



# COMMONWEALTH of VIRGINIA

Department of Health

Office of Licensure and Certification

M. Norman Oliver, MD, MA  
State Health Commissioner

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9960 Mayland Drive, Suite 401  
Henrico, Virginia 23233-1485  
FAX: (804) 527-4502

January 21, 2020

Mr. Kent Stevens  
President  
Berkeley Medical Group, Inc.  
107 Elderberry Drive  
Winchester, Virginia 22603

RE: **COPN Request No. VA-8468**  
**Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.**  
**Woodbridge, Virginia**  
**Establish a specialized center for CT and MRI imaging services by relocating and replacing existing CT and MRI equipment currently located in Woodbridge, Virginia. Add one MRI. Establish non-cardiac nuclear medicine services and establish PET/CT services with one PET/CT scanner.**

Dear Mr. Stevens:

For your consideration, I enclose the Division of Certificate of Public Need (DCOPN) report and recommendations on the above referenced project. The Health Systems Agency of Northern Virginia (HSANV) recommended approval of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.'s request to establish a specialized center for CT and MRI imaging services by relocating existing CT and MRI equipment, add one MRI, establish non-cardiac nuclear medicine services and establish PET/CT services with one PET/CT scanner. DCOPN is recommending **conditional approval** of this application for the reasons listed in the attached staff report.

If Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. is willing to accept the recommendation for conditional approval of this project, please provide documentation of this acceptance no later than **January 27, 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 Thursday, January 30, 2020 beginning at 10:00 a.m. in Training Room 2 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.vd.virginia.gov/OLC/copn/>.



DIRECTOR  
(804) 367-2102

ACUTE CARE  
(804) 367-2104

COPN  
(804) 367-2126

COMPLAINTS  
1-800-955-1819

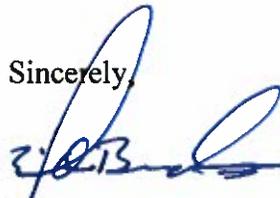
LONG TERM CARE  
(804) 367-2100

Mr. Kent Stevens  
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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 Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. 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.

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](mailto:Erik.Bodin@VDH.Virginia.Gov).

Sincerely,

A handwritten signature in blue ink, appearing to read 'Erik Bodin', is written over a vertical line that extends from the signature down to the typed name below.

Erik Bodin, Director  
Division of Certificate of Public Need

Enclosures

cc: Douglas R. Harris, J.D., Office of Adjudication, Virginia Department of Health  
Dean Montgomery, Executive Director, Health Systems Agency of Northern Virginia

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

January 21, 2020

#### **COPN Request No. VA-8468**

Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.  
Woodbridge, Virginia

Establish a specialized center for CT and MRI imaging services by relocating and replacing existing CT and MRI equipment currently located in Woodbridge, Virginia. Add one MRI. Establish non-cardiac nuclear medicine services and establish PET/CT services with one PET/CT scanner.

#### **Applicant**

Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. (Kaiser) is a Maryland non-stock, non-profit corporation founded in 2009. Kaiser has no subsidiaries. Kaiser is wholly-owned by Kaiser Foundation Health Plan, Inc., a California non-stock, non-profit corporation. Kaiser is located in Planning District (PD) 8 and Health Planning Region (HPR) II.

#### **Background**

The proposed project is part of an on-going, multi-faceted facility and service realignment and development plan, initiated by Kaiser in 2011, to better serve Kaiser's growing Northern Virginia membership base and expanding service area. The recent chronological development of diagnostic imaging services at Kaiser's northern Virginia diagnostic imaging facilities is as follows:

- In 2011, Kaiser established CT and MRI services at its Reston Medical Center (COPN No. VA-04264).
- In 2012, Kaiser opened a full-service outpatient medical center in Tysons Corner. One component of the Tysons Corner medical center project involved the centralization of diagnostic imaging services into a comprehensive outpatient imaging center. Today, those services include general radiology, fluoroscopy, nuclear medicine, mammography, ultrasound, CT, and MRI (COPN No. VA-04287).
- In 2012 and 2013, Kaiser introduced CT and MRI services at its Woodbridge Medical Center (COPN Nos. VA-04352 and 04372).
- In 2016, Kaiser added a CT and 3.0T MRI at its Tysons Corner Imaging Center (COPN No. VA-04507).

#### **Computed Tomography (CT) Scanners and Utilization in PD 8**

According to 2017 Virginia Health Information (VHI) data, the most recent year for which such data is available, there were 54 Certificate of Public Need (COPN) authorized Computed Tomography (CT) scanners in PD 8 in 2017 (**Table 1**), all of which were fixed units. For that year, the 54 CT

scanners reported by VHI operated at a cumulative utilization of 106.5% based on the State Medical Facilities Plan (SMFP) expansion threshold of 7,400 procedures per CT scanner per year. DCOPN observes that utilization of hospital-based CT scanners varies significantly from that of CT scanners at freestanding facilities. Specifically, the 30 hospital-based CT scanners in PD 8 operated at a collective utilization of 145.1% for 2017 while the 24 CT scanners located at freestanding facilities operated at a collective utilization of only 58.1%, well below the SMFP threshold for expansion. However, DCOPN notes that Anthem's 2018 policy change, which results in reimbursement for only those procedures performed in outpatient settings when available, will likely result in an increase in utilization of freestanding diagnostic imaging facilities.

DCOPN additionally notes that currently, the applicant operates four total CT scanners at its Tysons Corner, Reston, and Woodbridge locations; however, the 2017 VHI data failed to include these facilities. Accordingly, DCOPN cannot quantifiably confirm data provided by the applicant (**Table 2**) and has not included it in the calculations for total PD 8 utilization.

**Table 1. COPN Authorized CT Scanners in PD 8**

<b>Hospital Based Facility</b>	<b>Units</b>	<b>Scans</b>	<b>Scan/Unit</b>	<b>Utilization</b>
Inova Alexandria Hospital	3	34,678	11,559	156.2%
Inova Fair Oaks Hospital	4	29,752	7,438	100.5%
Inova Fairfax Hospital*	5	80,375	16,075	217.2%
Inova Loudoun Hospital	2	31,406	15,703	212.2%
Inova Mount Vernon Hospital	2	21,000	10,500	141.9%
Novant Health UVA Health System Haymarket	2	10,787	5,394	72.9%
Novant Health UVA Health System Prince William	2	17,126	8,563	115.7%
Reston Hospital Center**	4	23,539	5,885	79.5%
Sentara Northern Virginia Medical Center***	2	20,332	10,166	137.4%
Stone Springs Hospital Center	1	5,093	5,093	68.8%
Virginia Hospital Center****	3	48,085	16,028	216.6%
<b>Hospital Based TOTAL and Average</b>	<b>30</b>	<b>322,173</b>	<b>10,739</b>	<b>145.1%</b>
<b>Freestanding Facility</b>	<b>Units</b>	<b>Scans</b>	<b>Scan/Unit</b>	<b>Utilization</b>
Centerville/Clifton Imaging Center	1	8,208	8,208	110.9%
Fair Oaks Imaging Center	1	1,717	1,717	23.2%
Fairfax Diagnostic Imaging Center	1	5,719	5,719	77.3%
Fairfax MRI and Imaging Center at Tysons	1	2,096	2,096	28.6%
Inova Ashburn Healthplex	1	4,445	4,445	60.1%
Inova Emergency Room of Fairfax City	1	2,506	2,506	33.9%
Inova Imaging Center-Mark Center	1	3,265	3,265	44.1%
Inova Lorton HealthPlex	1	5,856	5,856	79.1%
Inova Loudoun Diagnostic Imaging Center	1	8,307	8,307	112.3%
Inova Springfield HealthPlex	1	12,707	12,707	171.7%
Insight Imaging—Fairfax	1	3,335	3,335	45.1%
Lakeside at Loudoun Tech Center	1	2,156	2,156	29.1%
Metro Region PET Center	1	1,109	1,109	15.0%
Novant Imaging Center	1	241	241	3.3%
Orthopaedic Foot & Ankle Center*****	1	0	0	0.0%
Prosperity Imaging Center	1	10,102	10,102	136.5%
Radiology Imaging Associates at Lansdowne	1	3,861	3,861	52.2%
Radiology Imaging Associates at Sterling	1	2,234	2,234	30.1%
Sentara Advanced Imaging Center-Lake Ridge	1	7,252	7,252	98.0%
Sentara Advanced Imaging Center-Lorton	1	14	14	0.19%
Sentara Advanced Imaging Center-Springfield	1	76	76	1.03%
Tysons Corner Diagnostic Imaging	1	1,357	1,357	18.34%
Woodburn Diagnostic Center	2	16,693	16,693	112.8%
<b>Freestanding TOTAL and Average</b>	<b>24</b>	<b>103,256</b>	<b>4,302</b>	<b>58.1%</b>
<b>GRAND TOTAL and Average</b>	<b>63<sup>1</sup></b>	<b>425,429</b>	<b>7,878</b>	<b>106.5%</b>

Source: VHI (2017) and DCOPN records.

<sup>1</sup> Though not used in the calculation for overall utilization, the total number of CT units reflects the five units added to the PD 8 inventory pursuant to COPN Nos. VA-04572, 04548, 04595, and 04663 (issued September 3, 2019) and the four Kaiser CT scanners not reported by VHI.

- \* 7<sup>th</sup> CT scanner added pursuant to COPN No. VA-4572, issued August 15, 2017.
- \*\* CT relocated from main hospital inventory to a newly established specialized center for CT imaging pursuant to COPN No. VA-04554 issued on February 21, 2017.
- \*\*\*CT relocated from main hospital inventory to newly established specialized center for CT imaging pursuant to COPN No. VA-04616, issued on August 13, 2018.
- \*\*\*\*4<sup>th</sup> CT scanner added pursuant to COPN No. VA-04548, issued on February 15, 2017.
- \*\*\*\*\*Approved, but no operations during reporting period. Use limited to practice patients.
- \*\*\*\*\*1 limited-purpose CT scanner added to a new specialized center for CT services established by Fairfax ENT and Facial Plastic Surgery pursuant to COPN No. VA-04595, issued on April 3, 2018.

**Table 2. 2017 Kaiser Permanente CT Utilization**

<b>Facility</b>	<b>Units</b>	<b>Scans</b>	<b>Scan/Unit</b>	<b>Utilization</b>
Tysons Corner Medical Center	2	16,842	8,421	113.8%
Reston Medical Center	1	5,770	5,770	78.0%
Woodbridge Medical Center	1	8,046	8,046	108.7%
<b>TOTAL and Average</b>	<b>4</b>	<b>30658</b>	<b>7665</b>	<b>103.6%</b>

Source: COPN Request No. VA-8468 and DCOPN calculations

DCOPN notes that while not included in the 2017 VHI data, DCOPN records indicate that in addition to the 54 CT scanners reported by VHI, an additional five CT scanners have been added to the PD 8 inventory since 2017. These additions, along with the four Kaiser CT scanners not reported by VHI, result in a current PD 8 inventory of 63 CT scanners.

Magnetic Resonance Imaging (MRI) Scanners and Utilization in PD 8

According to 2017 VHI data, there were 45 COPN authorized magnetic resonance imaging (MRI) scanners in PD 8 in 2017 (Table 3), all of which were fixed units. For that year, the 45 MRI scanners operated at a cumulative utilization of 88.1% based on the SMFP expansion threshold of 5,000 procedures per MRI scanner per year. Specifically, the 23 hospital-based MRI scanners in PD 8 operated at a collective utilization of 90.7% for 2017 while the 22 MRI scanners located at freestanding facilities operated at a collective utilization of 85.4%. However, DCOPN again notes that Anthem’s 2018 policy change, which results in reimbursement for only those procedures performed in outpatient settings when available, will likely result in an increase in utilization of freestanding diagnostic imaging facilities.

DCOPN additionally notes that currently, the applicant operates four total MRI scanners at its Tysons Corner, Reston, and Woodbridge locations; however, the 2017 VHI data failed to include these facilities. Accordingly, DCOPN cannot quantifiably confirm data provided by the applicant (Table 4) and has not included it in the calculations for total PD 8 utilization.

**Table 3. COPN Authorized MRI Scanners in PD 8**

<b>Hospital Based Facility</b>	<b>Units</b>	<b>Scans</b>	<b>Scan/Unit</b>	<b>Utilization</b>
Inova Alexandria Hospital	2	8,036	4,018	80.4%
Inova Fair Oaks Hospital	2	7,738	3,869	77.4%
Inova Fairfax Hospital*	8	41,178	5,147	102.9%
Inova Loudoun Hospital	1	6,291	6,291	125.8%
Inova Mount Vernon Hospital**	1	5,495	5,495	109.9%
Novant Health UVA Health System Haymarket Medical Center	1	5,279	5,279	105.6%
Novant Health UVA Health System Prince William Medical Center	2	6,100	3,050	61.0%
Reston Hospital Center	1	3,954	3,954	79.1%
Sentara Northern Virginia Medical Center	1	3,945	3,945	78.9%
Stone Springs Hospital Center	1	1,061	1,061	21.2%
Virginia Hospital Center	3	15,178	5,059	101.2%
<b>Hospital Based TOTAL and Average</b>	<b>23</b>	<b>104,255</b>	<b>4,533</b>	<b>90.7%</b>
<b>Freestanding Facility</b>				
	<b>Units</b>	<b>Scans</b>	<b>Scan/Unit</b>	<b>Utilization</b>
Fairfax MRI and Imaging Center at Tysons	1	9,482	9,482	189.6%
Fairfax MRI Center at Reston	1	5,671	5,671	113.4%
Inova Imaging Center-Mark Center	1	3,244	3,244	64.9%
Inova Loudoun Diagnostic Imaging Center	1	2,136	2,136	42.7%
Inova Springfield HealthPlex	1	4,091	4,091	81.8%
Insight Imaging - Arlington / Medical Imaging Center of Arlington	2	7,859	3,930	78.6%
Insight Imaging - Fairfax / Medical Imaging Center of Fairfax	1	4,665	4,665	93.3%
Insight Imaging Woodbridge / Medical Imaging Center of Woodbridge	2	8,133	4,067	81.3%
MRI of Reston	4	17,498	4,375	87.5%
Novant Imaging Centerville dba Vienna Diagnostic Imaging	1	3,371	3,371	67.4%
Radiology Imaging Associates at Lansdowne	2	7,576	3,788	75.8%
Radiology Imaging Associates at Sterling	1	3,532	3,532	70.6%
Sentara Advanced Imaging Center - Lake Ridge	1	2,419	2,419	48.4%
Tysons Corner Diagnostic Imaging	2	10,578	5,289	105.8%
Washington Radiology Associates, PC	1	3,672	3,672	73.4%
<b>Freestanding TOTAL and Average</b>	<b>22</b>	<b>93,927</b>	<b>4,269</b>	<b>85.4%</b>
<b>GRAND TOTAL and Average</b>	<b>51<sup>2</sup></b>	<b>198,182</b>	<b>4,404</b>	<b>88.1%</b>

Source: VHI (2017) and DCOPN records.

\*Ninth MRI added pursuant to COPN No. VA-04572, issued on August 15, 2017.

\*\*Second MRI added pursuant to COPN No. VA- 04571, issued on August 15, 2017.

<sup>2</sup> Though not used in the calculation for overall utilization, the total number of MRI units reflects the two units added to the PD 8 inventory pursuant to COPN Nos. VA-04571 and 04572 and the four Kaiser MRI scanners not reported by VHI.

**Table 4. 2017 Kaiser Permanente MRI Utilization**

Facility	Units	Scans	Scan/Unit	Utilization
Tysons Corner Medical Center	2	9,523	4,762	95.2%
Reston Medical Center	1	6,136	6,136	122.7%
Woodbridge Medical Center	1	4,002	4,002	80.0%
<b>TOTAL and Average</b>	<b>4</b>	<b>19,661</b>	<b>4,915</b>	<b>98.3%</b>

Source: COPN Request No. VA-8468 and DCOPN calculations

DCOPN notes that while not included in the 2017 VHI data, DCOPN records indicate that in addition to the 45 MRI scanners reported by VHI, an additional two MRI scanners have been added to the PD 8 inventory. These additions, along with the four Kaiser MRI scanners not reported by VHI, result in a current PD 8 inventory of 51 MRI scanners.

PET Scanners in PD 8

According to 2017 VHI data, there were five COPN authorized positron emission tomography (PET) units in PD 8 in 2017 (Table 5)—three stationary and two mobile. For that year, the three fixed units performed a cumulative total of 5,254 procedures (or 1,751.3 procedures per scanner) and operated at a collective utilization of 29.2% based on the SMFP expansion threshold of 6,000 procedures per existing and approved fixed site PET scanner. Mobile units performed a collective total of 1,213 procedures (606.5 procedures per unit) and operated at a collective utilization of 263.7% based on the SMFP expansion threshold of 230 procedures per existing scanner.

**Table 5. PET Services in PD 8**

Fixed PET Service	Units	Procedures	Procedures/Unit	Utilization
Fairfax PET/CT Imaging Center	1	1,678	1,678	28.0%
Metro Region PET Center	1	2,738	2,738	45.6%
Virginia Hospital Center	1	838	838	14.0%
<b>Fixed PET TOTAL</b>	<b>3</b>	<b>5,254</b>	<b>1,751.3</b>	<b>29.2%</b>
Mobile PET Service	Units	Procedures	Procedures/Site	Utilization
Novant Health UVA Cancer Center	1	598	598	260%
PET of Reston	1	615	615	267.4%
<b>Mobile PET TOTAL</b>	<b>2</b>	<b>1,213</b>	<b>606.5</b>	<b>263.7%</b>

Source: VHI (2017) and DCOPN records.

\*Note: Utilization based on SMFP mobile PET expansion threshold of 230 scans per existing scanner.

DCOPN notes that while not included in the 2017 VHI data, DCOPN records indicate that in addition to the five PET scanners (both fixed and mobile) reported by VHI, an additional two PET scanners have been added to the PD 8 inventory (COPN No. VA-04629 authorizing Sentara Northern Virginia Medical Center to introduce mobile PET/CT imaging and COPN No. VA-04642 authorizing Carient Heart & Vascular, PC to add one cardiac PET). These additions result in a current PD 8 inventory of seven PET scanners (three mobile and four fixed). DCOPN further notes that currently, the applicant does not operate a PET service in PD 8.

Non-Cardiac Nuclear Medicine in PD 8

According to 2017 VHI data, there were 24 COPN authorized single-photon emission computed tomography (SPECT) systems in PD 8 in 2017 (Table 6). For that year, the 24 systems performed a cumulative total of 9,107 procedures (379.5 procedures per system). DCOPN observes that utilization of hospital-based SPECT systems varies from that of SPECT systems at freestanding facilities. Specifically, the 19 hospital-based systems performed a collective total of 8,859 procedures (466.3 procedures per system) while the five systems located at freestanding facilities performed a collective total of only 248 procedures (49.5 procedures per system). DCOPN notes that while the applicant does not currently operate a SPECT system, it does currently operate two planar imaging systems at its Tyson’s Corner Medical Center. For 2017, VHI data indicated that the two systems performed a collective total of 1,672 procedures.

**Table 6. Nuclear Medicine Imaging Services in PD 8**

<b>Hospital Based Facility</b>	<b>Number of SPECT Systems</b>	<b>Procedures</b>	<b>Procedures per SPECT System</b>
Inova Alexandria Hospital	1	1,130	1,130
Inova Fair Oaks Hospital	3	1,429	476.3
Inova Fairfax Hospital	4	36	9
Inova Loudoun Hospital	1	433	433
Inova Mount Vernon Hospital	2	766	383
Novant Health Haymarket Medical Center	1	25	25
Novant Health Prince William Medical Center	1	298	298
Reston Hospital Center	2	378	189
Sentara Northern Virginia Medical Center	1	924	924
Stone Springs Hospital Center	1	63	63
Virginia Hospital Center	2	3,377	1,688.5
<b>Hospital Based TOTAL</b>	<b>19</b>	<b>8,859</b>	<b>466.3</b>
<b>Freestanding Facility</b>	<b>Number of SPECT Systems</b>	<b>Procedures</b>	<b>Procedure per SPECT System</b>
Radiology Imaging Associates at Sterling	1	39	39
Woodburn Nuclear Medicine	4	209	52.3
<b>Freestanding TOTAL</b>	<b>5</b>	<b>248</b>	<b>49.6</b>
<b>GRAND TOTAL</b>	<b>24</b>	<b>9,107</b>	<b>379.5</b>

Source: VHI (2017)

**Proposed Project**

Kaiser proposes to establish four diagnostic and treatment services at a new outpatient medical care complex the health plan is developing in Woodbridge, Virginia. The proposed project entails relocating and replacing the existing CT and MRI scanners currently located at the Kaiser Woodbridge Medical Center and acquiring one additional 3.0T MRI scanner. Additionally, the applicant proposes to establish non-cardiac nuclear medicine services and PET/CT services at this

location. The applicant has provided assurances that the CT functionality on the proposed PET/CT machine will be used solely in conjunction with the machine's PET functionality.

The proposed services will be located in a full-service outpatient hub similar in clinical scope to the Tysons Corner Hub that became operational in 2012. In addition to the four proposed services, the five-story multi-specialty hub, located on 14.7 acres, will also include:

1. 144 exam rooms and 102 provider offices for primary care and specialty care.
2. Ten behavioral health provider offices.
3. Clinical Decision Unit with 33 bays.
4. Outpatient surgery center with four general-purpose operating rooms (COPN No. VA-04691, issued on December 16, 2019).
5. Outpatient procedure center with five rooms, 11 pre and post-op bays, and two private pre and post-op rooms.
6. Additional imaging modalities, including one general radiology unit, two screening mammography, fluoroscopy, DEXA, three ultrasound, and interventional radiology.
7. Ancillary services including pharmacy, laboratory, and optical shop.
8. Six level parking garage and a surface lot totaling 1,210 parking spaces.

The new facility will replace the Woodbridge medical office building currently operated by Kaiser, which the applicant states will significantly improve functional and operational efficiencies.

The total projected capital cost of the proposed project is \$12,895,042 (Table 7), the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. The applicant anticipates construction to commence on July 1, 2020 and to be complete by May 6, 2021. The applicant anticipates a November 1, 2021 date of opening, assuming a Commissioner's decision in March 2020.

**Table 7. Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. Projected Capital Costs**

Direct Construction	\$4,709,650
Equipment Not Included in Contract	\$7,707,217
Architectural & Engineering Fees	\$418,175
Other Consultant's Fees	\$60,000
<b>TOTAL Capital Costs</b>	<b>\$12,895,042</b>

Source: COPN Request No. VA-8468

### **Project Definition**

§32.1-102.1 of the Code of Virginia (the Code) defines a project, in the relevant parts, as the "Establishment of a medical care facility." A medical care facility is defined, in part, as "specialized centers or clinics...developed for the provision of...computed tomographic (CT) scanning...magnetic resonance imaging (MRI)...positron emission tomographic (PET) scanning...nuclear medicine imaging, except for the purpose of nuclear cardiac imaging..."

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

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

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

Located approximately two miles from I-95 at the Prince William Parkway exit, the proposed project would be readily accessible geographically to residents of PD 8. Public bus service is available through the Potomac and Rappahannock Transit Commission (PRTC), which provides local scheduled and on-demand transportation as well as cross-county connector service from Manassas. The applicant has additionally stated that it intends to work with PRTC to construct an on-site bus shelter.

Regarding socioeconomic factors relevant to the proposed project, the Pro Forma income statement provided by the applicant proffered to provide charity care in the amount of 4.3% based on patient care expenses, an amount slightly higher than the 4.1% HPR II average (**Table 8**). Accordingly, should the proposed project be approved, DCOPN recommends a charity care condition consistent with the proffered amount of 4.3%.

**Table 8. HPR II 2018 Charity Care Contributions.**

<b>Health Planning Region II</b>			
<b>2018 Charity Care Contributions at or below 200% of Federal Poverty Level</b>			
<b>Hospital</b>	<b>Gross Patient Revenues</b>	<b>Adjusted Charity Care Contribution</b>	<b>Percent of Gross Patient Revenue:</b>
Novant Health UVA Health System Prince William Medical Center	\$495,433,432	\$44,647,076	9.01%
Sentara Northern Virginia Medical Center	\$789,301,159	\$56,962,621	7.22%
Inova Mount Vernon Hospital	\$479,308,693	\$25,072,214	5.23%
Inova Alexandria Hospital	\$924,056,506	\$46,277,537	5.01%
Inova Fairfax Hospital	\$3,422,077,165	\$157,062,195	4.70%
Inova Loudoun Hospital	\$730,947,536	\$26,227,153	3.59%
Novant Health UVA Health System Haymarket Medical Center	\$255,870,637	\$8,844,583	3.46%
Inova Fair Oaks Hospital	\$672,995,830	\$22,827,171	3.39%
Virginia Hospital Center	\$1,361,001,590	\$32,175,893	2.36%
StoneSprings Hospital Center	\$204,255,017	\$2,703,533	1.32%
Reston Hospital Center	\$1,323,668,487	\$14,710,834	1.20%
Total Facilities			11
Median			3.6%
<b>Total \$ &amp; Mean %</b>	<b>\$10,658,916,052</b>	<b>\$437,510,810</b>	<b>4.1%</b>

Source: VHI (2018)

With regard to poverty rates, the United States Census Bureau reports that the Virginia statewide poverty rate was 10.7% based on July 1, 2018 estimates. Comparatively, the same data demonstrates that the primary Kaiser service area (Prince William County) has a poverty rate percentage significantly lower than the state average (6.1%).

As will be discussed in more detail throughout this staff analysis report, Weldon-Cooper projects that the total population of PD 8 will increase by approximately 16% (356,377 people) from 2010 to 2020 and by an additional 14% (350,128 people) from 2020 to 2030. Regarding the 65+ age group for PD 8, Weldon-Cooper projects a more rapid increase in population growth (an approximate 56% increase (107,902 people) from 2010 to 2020 and approximately 38% (112,778 people) from 2020 to 2030). This is significant, as this population group typically uses health care resources, including the four services proposed by the applicant, at a rate much higher than those individuals under the age of 65. When compared to statewide population projections for the same period, it is evident that the population of PD 8 is increasing at a much faster rate than that of the Commonwealth as a whole. Weldon-Cooper projects that statewide, the total population will increase by approximately 8% from 2010 to 2020 and by another 8% from 2020 to 2030. Weldon-Cooper further projects that statewide, the 65+ age cohort population will increase at a rate of approximately 38% from 2010 to 2020 and approximately 27% from 2020 to 2030. The applicant states that as of 2019, Kaiser Permanente covers 252,883 people in the Northern Virginia area, an approximate 37% increase in plan membership since 2012.

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

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

DCOPN received numerous letters of support for the proposed project from Virginia elected officials and physicians associated with Kaiser. Collectively, the letters addressed the following:

- Currently, Kaiser members in the South NOVA submarket must drive 45 minutes to an hour to Springfield or Tysons Corner for specialty care. The Kaiser Permanente South NOVA Hub is centrally located to improve geographic access to care for Kaiser members living or working in southeastern Fairfax County, Prince William and points south along the I-95 corridor toward Fredericksburg.
- Since opening its Tysons Corner Hub in 2012, Kaiser's Northern Virginia membership has grown from 184,601 to 252,883 (37%). Over the next five years, Kaiser projects its membership base to increase to 350,000 (38%). The current Kaiser membership in the South NOVA catchment area is 82,016. This membership is projected to grow at 4.5% annually through 2026.
- Kaiser Permanente has been providing healthcare services to its members in Northern Virginia since 1980 and has an established record of providing low cost, high quality healthcare.
- The establishment of the South NOVA Hub will allow Kaiser to provide more comprehensive outpatient services to its patients with more complex conditions in a clinically integrated setting while strengthening the current delivery system to include a full complement of outpatient services and create a more integrated continuum of care.
- Co-location of outpatient surgery and a full array of diagnostic services together with urgent care allows for a more complete and efficient patient evaluation with greater patient convenience.
- The Kaiser brand of integrated, technologically advanced, multi-specialty care is recognized as a model of progressive healthcare delivery both nationally and regionally.

DCOPN did not receive any letters in opposition to the proposed project.

The Health Systems Agency of Northern Virginia conducted the required public hearing on December 9, 2019. There was no public comment other than the statements of support submitted with the application. The Board voted nine in favor and none opposed, with one abstention, to recommend approval of the application.

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

As will be discussed in more detail later in this staff analysis report, DCOPN has calculated a current surplus of five CT scanners in PD 8. However, because the applicant proposes to relocate the requested CT scanner from an existing facility, the proposed project will have a neutral impact on the existing PD 8 CT scanner inventory. With regard to MRI scanners, DCOPN has

calculated a current surplus of 11 MRI scanners. While the proposed project would add one additional scanner to this surplus, DCOPN again notes that the PD 8 population is growing at a rate much faster than the remainder of the Commonwealth as a whole, particularly with regard to the 65+ age cohort which uses healthcare services at a higher rate than the rest of the population. When these two factors are considered, this surplus is actually quite nominal. Regarding PET services, DCOPN notes that all existing PD 8 providers currently operate beneath the SMFP threshold for expansion. 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 of 6,000 procedures per existing and approved fixed site PET scanner. Lastly, with regard to the proposed non-cardiac nuclear medicine service, as will be discussed in more detail below, DCOPN does not believe the applicant will have difficulty upholding the projections outlined in its application and required for the establishment of this service under the SMFP.

DCOPN additionally notes that each of the four proposed services will serve only those individuals enrolled in Kaiser health plans. Accordingly, DCOPN concludes that it is not likely that the approval of any proposed service would have a significant negative impact on existing area providers. DCOPN also notes that according to the applicant, Kaiser's Northern Virginia membership has grown exponentially in recent years, and is projected to grow by an additional 38% over the next five years. For these reasons, DCOPN contends that maintaining the status quo is not a reasonable, less costly alternative to the proposed project.

**(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;**

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed at its December 9, 2019 meeting the COPN application filed by Kaiser Foundation Health Plan of the Mid-Atlantic States (COPN Request VA-8468) seeking authorization to establish CT, MRI, PET and non-cardiac nuclear medicine services in Woodbridge, Virginia. The Board voted nine in favor and none opposed, with one abstention, to recommend approval of the application.

The Board based the recommendation on its review of the application, on the HSANV staff report on the proposal, on the testimony and evidence presented at the December 9, 2019 public hearing and Board of Directors meeting held on the application, and on several basic findings and conclusions, including:

1. Kaiser Foundation Health Plan's Northern Virginia membership has grown significantly over the last decade and is expected to continue to grow steadily over the next five years.
2. The imaging services Kaiser proposes to establish at its Woodbridge, Virginia medical center have service volumes that demonstrate operational efficiency and need for additional capacity to meet internal demand as enrollment increases.
3. All of the imaging services Kaiser proposes to place in the Woodbridge facility have current and projected annual caseloads that are consistent with the applicable service and equipment planning standards specified in the Virginia State Medical Facilities Plan.

4. Though there is no compelling need for additional CT, MRI, PET, and non-cardiac nuclear medicine services region wide, Kaiser has demonstrated an internal plan need for the services and capacity requested, to permit the plan to meet demand and to function efficiently.
5. There is no indication, or reason to believe, that establishing the services proposed in Woodbridge would affect negatively other imaging services.
6. Kaiser is an experienced provider of imaging services and has acceptable charity care policies and practices.
7. The project is consistent with applicable COPN requirements, including the service volume standards specified in the Virginia State Medical Facilities Plan.
8. Projected capital and operating costs are within the ranges reported locally and elsewhere in Virginia. They would not be unnecessarily duplicative.
9. To the extent the project is necessary to permit continued health plan growth and development, arguably the project is likely to facilitate beneficial competition for health plan membership.

DCOPN agrees with the HSANV recommendation for approval, and concurs with, and adopts, the attached HSANV staff report and analysis.

**(iv) Any costs and benefits of the project;**

As demonstrated by **Table 7**, the total projected capital cost of the proposed project is \$12,895,042, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. When considering the large scale of the proposed project, DCOPN concludes that this projection is reasonable when compared to similar PD 8 projects. The HSANV provided the following in its staff analysis report with regard to this standard:

*“Kaiser’s projected capital outlay, and four service-specific expense estimates, are well within the ranges seen locally for comparable equipment and technology. Projected service-specific average costs, which in the case of Kaiser health plan include both facility and physician costs, compare favorably—are generally lower than—average charges and reimbursement (payment) for these services region wide.”*

Regarding the benefits of the proposed project, the applicant provided the following:

*“Strategic drivers for the new South NOVA Hub include:*

- *Improved access to care: The proposed Hub will increase the Northern Virginia service area’s 30-minute specialty care access from 55% in 2017 to 78% and from 18% to 71% in the south submarket.*
- *Addresses capacity constraints: The Northern Virginia service area is supported by one multi-specialty hub in the northern submarket with smaller specialty practices housed in medical office buildings across the service area. Membership growth projections and capacity modeling show that Northern Virginia will have significant*

*resource deficits—including exam rooms, operating rooms, and diagnostic imaging services.<sup>3</sup>*

- *Replaces Woodbridge MOB: The replacement of the facility with the South NOVA Hub will significantly improve functional and operation efficiencies.”*

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

The Pro Forma expense statement provided by the applicant (**Table 9**) proposes the provision of 4.3% charity care based on patient care expenses, an amount marginally higher than the 4.1% HPR II average. Accordingly, should the proposed project be approved, DCOPN recommends a charity care condition consistent with the proffered 4.3%.

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<sup>3</sup> The applicant states that since 2012, Kaiser’s Northern Virginia membership has grown from 184,601 to 252,883 in 2018 (37.0%). Over the next five years (through 2024), the applicant projects this membership base will increase by 38% to 349,908.

**Table 9. Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. Pro Forma**

<b>CT</b>				
<b>Statistics</b>	<b>Year 1</b>	<b>Cost Per Case</b>	<b>Year 2</b>	<b>Cost Per Case</b>
Cases	11,263		11,977	
<b>Costs</b>				
Indirect Fixed	\$1,027,765	\$91.25	\$1,124,772	\$93.91
Direct Fixed	\$120,192	\$10.67	\$120,192	\$10.04
Direct Variable	\$2,685,504	\$238.44	\$2,941,420	\$245.59
<b>Facility Subtotal</b>	<b>\$3,833,461</b>	<b>\$340.36</b>	<b>\$4,186,384</b>	<b>\$349.54</b>
Charity Care (4.3%)	\$164,839	\$15	\$180,014	\$15
<b>Facility Net</b>	<b>\$3,998,300</b>	<b>\$354.99</b>	<b>\$4,366,398</b>	<b>\$364.57</b>
<b>MRI</b>				
<b>Statistics</b>	<b>Year 1</b>	<b>Cost Per Case</b>	<b>Year 2</b>	<b>Cost Per Case</b>
Cases	7,418		7,889	
<b>Costs</b>				
Indirect Fixed	\$926,647	\$124.91	\$1,014,042	\$128.55
Direct Fixed	\$526,669	\$70.99	\$526,669	\$66.76
Direct Variable	\$2,124,661	\$286.40	\$2,327,059	\$294.99
<b>Facility Subtotal</b>	<b>\$3,577,977</b>	<b>\$482.31</b>	<b>\$3,867,770</b>	<b>\$490.30</b>
Charity Care (4.3%)	\$153,853	\$21	\$166,314	\$21
<b>Facility Net</b>	<b>\$3,731,830</b>	<b>\$503.05</b>	<b>\$4,034,084</b>	<b>\$511.39</b>
<b>PET/CT</b>				
<b>Statistics</b>	<b>Year 1</b>	<b>Cost Per Case</b>	<b>Year 2</b>	<b>Cost Per Case</b>
Cases	1,532		1,629	
<b>Costs</b>				
Indirect Fixed	\$636,493	\$415.46	\$695,962	\$427.21
Direct Fixed	\$240,536	\$157.01	\$240,536	\$147.65
Direct Variable	\$1,177,965	\$768.90	\$1,290,179	\$791.97
<b>Facility Subtotal</b>	<b>\$2,054,965</b>	<b>\$1341.37</b>	<b>\$2,226,676</b>	<b>\$1366.83</b>
Charity Care (4.3%)	\$88,365	\$58	\$95,747	\$59
<b>Facility Net</b>	<b>\$2,143,358</b>	<b>\$1399.05</b>	<b>\$2,322,423</b>	<b>\$1425.60</b>
<b>Nuclear Medicine</b>				
<b>Statistics</b>	<b>Year 1</b>	<b>Cost Per Case</b>	<b>Year 2</b>	<b>Cost Per Case</b>
Cases	862		917	
<b>Costs</b>				
Indirect Fixed	\$117,216	\$135.98	\$128,237	\$139.90
Direct Fixed	\$169,052	\$192.12	\$169,052	\$184.43
Direct Variable	\$219,380	\$254.50	\$240,278	\$262.14
<b>Facility Subtotal</b>	<b>\$505,647</b>	<b>\$586.60</b>	<b>\$537,566</b>	<b>\$586.47</b>
Charity Care (4.3%)	\$21,743	\$25	\$23,115	\$25
<b>Facility Net</b>	<b>\$527,390</b>	<b>\$611.83</b>	<b>\$560,682</b>	<b>\$611.69</b>
<b>COMBINED TOTAL</b>	<b>\$10,400,878</b>		<b>\$11,283,587</b>	

Source: COPN Request No. VA-8468

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

DCOPN did not identify any other 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 project.

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

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

**12VAC5-230-90. Travel Time.**

**CT services should be within 30 minutes driving time one way under normal driving 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** identifies the boundary of PD 8. The blue “H” sign marks the location of the proposed project. The white “H” signs mark the locations of all other COPN approved CT scanners located within PD 8. The yellow shaded area in **Figure 1** illustrates the area of PD 8 and the surrounding area that is within a 30-minute drive of existing CT services. The light green shaded area illustrates the area within 30 minutes of the proposed project that is not already within a 30-minute drive of existing CT services. Given the amount of shaded area, it is reasonable to conclude that CT services are currently available within 30 minutes normal driving time, one way, under normal conditions of 95% of the population of PD 8. Additionally, DCOPN notes that existing CT scanners are widely distributed throughout the planning district and that as a result, there are no underserved areas or populations in PD 8. DCOPN concludes that approval of the proposed project would not significantly improve access to CT services in PD 8.

Figure 1.



**12VAC5-230-100. Need for a 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.**

Using 2017 VHI data, based on 54 authorized CT scanners in PD 8 (Table 1) and reported CT volume of 425,429 CT scans (7,878 scans per scanner), there is a calculated deficit of 4 CT scanners in PD 8 as follows:

$$\begin{aligned} \text{COPN authorized scanners: } & 54 \\ \text{Needed CT scanners: } & 425,429 \div 7,400 = 58 \\ \text{Utilization percentage} & = 106.5\% \\ \text{CT scanner deficit: } & 4 \end{aligned}$$

However, as already discussed, five CT scanners have subsequently been added to the PD 8 inventory which are not included in the 2017 VHI data. Additionally, the four CT scanners currently operated by Kaiser were not included in the VHI data. When those additions are considered, there is **currently a calculated surplus of five CT scanners in PD 8**. Because the applicant proposes to relocate the requested CT scanner from an existing facility, the proposed project will have a neutral impact on the existing PD 8 inventory.

- 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.**

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from the average utilization of CT scanners in PD 8 with respect 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 proposing to expand a fixed site service.

**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 scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.**

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

**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 the proposed project would be under the direction or supervision of one or more qualified physicians.

**Article 2. Criteria and Standards for Magnetic Resonance Imaging**

**12VAC5-230-140. Travel Time.**

**MRI services should be within 30 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 2** identifies the boundary of PD 8. The blue “H” sign marks the location of the proposed project. The white “H” signs mark the locations of all other COPN approved MRI scanners located within PD 8. The yellow shaded area in **Figure 2** illustrates the area of PD 8 and the surrounding area that is within a 30-minute drive of existing MRI services. The light green shaded area illustrates the area within 30 minutes of the proposed project that is not already within a 30-minute drive of existing MRI services. Given the amount of shaded area, it is reasonable to conclude that MRI services are currently available within 30 minutes normal driving time, one way, under normal conditions of 95% of the population of PD 8. Additionally, DCOPN notes that existing MRI scanners are widely distributed throughout the planning district and that as a result, there are no underserved areas or populations in PD 8. DCOPN concludes that approval of the proposed project would not significantly improve access to MRI services in PD 8.



**12VAC5-230-150. Need for New Fixed Site Service.**

**No new fixed site MRI services should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI 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 MRI scanners in such health planning district.**

Using 2017 VHI data, based on 45 authorized MRI scanners in PD 8 (Table 3) and reported MRI volume of 198,182 MRI scans (4,404 scans per scanner), there is a calculated surplus of 5 MRI scanners in PD 8 as follows:

COPN authorized scanners: 45  
Needed MRI scanners:  $198,182 \div 5,000 = 40$   
Utilization percentage = 88.1%  
**MRI scanner surplus: 5**

However, as already discussed, two MRI scanners have subsequently been added to the PD 8 inventory which are not included in the 2017 VHI data. Additionally, the four MRI scanners currently operated by Kaiser were not included in the 2017 VHI data. When those additions are considered, there is **currently a calculated surplus of 11 MRI scanners in PD 8**. The proposed project would add one additional MRI scanner to this existing surplus, resulting in a net surplus of 12 MRI scanners in PD 8. However, DCOPN concludes that the MRI portion of the proposed project warrants approval despite this standard not being met. First, as already discussed, the PD 8 population is projected to continue to grow at a rate faster than that of the Commonwealth as a whole, particularly with regard to the 65+ age cohort which uses health care services at a higher rate than the rest of the population. When this is considered, DCOPN concludes that the existing surplus is actually quite nominal. Additionally, and perhaps more importantly, the proposed facility will serve only those residents enrolled in a Kaiser health plan. Accordingly, DCOPN concludes that the proposed project is not likely to have a significant negative impact on the utilization of existing providers of MRI services in PD 8.

**12VAC5-230-160. Expansion of Fixed Site Service.**

**Proposals to expand an existing medical care facility's MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant's existing medical care facility, or at a separate location within the applicant's primary service area for MRI 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 proposing the expansion of a fixed site service, but rather the establishment of a new service through the relocation and replacement of existing equipment and the addition of one new MRI scanner. If approved, the proposed project would add one additional MRI scanner to the existing PD 8 inventory.

**12VAC5-230-170. Adding or Expanding Mobile MRI Services.**

- A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health planning district.**
- B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health planning district.**

Not applicable. The applicant is not proposing the addition or expansion of a mobile MRI service, nor is the applicant proposing the conversion of a mobile MRI service to a fixed site scanner.

**12VAC5-230-180. Staffing.**

**MRI services should be under the direct supervision of one or more qualified physicians.**

The applicant has provided assurances that the proposed project would be under the direction or supervision of one or more qualified physicians.

**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 3** identifies the boundary of PD 8. The blue "H" sign marks the location of the proposed project. The white "H" signs mark the locations of all other COPN approved PET services located within PD 8. The yellow shaded area in **Figure 3** illustrates the area of PD 8 and the surrounding area that is within a 60-minute drive of existing PET services. Given the amount of shaded area, it is reasonable to conclude that PET services are currently available within 60 minutes normal driving time, one way, under normal conditions of 95% of the population of PD 8. DCOPN concludes that approval of the proposed project would not significantly improve access to PET services in PD 8.

Figure 3.



**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 individual PET procedures and CT procedures respectively, unless those images are not made concurrently.**

The three fixed site PET scanners in PD 8 performed a collective total of 5,254 procedures (1,751.3 procedures per scanner) in 2017, approximately 29.2% of the SMFP threshold of 6,000 procedures per scanner per year (**Table 5**). However, DCOPN notes that few PET services in the Commonwealth actually meet the SMFP's utilization thresholds of 6,000 procedures per existing and approved fixed site PET scanner and believes that the threshold reflects a misconception about the utilization of PET technology at the time the SMFP PET criteria and standards were written.<sup>4</sup> Furthermore, DCOPN again notes the proposed project is not likely to negatively affect existing providers as the proposed service would serve only those individuals enrolled in a Kaiser health plan.

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<sup>4</sup> 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, issued on September 3, 2019, 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.

**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 service, but rather, is proposing to establish a new 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 an existing mobile service, but rather, is proposing to establish a new service.

**12VAC5-230-240. Staffing.**

PET service 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 assurances that the proposed project would be under the direction or supervision of one or more qualified physicians.

**Article 5. Non-cardiac Nuclear Imaging Criteria and Standards**

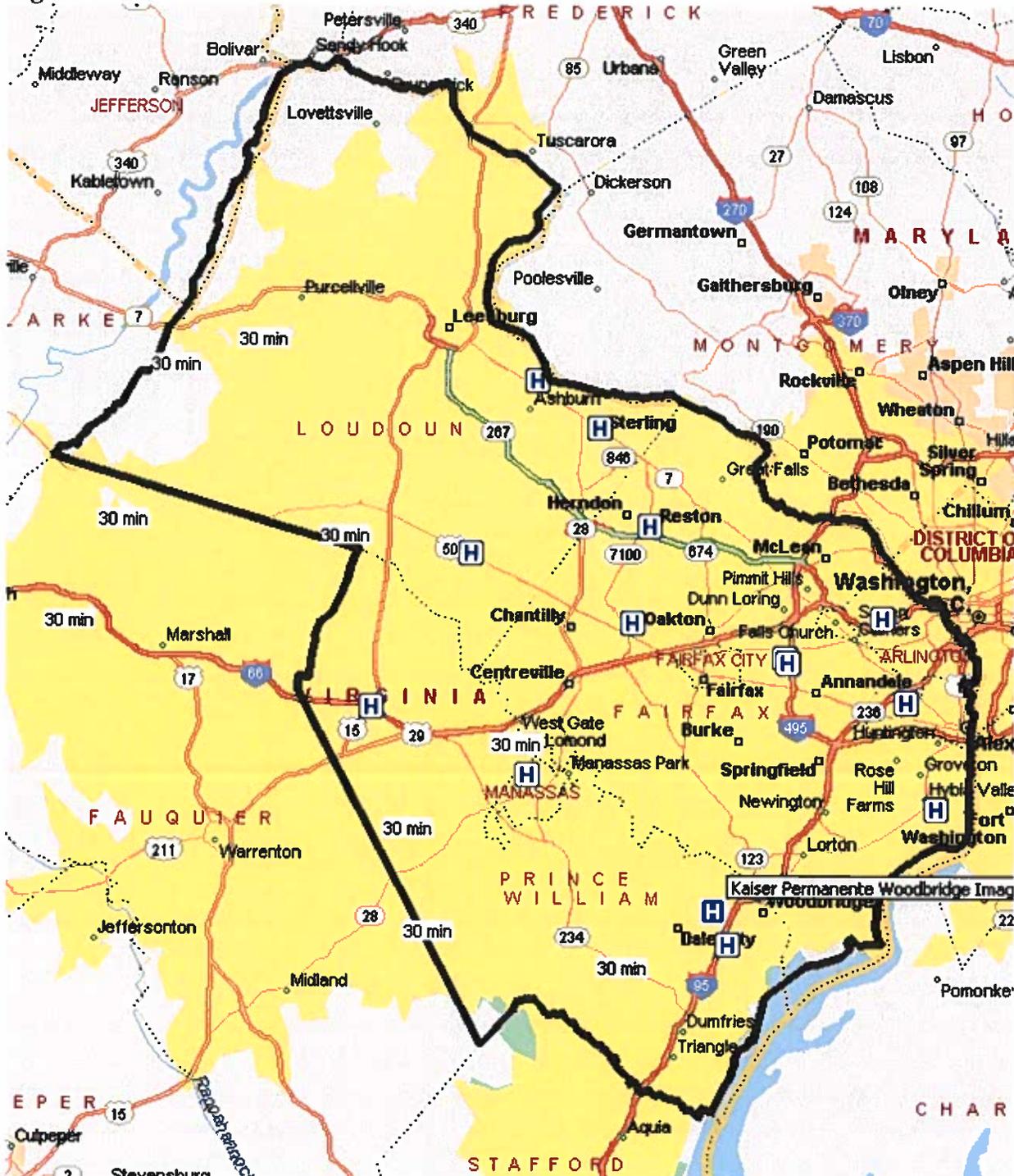
**12VAC5-230-250. Travel Time.**

Non-cardiac nuclear imaging 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 a mapping software as determined by the commissioner.

The heavy black line in **Figure 4** identifies the boundary of PD 8. The blue “H” sign marks the location of the proposed project. The white “H” signs mark the locations of all other COPN approved non-cardiac nuclear imaging services located within PD 8. The yellow shaded area in **Figure 4** illustrates the area of PD 8 and the surrounding area that is within a 30-minute drive of existing non-cardiac nuclear imaging services. The light green shaded area illustrates the area within 30 minutes of the proposed project that is not already within a 30-minute drive of existing non-cardiac nuclear imaging services. Given the amount of shaded area, it is reasonable to conclude that non-cardiac nuclear imaging services are currently available within 30-minutes normal driving time,

one way, under normal conditions of 95% of the population of PD 8. Additionally, DCOPN notes that existing non-cardiac nuclear imaging services are widely distributed throughout the planning district and that as a result, there are no underserved areas or populations in PD 8. DCOPN concludes that approval of the proposed project would not significantly improve access to non-cardiac nuclear imaging services in PD 8.

Figure 4.



**12VAC5-230-260. Need for New Service.**

**No new non-cardiac imaging services should be approved unless the service can achieve a minimum utilization level of:**

- 1. 650 procedures in the first 12 months of operation;**
- 2. 1,000 procedures in the second 12 months of service; and**
- 3. The proposed new service would not significantly reduce the utilization of existing providers in the health planning district.**

**Note: The utilization of an existing service operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of non-cardiac nuclear imaging services in such health planning district.**

The pro forma submitted by the applicant projects that if approved, the non-cardiac nuclear medicine service at the proposed new facility will provide 862 procedures in the first twelve months of operation (2022), and 917 procedures in the second twelve months of operation. When calculating these projections, the applicant took into consideration current utilization of existing Kaiser nuclear medicine services. The applicant reports providing 2,731 nuclear medicine procedures to Northern Virginia subscribers in 2017 and 2,713 procedures in 2018, with approximately three-fourths of these procedures being non-cardiac scans. Additionally, the applicant states that approximately 90% of nuclear medicine studies obtained by Kaiser's health plan members are performed in the plan's facilities. DCOPN contends that because the facility will serve only those persons enrolled in a Kaiser health plan, the proposed project is not likely to have a significant negative effect on the costs or utilization of existing area providers. For these reasons, DCOPN concludes that this portion of the project warrants approval, despite the applicant's projections falling just short of the 1,000 procedure standard as set out in the SMFP.

**12VAC5-230-270. Staffing.**

**The proposed new or expanded non-cardiac nuclear imaging service 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 the proposed project would be under the direction or supervision of one or more qualified physicians.

**Eight Required Considerations Continued**

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

Because the proposed project would serve only those residents enrolled in a Kaiser health plan, DCOPN contends that the proposed project is not intended to foster institutional competition that benefits the area to be served. DCOPN again notes that the approval of any of the four proposed services is not likely to have a significant negative impact on existing area providers.

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

As already discussed, the proposed project will have a neutral impact on the existing PD 8 CT inventory. With regard to MRI scanners, the proposed project would add one additional scanner to the existing calculated surplus of 11 MRI scanners. However, DCOPN contends that the MRI portion of this project warrants approval despite this surplus. To briefly reiterate, because the total population of PD 8 is expected to continue to increase at a rate faster than that of the Commonwealth as a whole, especially with regard to the 65+ age cohort which uses health care services at a higher rate than the rest of the population, DCOPN contends that the surplus of 11 scanners is actually quite nominal. Additionally, because the proposed additional scanner will serve only those individuals enrolled in a Kaiser health plan, approval of the project is not likely to significantly impact existing providers. For the same reason, DCOPN concludes that approval of the PET/CT and non-cardiac nuclear medicine portions of this project would not necessarily be problematic.

In its Northern Virginia service area, Kaiser currently has operating agreements with its three partner hospitals: Virginia Hospital Center, Reston Hospital, and Stafford Hospital.

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

As demonstrated by **Table 7**, the total projected capital cost of the proposed project is \$12,895,042, the entirety of which will be funded using the accumulated reserves of the applicant. As already discussed, DCOPN concludes that the costs are reasonable when compared to similar projects in PD 8. Also as already discussed, DCOPN additionally concludes that the proposed project would be beneficial, despite adding new services to existing PD 8 inventories, and that approval of any of the four proposed services would not likely have a negative impact on existing providers.

Because this project represents an integrated health insurance and health service delivery care plan provided for a specific set of enrollees in Northern Virginia, only the expenses of operating each service were provided by the applicant, i.e. the applicant collects “insurance premiums” that cover a comprehensive array of services, from primary care to the most complex of clinical conditions. As demonstrated by **Table 9**, the applicant projects that cost per CT scan will increase by approximately 2.7% by the end of the second year of operation, with cost per MRI and PET scans increasing by approximately 1.7% and 1.9%, respectively. However, DCOPN notes that cost per case should theoretically decrease as Kaiser’s caseload grows and fixed costs are distributed over a greater number of cases. The applicant projects that the cost of each nuclear medicine procedure will decrease by approximately 0.02% by the end of the second year of operation.

The applicant anticipates the need to hire a total of 23.5 additional FTEs to staff the proposed project. With regard to staffing, the applicant provided the following:

*“Historically, Kaiser Permanente has not had any difficulty maintaining full time levels of staffing for its imaging services. On-going recruitment and retention activities include advertisements in The Washington Post Employment Section and Tuesday Health Section, internal postings announcing new positions to Kaiser employees who may want to transfer, Open House for technologists, employee referrals, and career fairs.”*

DCOPN does not have any concern that the applicant will be able to fill the required positions or that doing so will have a significant negative impact on existing providers. DCOPN again notes that there is no known opposition to the proposed project.

- 7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; (iv) At the discretion of the Commissioner, any other factors as may be appropriate;**

The proposed project does not offer the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. However, the proposed project does increase the provision of services on an outpatient basis. It is reasonable to assume that, as an outpatient facility, the proposed project would function as a lower-cost alternative to the proposed services. DCOPN did not identify any other factors that have not been discussed elsewhere in this staff analysis report to bring to the attention of the Commissioner.

- 8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served: (i) The unique research, training, and clinical mission of the teaching hospital or medical school; (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.**

Not applicable. 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.

#### **DCOPN Staff Findings and Conclusions**

DCOPN finds that the proposed project to establish CT, MRI, PET/CT, and non-cardiac nuclear medicine at the Kaiser Permanente Woodbridge Imaging Center is generally consistent with applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia. With regard to the proposed CT service, the project would have a neutral impact on the existing PD 8 inventory. Although the proposed project would add one unit to the existing calculated surplus of MRI scanners, DCOPN concludes that the MRI portion of the project warrants approval because the calculated surplus is relatively small and the total population of PD 8 is expected to continue to increase at a rate faster than the rest of the Commonwealth as a whole. Furthermore, the additional MRI would serve only Kaiser health plan members, thereby failing to significantly impact the utilization of existing providers.

For the same reason, DCOPN concludes that the establishment of PET and non-cardiac nuclear medicine services is also unlikely to have a significant negative impact on existing providers.

DCOPN concludes that the projected capital costs, which will be funded entirely using the accumulated reserves of the applicant, are reasonable when compared to similar PD 8 projects. DCOPN further concludes that the proposed project is more advantageous than maintaining the status quo and that a reasonable, less costly, more efficient alternative to the proposed project does not exist.

### **DCOPN Staff Recommendations**

The Division of Certificate of Public Need recommends **conditional approval** of this project for the following reasons:

1. The 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. A reasonable, less costly, more efficient alternative to the proposed project does not exist.
3. The Board of the Health Systems Agency of Northern Virginia recommended approval of the proposed project.
4. Approval of the proposed project is not likely to have a negative impact on the costs or utilization of existing providers.
5. There is no known opposition to the proposed project.
6. The projected capital costs are reasonable.

DCOPN's recommendation is contingent upon Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.'s agreement to the following charity care condition:

Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. must provide CT, MRI, PET/CT and non-cardiac nuclear medicine services to all members enrolled in the Charitable Health Access Program, the Medical Care for Children Partnership Program, the Medical Financial Assistance Program, and will facilitate the development and operation of primary medical care services to medically underserved persons in Planning District 8 in an aggregate amount equal to at least 4.3% of Kaiser Permanente Woodbridge Surgery Center's patient service expenses. Compliance with this condition will be documented to the Division of Certificate of Public Need and the Health Systems Agency of Northern Virginia annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. 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.