



COMMONWEALTH of VIRGINIA

Department of Health

Office of Licensure and Certification

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State Health Commissioner

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July 20, 2020

Ms. Jamie Martin
Williams Mullen
200 South 10th Street, Suite 1600
Richmond, Virginia 23219

RE: **COPN Request No. VA-8508**
Children's Hospital of the King's Daughters, Norfolk, Virginia
Establish Fixed PET/CT Services

Dear Ms. Martin:

For your consideration, I enclose the Division of Certificate of Public Need (DCOPN) report and recommendations on the above referenced project. DCOPN is recommending **conditional approval** of this application for the reasons listed in the attached staff report.

If Children's Hospital of the King's Daughters is willing to accept the recommendation for conditional approval of this project, please provide documentation of this acceptance *no later than July 24, 2020*. If not willing to accept, before the State Health Commissioner makes his decision on this project, the Department will convene an informal-fact-finding-conference (IFFC) pursuant to Title 2.2 of the Code of Virginia. This IFFC has been scheduled for Wednesday, August 5, 2020 beginning at 10:00 a.m. in Board Room 3 of the Perimeter Center located at 9960 Mayland Drive in Henrico, Virginia. A copy of the procedures for conduct at IFFCs may be found at <http://www.vdh.virginia.gov/OCL/copn/>

Persons wishing to participate in an IFFC have four days from the date of this letter to submit written notification to the State Health Commissioner, DCOPN and the applicant stating a factual basis for good cause standing. If no person has submitted written notification stating grounds and providing a factual basis for good cause standing and Children's Hospital of the King's Daughters accepts the conditional approval, DCOPN will then notify you of the cancellation of the scheduled IFFC. DCOPN would then anticipate action by the State Health Commissioner within a few weeks of transmission.

DIRECTOR
(804) 367-2102

ACUTE CARE
(804) 367-2104

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(804) 367-2126



www.vdh.virginia.gov

COMPLAINTS
1-800-955-1819

LONG TERM CARE
(804) 367-2100

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Should you have questions or need further clarification of this report and/or its recommendations, please feel free to call me at (804) 367-1889 or email me at Erik.Bodin@VDH.Virginia.Gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Erik Bodin', written over a horizontal line.

Erik Bodin, Director
Division of Certificate of Public Need

Enclosures

cc: Douglas R. Harris, J.D., Office of Adjudication, Virginia Department of Health

VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 20, 2020

COPN Request No. VA-8508

Children's Hospital of the King's Daughters

Norfolk, Virginia

Establish Fixed PET/CT Services

Applicant

Children's Hospital of the King's Daughters, Inc., doing business as Children's Hospital of the King's Daughters (CHKD), is a non-profit corporation, incorporated in the Commonwealth of Virginia. CHKD is a wholly owned subsidiary of Children's Health System, Inc. Subsidiaries of the applicant include Children's Medical Tower, LLC and Children's Health System Insurance, LLC. CHKD is located in the City of Norfolk, Virginia in Health Planning Region (HPR) V, Planning District (PD) 20.

Background

CHKD is Virginia's only freestanding, full-service children's hospital. CHKD currently operates 206 beds and special units for neonatal and pediatric intensive care, cancer care, acute inpatient rehabilitation, medical and surgical care, and transitional care. CHKD also supports and participates in pediatric research and clinical trials that benefit children's health.

According to 2018 Virginia Health Information (VHI) data, the most recent year for which such data is available, there was one fixed-site PET unit in operation in PD 20. Additionally, there were four operational PET mobile sites in operation in 2018

Table 1. PD 20 COPN Authorized PET Mobile Sites and Fixed PET Units: 2018

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

*Fixed PET/CT unit to be surrendered pursuant to COPN No. VA-04668.

**COPN No. VA-04625, issued on October 9, 2018, 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.

***COPN No. VA-04648, issued on February 19, 2019, authorized the establishment of a mobile PET/CT site at Chesapeake Regional Medical Center, to be operational in November 2019. DCOPN notes that this certificate will be surrendered pursuant to COPN No. VA-04668.

****COPN No. VA-04668, issued on September 3, 2019, authorized the introduction of fixed PET/CT services at Chesapeake Regional Medical Center, together with (i) the cessation of PET services at the PET Institute of Hampton Roads and the surrender of PET Institute's COPN No. VA-03490; and (ii) the cessation of mobile PET/CT services at CRMC and the surrender of COPN No. VA-04648. The project is anticipated to be operational by February 2021.

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 reported by VHI, an additional two fixed PET/CT units 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, and 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, and is expected to be operational by February 2021. Similarly, one additional mobile PET/CT site was added pursuant to COPN No. VA-04648, which 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 1**, as this data is not yet available from VHI.

Proposed Project

CHKD proposes to establish fixed PET/CT services at its facility located at 601 Children's Lane in Norfolk, Virginia. To accommodate the scanner, the applicant intends to relocate administrative offices from its existing radiology suite located on the first floor of the hospital. This will involve the remodeling of the existing radiology suite to upgrade the electrical and mechanical infrastructure to accommodate the PET/CT scanner. The radiology suite is directly below CHKD's oncology suite

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.

and adjacent to the sedation suite, making access between these suites convenient for the clinical teams to collaborate on patient care. Housing all radiology services together will also allow for efficient staffing, given that many modalities are used and served by the same clinicians.

The applicant states that the addition of a fixed PET/CT scanner is essential to CHKD's ability to provide the accepted standard of care for diagnosis and treatment to its pediatric cancer patients and is critical to its ability to be designated as a Level 4 Epilepsy Center. The applicant further states that the equipment is necessary to CHKD's ability to participate in vital clinical trials for which PET/CT is required. Without on-site PET/CT services, the applicant contends that its patients, at least those who are not too ill to travel, will continue to require medical transport from the hospital's main campus and away from their clinical care team to receive PET/CT scans. CHKD considered the use of a mobile PET/CT unit, but decided that option was not in patients' best interest and could not be accommodated due to space constraints on the hospital's campus.

The applicant anticipates construction for the proposed project to commence in December 2021 and to be complete in April 2022. The applicant anticipates a June 2022 date of opening. The total projected capital costs of the proposed project total \$4,024,978, 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 2. CHKD Projected Capital Costs

Direct Construction Costs	\$781,890
Equipment Not Included in Construction Contract	\$3,113,088
Architectural and Engineering Fees	\$100,000
Other Consultant Fees	\$30,000
TOTAL Capital Costs	\$4,024,979

Source: COPN Request No. VA-8508

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... positron emission tomographic (PET) scanning... treatment when such medical care facility has not provided such service in the previous 12 months." 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;**

CHKD is located in downtown Norfolk on the Eastern Virginia Medical Campus adjacent to Sentara Norfolk General Hospital and Eastern Virginia Medical School. CHKD is easily accessible from major Norfolk thoroughfares, including Interstates 264, 664, and 64. Public transportation is available in the area, including the public bus system and Norfolk's light rail train, the Tide. As will be discussed in more detail later in this staff analysis report, DCOPN concludes that at least 95% of the population of PD 20 is within 60 minutes' drive time, one way, under normal driving conditions of existing PET/CT services. However, DCOPN notes while PET is a PD-level review under the SMFP, no existing providers offer specialized pediatric services in all of HPR V. Accordingly, DCOPN contends that approval of the proposed project would improve geographic access to PET/CT services for pediatric patients residing in PD 20 and all of HPR V.

Regarding socioeconomic barriers to access to services, the applicant has provided assurances that PET/CT services will be available to all patients, regardless of ability to pay or payment source. While the applicant did not proffer a charity care contribution as part of this proposal, DCOPN notes that CHKD provided \$6,094,726 in charity care in 2018 (Table 3). Because the overwhelming majority of patients at CHKD qualify for Medicaid coverage, this amount approximates only 0.60% of CHKD's total gross patient revenues for 2018 and is significantly lower than the HPR V average of 5.1% for the same period. 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 of 0.60% of gross patient services revenue derived from PET/CT services at CHKD, an amount consistent with CHKD's most recent contribution. 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 3. 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	Percent 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)

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, only three localities in PD 20 had poverty rates beneath the statewide average of 10.7%.

Table 4. Statewide and PD 20 Poverty Rates

Locality	Poverty Rate
Virginia	10.7%
Isle of Wight	9.2%
Southampton	14.7%
Chesapeake City	9.0%
Franklin City	16.2%
Norfolk City	19.7%
Portsmouth City	17.2%
Suffolk City	10.8%
Virginia Beach City	7.6%

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

The most recent Weldon-Cooper data projects a total PD 20 population of 1,255,394 persons by 2030 (Table 5). This represents an approximate 9.6% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the total population of Virginia as a whole to increase by approximately 16.63% for the same period. With regard to the birth to age 19 cohort, Weldon-Cooper projects a much more gradual increase. For that age group, Weldon Cooper projects a population of 308,857 by the year 2030, representing only a 0.6% increase from 2010.

Table 5. Statewide and PD 20 Population Projections, 2010-2030

	2010	2020	% Change	2030	% Change	2010-2030 % Change
Total Population	1,145,548	1,207,652	5.4%	1,255,394	4.0%	9.6%
Age 0-20	307,017	303,076	(1.3%)	308,857	1.9%	0.6%

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

*Weldon Cooper Center breaks population data down by age using five-year increments. Accordingly, Table 5 does not include data for adolescents who are 21 years of age, the oldest age at which one can receive treatment at CHKD.

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 from local and state elected officials and medical professionals. Collectively, these letters addressed the following:

- The application and equipment is critically important to support CHKD’s commitment to provide high quality care to our community’s most vulnerable citizens, our sick children, and will help treat and save the lives of our community’s children suffering from cancer.
- The addition of PET/CT services at CHKD will not only improve patient care by increasing convenience and safety for their young and often very sick patients, but it will also allow for improved educational experiences and increased research participation throughout the hospital, which are each essential to CHKD’s ability to continue to lead the Commonwealth in pediatric care.
- As PET/CT technology has become a more prevalent diagnostic imaging tool, its application has broadened to include imaging tests on newborns to detect conditions such as hypoxic ischemic encephalopathy, neonatal seizures, and neuroinflammation. Early detection of these, and other cellular abnormalities in newborns, can provide substantial benefits in determining supportive treatments and therapies.
- To obtain accurate images, pediatric patients often require sedation prior to a PET/CT scan. CHKD is the only hospital in Eastern Virginia with a dedicated pediatric anesthesiology team, trained to provide specialized care to young patients needing sedation for imaging procedures. However, CHKD’s lack of PET/CT technology means its pediatric patients must travel to a PET/CT scanner offsite and away from their dedicated team of pediatric specialists and anesthesiologists. Not only does transporting

patients offsite require significant coordination and hospital resources, it also increases risk among some of the sickest and most fragile cancer patients.

- The PET/CT unit proposed will fill a significant void in CHKD's otherwise comprehensive provision of cancer care.
- As a teaching hospital, the lack of PET/CT services onsite negatively impacts clinical students' educational experience.
- CHKD's lack of a PET/CT significantly limits CHKD's ability to perform research and participate in clinical trials.
- The establishment of on-site PET/CT imaging services would significantly improve CHKD's ability to more comprehensively serve unique neurosciences populations.
- The addition of PET/CT equipment in the hospital is a critical component to CHKD's designation as a Level 4 Epilepsy Center. With its current designation as a Level 3 Epilepsy Center, CHKD is limited in its ability to provide the full spectrum of neurological care to its epilepsy patients. CHKD currently serves approximately 7,000 epilepsy patients.
- For the first time ever, CHKD had to forego participation in a lymphoma clinical trial that includes children due to the PET requirement and our inability to ensure we are capable of meeting study timelines, training PET staff, credentialing of equipment as well as the ability to provide sedation to patients that need the test. Our dependence on an outside facility to provide this service has affected and will continue to affect treatment opportunities for patients.

DCOPN received no letters in opposition to the proposed project.

DCOPN conducted the required public hearing for this project on June 22, 2020. Nineteen people called in, one of which spoke in support of the proposed project. No individual indicated 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 20 PET inventory to provide care for CHKD's patients, as no existing PET scanner operated at or above the SMFP threshold for expansion of 6,000 procedures per scanner per year. However, DCOPN nonetheless contends that maintaining the status quo is less favorable than the proposed project. As discussed, no existing PD 20 or HPR V provider of PET services specializes in pediatric care. Similarly, none offers the pediatric anesthesia services needed by most young patients due to their inability to remain still for the amount of time required for a PET study. For these reasons, pediatric patients must be sedated at CHKD and then transported for needed imaging—a process which can take hours, gives rise to numerous logistical burdens for patients and their caregivers, and results in added risk to the patient. On its campus, CHKD has an anesthesia team experienced in handling the unique challenges associated with sedating pediatric patients, as well as child life specialists to help prepare and support the child during the procedure by explaining the PET/CT scan in developmentally appropriate ways. Together, this helps children better cope with the stress of the experience. DCOPN contends that CHKD's specialized and pediatric-focused

services make it the safest and most clinically appropriate location for its patients to receive PET/CT services.

- (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;**

The total projected capital cost of the proposed project is \$4,024,979, the entirety of which will be funded using the accumulated reserves of the applicant (**Table 2**). Accordingly, there are no financing costs associated with this project. DCOPN concludes that the costs for the proposed project are reasonable and consistent with previously approved projects similar in scope.³

The applicant cited the following benefits of the proposed project:

- Improved availability and accessibility of dedicated pediatric PET/CT procedures for CHKD's young and vulnerable pediatric population;
- Eliminated need for patient transports and the risks associated with transfers of very ill and/or sedated patients to another facility that lacks pediatric specialization;
- Increased efficiencies in care coordination and integration between healthcare providers of various specialties;
- Enhanced continuity of care for CHKD's patients;
- Ability to qualify for NAEC Level 4 Epilepsy Center designation;
- Increased participation in clinical trials and pediatric research; and
- Expanded educational opportunities for future pediatric clinicians in Eastern Virginia.

- (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 CHKD 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 of 0.6%, consistent with CHKD's 2018 contribution, to be derived from PET/CT gross patient services revenue.

With regard to this standard, the applicant provided the following:

³ 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.

“As a children’s hospital, CHKD serves many patients who are covered by Medicaid. In fact, CHKD is a “disproportionate share hospital” or (“DSH”), serving one of the highest proportions of Medicaid patients in the entire Commonwealth. Within this context the Division of Certificate of Public Need and the Commissioner have historically recognized CHKD’s commitment to serve those in need and have consistently concluded that CHKD meet’s DCOPN’s and the Commissioner’s charity care expectations. Accordingly, DCOPN and the Commissioner have routinely decided that imposing charity care conditions on CHKD’s COPNs is not appropriate or necessary.”

- (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;

The State Medical Facilities Plan (SMFP) contains the criteria and standards for the establishment of PET/CT services. They are as follows:

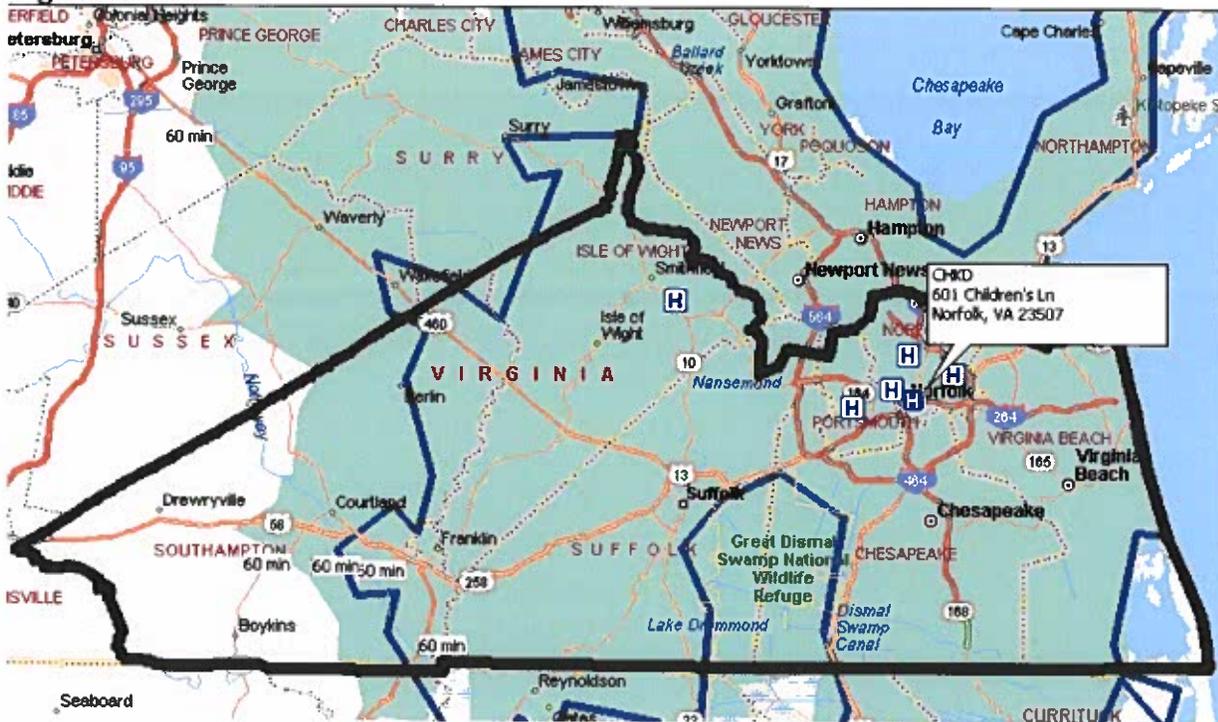
Part II. Diagnostic Imaging Services Article 4. Positron Emission Tomography

12VAC5-230-200. Travel Time.

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the 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 CHKD. The white “H” signs mark the locations of all other existing fixed PET and mobile PET 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 PD 20 PET services. The thin blue line represents the area with 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 20. However, DCOPN notes that PET scanners in PD 20 are not well distributed, with all but one machine being located in the northeastern portion of the planning district. Additionally, DCOPN notes that most of these sites are mobile sites and do not provide the same level of availability that would be provided by a fixed PET service. More importantly, DCOPN notes that although PET services may generally be available in PD 20 within 60 minutes’ driving time, no authorized PET providers offer specialized pediatric services. The applicant states that use of existing providers requires pediatric patients to be sedated at CHKD and then transported for needed imaging—a process which can take hours, gives rise to numerous logistical burdens for patients and their caregivers, undermines the continuity, coordination, and integration of care, and can jeopardize quality and safety of the procedure.

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.**

The applicant states that it currently serves 322 solid tumor cancer patients, with each patient receiving 3.5 PET/CT studies over a three-year course of treatment, on average. Additionally, CHKD's epilepsy population, which relies on PET/CT services to determine whether the patient is a candidate for surgery, would benefit from the service. Approximately 40 epilepsy patients meet the criteria for surgical evaluation per year at CHKD, and each of the 40 epilepsy patients is projected to receive one pre-surgical PET/CT. Together, solid tumor cancer patients and epilepsy patients account for approximately 416 scans per year. In both instances, CHKD anticipates that with the availability of PET services, CHKD will be able to retain approximately 50% of its outmigration patient volume and to participate in additional clinical trials for its patients, likely increasing PET/CT utilization further.

The applicant anticipates that the proposed PET/CT services will serve 355 patients and perform 409 studies in the first full year of operation, with 381 patients served and 438 studies performed by year two. While the projected utilization of the proposed PET/CT unit is lower than the SMFP's current thresholds, the applicant asserts, and DCOPN agrees, that the project meets a compelling and identified public and institutional need and is critically necessary to improve access to needed services for a unique and vulnerable patient population. Moreover, the Commissioner has

historically recognized that the SMFP's PET utilization thresholds are too high, outdated, and do not appropriately capture pediatric needs. The DCOPN staff report for COPN Request No. VA-7191, which ultimately resulted in COPN No. VA-04151, states:

“[T]here are few PET services in the state that have actually met [the SMFP's] goal[s]” which reflect “a misconception about the utilization of this modality at the time the SMFP was written.”

Similarly, the Health Systems Agency of Northern Virginia staff report for COPN Request No. VA-8327, which ultimately resulted in COPN No. VA-04629, states:

“..it is arguable that the public need determination provisions of the [SMFP] are dated and do not offer meaningful advice and guidance...[and accordingly, they have] been ignored routinely.

Additionally, the Commissioner and DCOPN have recognized that pediatric patients have special medical needs and that pediatric providers face “unique challenges involved in treating a pediatric population.”⁴ CHKD is the only freestanding children's hospital in Eastern Virginia and the only facility that offers specialized anesthesiology services. At the same time, however, CHKD is the only health care system in the area that lacks PET/CT imaging. DCOPN contends that by integrating diagnostic imaging services with specialized pediatric anesthesia and radiology services, the project would significantly improve young patients' access to care.

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 20's sole fixed-site PET scanner performed 620 procedures, well beneath the SMFP's 6,000 procedure threshold. However, as already discussed, The Commissioner has historically approved PET proposals despite a lack of strict compliance with the standard, recognizing that the SMFP's current thresholds are too high and outdated. To emphasize this point, DCOPN notes that in 2018, no existing PET scanner met this threshold.

⁴ DCOPN Staff Report re COPN Request No. VA-8230, at 8.

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 establish a fixed-site PET/CT 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.**

Not applicable. The applicant is not proposing to expand mobile PET or PET/CT services.

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 the proposed PET/CT service will be under the direction of qualified Board-certified physicians, credentialed by the American Board of Radiology and specifically certified in pediatric radiology.

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;**

Recognizing CHKD's pediatric specialization, DCOPN does not find that this proposal is intended to foster institutional competition, but rather is intended to ensure CHKD's patients access to needed PET/CT services in the safest manner possible. DCOPN notes that CHKD's patients currently receive PET/CT scans primarily at the PET Institute of Hampton Roads. Accordingly, while the approval of the proposed project is likely to have some impact on the utilization of this facility, DCOPN does not expect this impact to be destabilizing. Furthermore, DCOPN again notes that the COPN authorizing the fixed-site PET scanner at this facility will soon be surrendered pursuant to COPN No. VA-04668. Finally, DCOPN notes that PET Institute

of Hampton Roads did not submit a letter in opposition to this project. DCOPN contends that approval of the proposed project would result in the only specialized pediatric PET/CT service in the planning district and would significantly improve access to timely specialized PET/CT services for pediatric patients of PD 20. Moreover, DCOPN notes that approval of the proposed project will allow CHKD to compete more effectively with children’s hospitals in nearby states while also facilitating CHKD’s participation in clinical trials and research.

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 20 PET inventory to provide care for CHKD’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, no existing PD 20 provider of PET/CT services specializes in pediatric care. Similarly, none offers the pediatric anesthesia services needed by most young patients to undergo an imaging study. DCOPN contends that approval of the proposed project would allow CHKD to better care for its patients by eliminating risks associated with transporting patients 20 minutes away, under anesthesia, for a PET/CT scan. Furthermore, DCOPN again notes that while approval of the project is likely to have some impact on the utilization of existing PET/CT services, that impact is not likely to be significant, due to the service being specifically used for specialized pediatric care.

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 scope. Furthermore, the Pro Forma Income Statement provided by the applicant projects a net loss of \$85,658 in the first year of operation, with a projected profit of \$1,469 in year two (**Table 6**). The applicant will fund the project entirely with accumulated reserves. Accordingly, there are no financing costs associated with this project.

Table 6. CHKD Pro Forma Income Statement

	Year 1	Year 2
Net Patient Revenue	\$965,085	\$1,063,395
Operating Expenses	\$1,050,743	\$1,061,925
Net Income	(\$85,658)	\$1,469

Source: COPN Request No. VA-8508

With regard to staffing, the applicant anticipates the need to hire one additional full-time equivalent (FTE) employee to serve as a nuclear imaging technologist. The applicant states that it will advertise for the position in professional journals and newspapers of regional circulation throughout Eastern Virginia. Due to the small number of employees needed to staff this project, DCOPN does not anticipate that the applicant will have any difficulty staffing the proposed project or that doing so will have a negative impact on other PD 20 facilities.

- 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;**

While the PET/CT unit proposed by CHKD does not constitute “new technology,” it would allow CHKD to offer a currently unavailable, yet critical diagnostic imaging modality, and would represent the first and only specialized pediatric PET/CT unit in the Commonwealth. DCOPN contends that the project would significantly improve access to PET/CT services for CHKD’s vulnerable patient population. Moreover, DCOPN again notes that the proposed PET/CT unit is necessary to further CHKD’s participation in research and clinical trials.

With regard to the potential for provision of health care services on an outpatient basis, DCOPN notes that although adult PET/CT services are commonly provided as outpatient services, pediatric PET/CT services are unique. Patients who can remain still for the duration of the scan and do not require anesthesia may undergo a PET/CT scan on an outpatient basis; however, the vast majority of CHKD’s patients which require a PET/CT scan must be admitted to the hospital to be sedated prior to the imaging procedure. With fixed PET/CT services on-site, CHKD would be able to offer needed PET/CT studies to all of its patients—those who can undergo a study on an outpatient basis and those who need anesthesia and must be admitted.

CHKD has various agreements with other health care providers including University of Virginia and Sentara. Further, CHKD has agreements with Eastern Virginia Medical School and Children’s Specialty Group, LLC.

- 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.**

CHKD is a teaching hospital and has a cooperative relationship with Eastern Virginia Medical School for training pediatric providers. The applicant provided the following with regard to this standard:

“CHKD has long been an innovator and pioneer in pediatric research. However, the lack of in-house PET/CT services significantly circumscribes CHKD’s ability to qualify for a number of research projects and clinical trials, especially those related to oncology. With increasing use of PET/CT, clinical trial and research programs increasingly require PET/CT capabilities. This includes many oncological and hematological clinical trials. Access to PET/CT technology at the hospital would eliminate this barrier to participation

and bring many groundbreaking research opportunities and potential treatments and procedures to the pediatric patients of Eastern Virginia.

“CHKD is also a teaching hospital and plays a vital role in educating the next generation of leaders in children’s health. However, without PET/CT, CHKD is limited in its ability to train clinical students in such technology. This impairs students’ and residents clinical experiences and undermines CHKD’s ability to recruit top clinical candidates who understand the necessity of PET/CT in diagnosing and treating certain pediatric illnesses. The availability of PET/CT services on site would significantly enhance CHKD’s ability to fulfill its teaching responsibilities.”

DCOPN Staff Findings and Conclusions

The proposed project enjoys broad support from elected officials and medical professionals. Additionally, there is no known opposition to the project. DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Furthermore, DCOPN finds that although the project is anticipated to operate at a loss in the first year of operation, it appears to be economically feasible 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 20 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 20, DCOPN contends that maintaining the status quo is less favorable than the proposed project. Approval of the requested PET/CT scanner would allow CHKD to provide care to its patients in the safest way possible while simultaneously allowing the applicant to take part in vital research and clinical trials.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends the **conditional approval** of Children’s Hospital of the King’s Daughters’ request to establish fixed PET/CT services 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 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 Children’s Hospital of the King’s Daughters’ agreement to the following charity care condition:

Children's Hospital of the King's Daughters 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 20 in an aggregate amount equal to at least 0.6% of Children's Hospital of the King's Daughters' 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. Children's Hospital of the King's Daughters 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.

Children's Hospital of the King's Daughters 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 Children's Hospital of the King's Daughters will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.