagnostic imaging, making it an invaluable tool for physicians treating a variety of conditions.
- Clinical research has shown that PET/CT is superior to conventional imaging and PET or CT used alone for the diagnosis and monitoring of most types of cancer.
- A PET/CT scanner is especially suited for the diagnosis and evaluation of lung cancer, and other difficult-to-diagnose cancers, because of its enhanced sensitivity and detail.
- New PET technologies, such as Rubidium-82 myocardial perfusion imaging ("MPI"), are being developed to improve patient care, and the installation of a fixed PET/CT scanner at HDH-Forest will facilitate the hospital's implementation of these technologies as they become available. MPI is the preferred diagnostic tool for certain cardiac patients, both because of the high sensitivity and diagnostic accuracy with which coronary artery disease may be detected using this method, and because Rubidium-82's short half-life means reduced patient exposure to radiation.

DCOPN received no letters in opposition to the proposed project.

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

As **Table 1** demonstrates, there is arguably ample capacity within the existing PD 15 PET inventory to provide care for HDH-Forest's patients. DCOPN notes that no existing PD 15 fixed PET scanner operated at or above the State Medical Facilities Plan ("SMFP") expansion threshold of 6,000 procedures per scanner per year in 2018, nor did any mobile scanner operate at or above the SMFP conversion threshold of 1,400 procedures per scanner per year. However, as will be discussed in more detail later in this staff analysis report, DCOPN notes that few PET services in the Commonwealth actually meet the SMFP's utilization threshold. DCOPN also again notes that the applicant projects the fixed scanner to operate above 1,400 procedures by the

second year of operation (**Table 2**). As already discussed, DCOPN finds this projection to be reasonable.

Approval of the proposed project would likely result in shorter wait times for patients by alleviating the delays to patient care that are caused by a mobile unit's limited availability. The applicant also states that the addition of a fixed scanner would allow HDH to expand PET/CT services to treat cardiac patients by creating a Rubidium-82 myocardial perfusion-imaging program ("PET MPI"), an imaging technology used to diagnose patients with coronary artery disease. The applicant states that this is the preferred test for cardiac patients because it offers higher sensitivity, specificity, and diagnostic accuracy than the imaging that is currently used, and it decreases patients' exposure to radiation. The applicant anticipates that the addition of this service will increase HDH-Forest's use of PET/CT services, further necessitating a fixed unit that will have substantially more availability than the current mobile unit. For these reasons, DCOPN maintains that the proposed project is a better alternative than maintaining 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 15. Therefore, this consideration is not applicable to the review of the proposed project.

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

As illustrated in **Table 3**, the total projected capital cost of the proposed project is \$3,979,077, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN contends that the costs for the proposed project are reasonable and consistent with previously approved projects similar in scope.⁶

The applicant cited the following benefits of the proposed project:

- The fixed PET/CT scanner will alleviate delays to patient care that are caused by a mobile unit's limited availability.
- The project will allow HDH-Forest to perform more specialized diagnostic studies, specifically, Axium studies, which are currently only scheduled on one time slot per week due to volume restrictions.
- A fixed scanner will allow HDH-Forest to expand PET/CT services to treat cardiac patients.

⁶ COPN No. VA-04625 authorized Sentara Leigh Hospital to establish a fixed-site PET/CT service and had an authorized cost of \$2,452,175; COPN No. VA-04668 authorized Chesapeake Regional Medical Center to introduce fixed PET/CT services and had an authorized cost of \$2,354,991; COPN No. VA-04715 authorized the establishment of fixed PET/CT services at Children's Hospital of the King's Daughters and had an authorized cost of \$4,024,979.

- The fixed unit will eliminate patient care issues associated with the cramped nature of a mobile unit, such as challenges in moving inpatients who must be transported using a gurney.
- The establishment of a fixed PET/CT service will permit HDH-Forest to provide important diagnostic procedures it is currently unable to provide with its current unit due to short half-lives of certain PET/CT radiotracers.
- Converting the mobile unit to a fixed service is more cost-effective. The price of investing in a fixed scanner is relatively modest when compared to HDH's annual payments to its mobile vendor, and HDH expects its operating expenses for the provision of PET/CT imaging will be significantly reduced over time as a result of the project.

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

As already discussed, the applicant has provided assurances that PET/CT services at HDH-Forest will be accessible to all patients, regardless of financial considerations. However, recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. Accordingly, should the Commissioner approve the proposed project, DCOPN recommends a charity care condition consistent with the 3.7% HPR IV average, to be derived from PET/CT gross patient services revenue.

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

Section 32.1-102:1 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, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the SMFP.

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

Part II of the SMFP contains criteria and standards for the addition of Diagnostic Imaging Services. They are as follows:

**Part II. Diagnostic Imaging Services
Article 1. Computed Tomography**

The applicant has provided assurances that the CT modality of the requested PET/CT scanner will be used only in conjunction with the PET modality. Accordingly, in the interest of brevity, DCOPN has omitted this section from its staff analysis report.

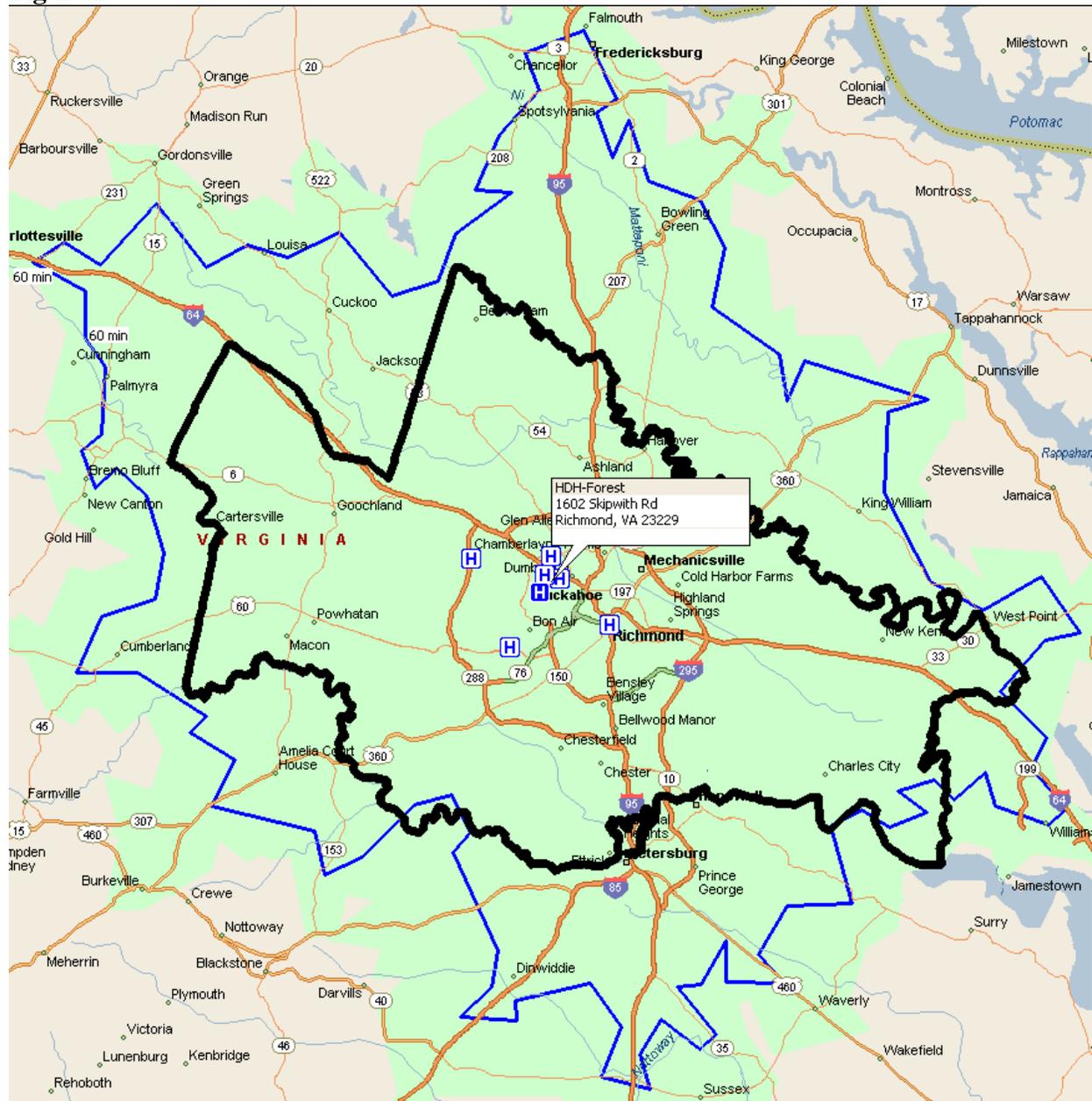
Article 4. Positron Emission Tomography

12VAC5-230-200. Travel Time.

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

The heavy black line in **Figure 1** represents the boundary of PD 15. The blue “H” sign marks the location of HDH-Forest. The white “H” signs mark the locations of all other existing fixed PET and mobile PET site services in PD 15. The green shaded area represents the area of PD 15 and surrounding areas that are within 60 minutes’ drive time of existing PD 15 PET services. The thin blue line represents the area within a 60 minutes’ drive time of the proposed project. 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 15. Furthermore, the applicant currently provides this service. Accordingly, DCOPN concludes that approval of the proposed project would not improve geographic access to PET services for residents of PD 15 in any meaningful way.

Figure 1.



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.**
- 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.**

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as 1 individual PET procedure and CT procedure respectively, unless those images are made concurrently.

As **Table 1** demonstrates, in 2018, PD 15's sole fixed-site PET scanner performed 1,739 procedures, approximately 29% of the SMFP threshold of 6,000 procedures per scanner per year. However, DCOPN notes that few PET services in the Commonwealth actually meet the SMFP's utilization thresholds, indicating that the threshold reflects a misconception about the utilization of PET technology at the time the SMFP PET criteria and standards were written.⁷ The Commissioner has historically approved PET proposals despite a lack of strict compliance with this standard, recognizing that the SMFP's current thresholds are too high and outdated. To emphasize this point, DCOPN notes that in 2018, no existing PD 15 PET scanner met this threshold. DCOPN again notes that approval of the proposed project is not likely to have a significant negative impact on existing providers of PD 15 because the applicant is already a provider of PET/CT services and the project would ultimately have a neutral impact on the PD 15 PET inventory.

The applicant stated that in 2019, its existing mobile service performed 1,035 procedures, a 79.7% increase from 2014. DCOPN again notes that while it cannot quantifiably confirm this data, it finds it to be reasonable based on the consistent increase in utilization of HDH-Forest's mobile PET/CT service recent years. Additionally, DCOPN again notes that it finds the applicants projection of 1,430 procedures for the fixed unit by the second year of operation to be reasonable. While the projected utilization of the proposed fixed PET/CT unit is lower than the SMFP's current thresholds, DCOPN again notes that the Commissioner has historically recognized that the SMFP's PET utilization thresholds do not appropriately capture patient needs.

Installation of a fixed PET/CT scanner at HDH-Forest will allow the applicant to better serve its existing patients by improving the timeliness of patient service and permitting it to perform procedures it cannot offer with a mobile unit. DCOPN contends that because the requested fixed

⁷ DCOPN Staff Analysis Report for COPN Request No. VA-8449, at page 9. This COPN request ultimately resulted in the issuance of COPN No. VA-04668, authorizing Chesapeake Regional Medical Center to introduce fixed PET/CT services in PD 20 despite the PD's sole fixed PET unit performing at only 8.1% of the SMFP threshold.

PET/CT will serve patients already receiving care at HDH-Forest, the project is not likely to have a significantly negative impact on existing providers. Furthermore, the applicant argues that the installation of a fixed PET/CT scanner would substantially reduce HDH's operating expenses associated with the provision of PET/CT imaging. The applicant also argues that the addition of a fixed PET/CT scanner would reduce costs for patients that are incurred when an inpatient must stay in the hospital one or more extra nights in order to receive a PET/CT scan. DCOPN agrees that the installation of a fixed PET/CT scanner would better equip the applicant to meet the needs of its patients in a cost effective and timely manner.

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 proposing to expand an existing fixed-site PET service, but rather, is proposing to convert its existing mobile service to a fixed-site service.

12VAC5-230-230. 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.**
- 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.**

To reiterate, DCOPN has historically characterized this standard as a "misconception" that should not be used to deny an otherwise meritorious application. DCOPN again notes that in 2019, the existing mobile PET/CT unit at HDH-Forest performed 1,035 PET/CT scans, 74% of the required conversion threshold. DCOPN also notes that the applicant's projections, which DCOPN finds to be reasonable, project the requested fixed PET/CT scanner to perform 1,430 procedures by the second year of operation. Furthermore, for reasons already discussed in more detail elsewhere in this staff analysis report, DCOPN maintains that approval of the proposed project is a better alternative than maintaining the status quo. Accordingly, DCOPN contends that the proposed project warrants approval despite not satisfying this standard.

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 provided assurances that PET services will continue to be performed under the direction of the qualified physicians at Radiology Associates of Richmond, one of the oldest radiology practices in the country.

Eight 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;

DCOPN does not find that the proposed project is intended to foster institutional competition, but rather is intended to ensure HDH-Forest's patients access to PET/CT services in an efficient, cost-effective, and timely manner. Furthermore, because the applicant is a current provider of PET/CT services and the project would have a neutral impact on the PD 15 PET inventory, DCOPN does not anticipate a significant impact on existing providers of the service. DCOPN again notes that it is unaware of any opposition to the proposed project.

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;

Table 1 demonstrates that there is arguably ample capacity within the existing PD 15 PET inventory to provide care for HH-Forest's patients. However, for reasons previously discussed in more detail throughout this staff analysis report, DCOPN nonetheless contends that maintaining the status quo is less favorable than the proposed project. To reiterate, approval of the proposed project would likely result in shorter wait times for patient by alleviating the delays to patient care that are caused by a mobile unit's limited availability. Furthermore, the fixed PET/CT scanner would allow the applicant to expand PET/CT services to treat cardiac patients by creating a Rubidium-82 myocardial perfusion-imaging program, a program that is likely to increase HDH-Forest's use of PET/CT services. Finally, the applicant argues, and DCOPN agrees, that investing in a fixed PET/CT scanner is more cost-efficient for the applicant than maintaining a yearly mobile contract. DCOPN again notes that because the fixed PET/CT will serve patients already being treated at HDH-Forest, approval of the proposed project is not likely to have a significant negative impact on existing PD 15 providers of PET services.

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 reasonable when compared to previously authorized projects similar in clinical scope. The project

will be funded entirely using the accumulated reserves of the applicant and accordingly, there are no financing costs associated with this project. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a net profit of \$1,918,144 in the first year of operation and \$2,401,010 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. (Table 4).

With regard to staffing, the applicant anticipates the need to hire four additional full-time radiologic technologists in order to staff the proposed project. DCOPN notes that this is *in addition to* the 148 positions currently vacant at HDH-Forest, the majority of which are registered nurse positions. However, the applicant is a current provider of PET/CT services with a robust employee recruitment and retention program. Accordingly, DCOPN does not anticipate that the applicant will have difficulty staffing the proposed project or that doing so will have a significant negative impact on other PD 15 facilities.

The applicant provided the following, in part, with regard to this standard:

“To address short-term fluctuations in staffing or to provide interim staffing solutions for its facilities, HCA hospitals develop per diem staff and certified “float” pools, which are hospital-based reserve staff for peaks in volume. This provides hospitals with a group of highly trained health workers that can be accessed in periods of high demand. Beyond allowing hospitals to accommodate fluctuating patient volumes with appropriate staffing levels, this approach also serves to reduce costs.”

- 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;**

The proposed project does not provide improvements or innovations in the financing and delivery of health services as demonstrated by the introduction of new technology that promotes quality or cost effectiveness, nor does it provide improvements in the potential for provisions of health care services on an outpatient basis. Regarding cooperative efforts to meet regional health care needs, the applicant provided the following:

“The HCA facilities in Richmond have clearly demonstrated, both formally and informally, the ability to share staff and equipment in an effort to bring economies to the market place. Areas such as the business office, materials management, and central scheduling have been formally consolidated and provide a very high level of service to all of the HCA hospitals in Central Virginia. The HCA business office also provides services to HCA facilities outside of Central Virginia. IN addition, informal sharing of staff, equipment, and supplies occurs on a routine basis as our hospitals respond to fluctuating demand and patient needs.”

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 services for citizens of the Commonwealth, including indigent or underserved populations.**

The applicant is not a teaching hospital associated with a public institution of higher education or a medical school in the area to be served. However, the applicant does sponsor and endorse statewide education and outreach programs intended to attract current student enrollees in state nursing schools by offering on-site preceptor clinical training to support student nursing education. The applicant states that the goal of the preceptor program is to make a positive impact on the labor pool, build relationships with educators while assisting with curriculum development, support nurse training programs, expose students to the world of healthcare, and support the communities that HCA serves. HCA also provides additional support through clinical rotation sites and provides adjunct faculty in their health service programs.

DCOPN Staff Findings and Conclusions

HDH-Forest is requesting authorization to convert its existing mobile PET/CT scanner to a fixed-site service. The total projected capital cost of the proposed project is \$3,979,077, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN concludes that this cost is reasonable and consistent with previously approved projects similar in clinical scope. Furthermore, DCOPN concludes that the proposed project appears to be economically feasible both in the immediate and in the long-term. Finally, DCOPN concludes that approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PD 15 providers of PET services.

DCOPN finds that the project is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. While it is arguable that excess PET capacity exists within PD 15, DCOPN contends that maintaining the status quo is less favorable than the proposed project. Approval of the proposed project would likely result in shorter wait times for patients and allow HDH to expand PET/CT services to treat cardiac patients, thereby increasing HDH-Forest's use of PET/CT services. Additionally, DCOPN contends that it would be more economically efficient for HDH-Forest to invest in a fixed PET/CT scanner than to maintain its yearly contract with a mobile vender.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends the **conditional approval** of HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital's request to convert its existing mobile PET/CT service to a fixed-site service at Henrico Doctors' Hospital-Forest for the following reasons:

1. The proposed project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The capital costs are reasonable.
3. The proposed project appears economically viable in the immediate and in the long-term.
4. There is no known opposition to the proposed project.
5. The project is more favorable than maintaining the status quo.

DCOPN's recommendation is contingent on HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital's agreement to the following charity care condition:

HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital will provide PET/CT services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 15 in an aggregate amount equal to at least 3.7% of Henrico Doctors' Hospital-Forest's gross patient revenue derived from PET/CT services. 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. HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital 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 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.

HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital will provide 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 HCA Health Services of Virginia, Inc. d/b/a Henrico Doctors' Hospital will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.