

# VIRGINIA DEPARTMENT OF HEALTH

## Office of Licensure and Certification

### Division of Certificate of Public Need

#### Staff Analysis

May 20, 2024

RE: **COPN Request No. VA-8747**  
**Inova Fairfax Hospital**  
**Falls Church, Virginia**  
**Add 1 cardiac catheterization laboratory**

#### Applicant

Inova Fairfax Hospital (IFH) is a 501(c)(3) Virginia non-stock corporation. Inova Health System Foundation, a 501(c)(3) Virginia non-stock corporation, is the sole owner of IFH. IFH is located in Falls Church, Virginia, Planning District (PD) 8, Health Planning Region (HPR) II.

#### Background

Cardiac catheterization laboratories (catheterization lab) are laboratories that examine how well the heart is working by inserting a catheter, a thin, hollow tube, into a large blood vessel that leads to the heart.<sup>1</sup> Cardiac catheterization services are performed to find diseases of the heart muscle, valves, or coronary (heart) arteries by measuring the pressure and blood flow in the heart.<sup>2</sup> To measure the pressure and blood flow of the heart and associated tissues, coronary angiography is utilized; a contrast dye, visible in X-rays, is injected through the catheter and the x-ray images show the dye as it flows through the heart arteries, indicating where arteries are blocked.<sup>3</sup>

Catheterization labs are essential in treating heart conditions in a minimally invasive manner as an alternative to surgery.<sup>4</sup> Some common catheterization lab procedures are:

- Cardiac coronary angiogram (procedure to evaluate the blood vessels supplying the heart using catheters and x-ray dye)
- Coronary stent placement (a procedure where small metal scaffolds are placed within a blocked artery to keep the artery open)

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<sup>1</sup> <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization>

<sup>2</sup> Ibid.

<sup>3</sup> <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/cardiac-catheterization>

<sup>4</sup> Saira Samani, MD. "What Is a Cath Lab?: Ochsner Health." Ochsner Health System. Ochsner Health System, August 5, 2022. <https://blog.ochsner.org/articles/cath-lab-101-behind-the-laboratory-door>.

- Right heart catheterization (a procedure where physicians examine blood flow and pressure filling in the right side of the heart)
- Peripheral angiogram (a procedure that evaluates the flow of blood through arteries in the upper extremities, similar to a coronary angiogram)
- Valve replacement (a minimally invasive procedure that implants an artificial valve in the heart to replace a narrowed heart valve)<sup>5</sup>

**Table 1** displays Virginia Health Information (VHI) data on cardiac catheterization labs in PD 8 from 2022, the latest year for which such data are available. There were 22 cardiac catheterization labs reported in PD 8 that year. The State Medical Facilities Plan (SMFP) uses diagnostic equivalent procedures (DEP) as a means to evaluate utilization of cardiac catheterization labs. The SMFP at 12VAC5-230-10, provides the following definition for DEP and its calculation:

*“DEP” means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a complex therapeutic cardiac catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)*

The SMFP amendments in March of 2021 newly incorporated complex therapeutic cardiac catheterizations into the DEP definition; however, as of the collection of data for 2022, complex therapeutic cardiac catheterizations is not available separately. IFH and Virginia Hospital Center (VHC) are the only facilities in PD 8 that provide open heart surgery services, so they are the only two facilities in PD 8 eligible to perform complex therapeutic cardiac catheterizations, consistent with 12VAC5-230-420, which reads:

*“Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located...”*

The calculations in **Table 1** utilize data reported to VHI and do not include the higher relative values for complex therapeutic cardiac catheterizations for IFH and VHC, and underestimate DEPs as defined above. With this caveat, **Table 1** demonstrates that the 22 cardiac catheterization labs in PD 8 were 76.6% utilized in 2022. The applicant, IFH, had the highest utilization per catheterization lab in PD 8, at 1,371, and operated at 114.3% of the SMFP threshold that year.

The current inventory of cardiac catheterization labs in PD 8 is unchanged from the 2022 VHI report, with one exception: COPN No. VA-04847 authorized the relocation of one of Sentara Northern Virginia Medical Center’s catheterization labs to a new facility, Sentara Heart and

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<sup>5</sup> Ibid.

Vascular Center. It is the only cardiac catheterization lab in PD 8 that is not hospital-based. The total PD 8 inventory of cardiac catheterization labs remains at 22.

**Table 1. VHI 2022 Utilization, PD 8**

<i>Visits</i>										
Facility	Cath Labs	Adult Dx	Adult Simple Tx	Adult Same Session Dx & Simple Tx	Pediatric Dx	Pediatric Tx	Pediatric Same Session Dx&Tx	Total DEPs	DEPs/Cath Lab	% of SMFP Threshold
Inova Alexandria Hospital	2	809	37	257	0	0	0	1,656	828.0	69.0%
Inova Fairfax Hospital	7	4,222	1,013	997	42	66	1	9,600	1371.4	114.3%
Inova Loudoun Hospital	2	816	11	349	0	0	0	1,887	943.5	78.6%
Reston Hospital Center	2	362	182	168	0	0	0	1,232	616.0	51.3%
Sentara Northern Virginia Medical Center	2	753	8	174	0	0	0	1,293	646.5	53.9%
Stone Springs Hospital Center	1	0	1	0	0	0	0	3	3.0	0.3%
UVA Health Prince William Medical Center	2	320	129	24	0	0	0	652	326.0	27.2%
Virginia Hospital Center	4	1,162	375	662	0	0	0	3,902	975.5	81.3%
<b>PD 8 Total</b>		<b>8,444</b>	<b>1,756</b>	<b>2,631</b>	<b>42</b>	<b>66</b>	<b>1</b>	<b>20,225</b>	<b>919.3</b>	<b>76.6%</b>
<i>DEP Multipliers:</i>		1	2	3	2	4	6			

Source of Visits: 2022 VHI

The applicant provided the breakout of its complex therapeutic catheterizations from internal data in its application (**Table 2**) and the resulting number of DEPs was 12,281, equal to 1,754 DEPs per catheterization lab, or 146% of the SMFP threshold. Using the corrected number of DEPs for IFH brings the PD 8 total to 22,906 DEPs, 1,041 per catheterization lab, or 86.8% of the SMFP threshold (still excluding unavailable VHC complex therapeutic catheterization data).

**Table 2. Inova Fairfax Hospital, 2022 DEPs with Complex Therapeutic Visits**

	Cath Labs	Adult Dx	Adult Simple Tx	Adult Same Session Dx&Tx	Adult Complex Tx	Pediatric Dx	Pediatric Tx	Pediatric Same Session Dx&Tx	Pediatric Complex Tx	Total DEPs
Historical Visits	7	4,222	243	997	770	42	3	1	63	
DEP Multiplier		1	2	3	5	2	4	6	10	
DEPs		4,222	486	2,991	3,850	84	12	6	630	12,281
<b>DEPs per Cath Lab</b>										<b>1,754</b>
<b>% of SMFP Threshold</b>										<b>146%</b>

Source: COPN Request No. VA-8747

**Proposed Project**

The applicant proposes to add an eighth cardiac catheterization lab at IFH within its existing cardiac catheterization lab suite, located at 3300 Gallows Road, Falls Church, Virginia. Falls Church is an independent city surrounded by Fairfax County and bordered by Arlington County on its east side (**Figure 1**). Projected capital costs for the proposal are \$6,254,596 (**Table 3**), all of which will be funded with accumulated reserves, so no financing costs will be incurred. The space allocated for the proposed project is 1,420 net and 1,704 gross square feet. Should the proposed project be approved, the targeted opening date is September 1, 2025.

**Table 3. Capital Costs, Add One Cardiac Catheterization Lab at IFH**

Direct Construction Costs	\$3,616,215
Equipment not included in construction costs	\$1,956,715
Architectural and Engineering fees	\$681,666
<b>TOTAL CAPITAL COST</b>	<b>\$6,254,596</b>

Source: COPN No. VA-8747

**Figure 1. City/County Boundaries in PD 8**



**Project Definition**

Section 32.1.1-102.1 of the Code of Virginia defines a project, in part, as “the addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization...” A medical care facility includes “general hospitals...”

**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.**

PD 8 is a large and fast-growing area of Virginia, estimated to grow to 2.8 million people, adding nearly 280,000 people between 2020 and 2030. This projected growth rate of 10.9% for PD 8 in the current decade is nearly twice the growth rate projected for Virginia at 5.8% (Table 4). Falls Church City where the proposed project is located, is relatively small, representing about 1% of the population of PD 8 (Figures 1 & 2). It is mostly surrounded by Fairfax County, however, which makes up about 42% of PD 8’s population, and bordered by Arlington County on its east side, which represents about 9% of the PD 8 population (Figures 1 & 2). It is projected that there will be 80,000 more people in the area surrounding Falls Church in 2030 versus 2020 (Table 4 & Figure 3).

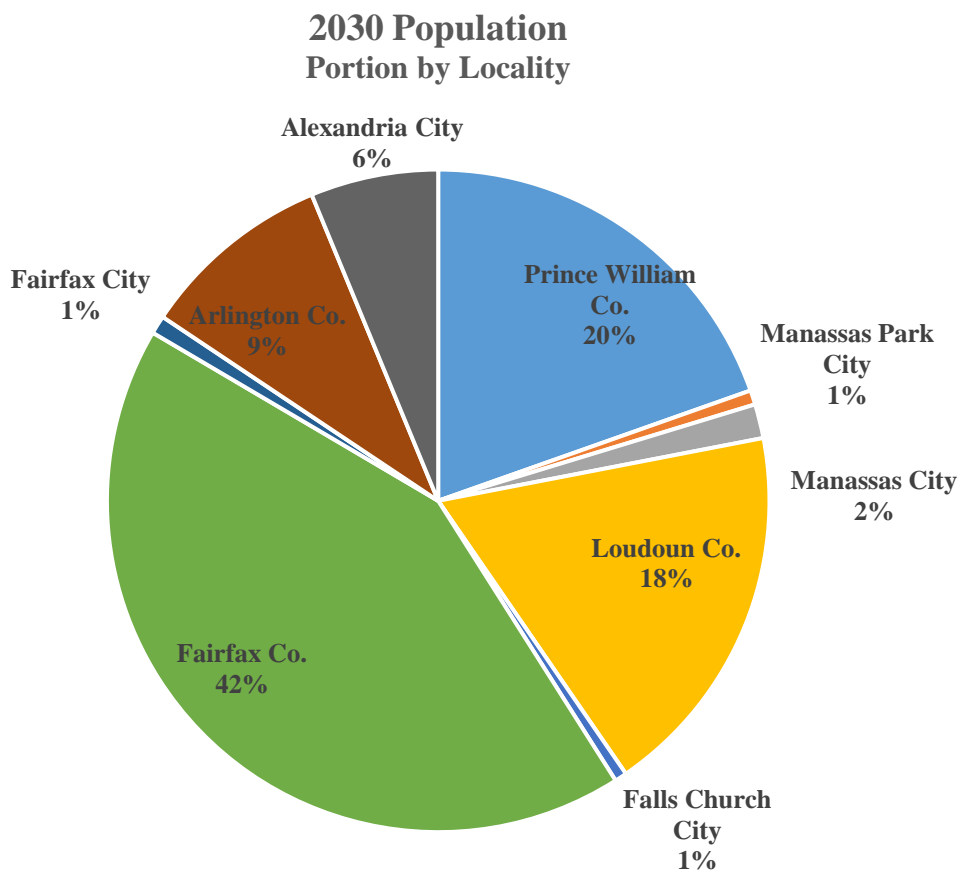
**Table 4. Population by Locality, PD 8**

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Arlington Co.	238,643	265,794	27,151	11.4%	25,333	28,501	3,168	12.5%
Fairfax Co.	1,150,309	1,201,420	51,111	4.4%	158,687	195,132	36,445	23.0%
Loudoun Co.	420,959	522,015	101,056	24.0%	41,497	65,844	24,347	58.7%
Prince William Co.	482,204	554,344	72,140	15.0%	50,522	76,112	25,590	50.7%
Alexandria City	159,467	176,403	16,936	10.6%	18,758	22,941	4,183	22.3%
Fairfax City	24,146	25,358	1,212	5.0%	3,871	4,726	855	22.1%
Falls Church City	14,658	16,741	2,083	14.2%	2,185	2,545	360	16.5%
Manassas City	42,772	47,039	4,267	10.0%	4,505	6,593	2,088	46.4%
Manassas Park City	17,219	19,876	2,657	15.4%	1,343	2,162	819	61.0%
<b>PD 8</b>	<b>2,550,377</b>	<b>2,828,990</b>	<b>278,613</b>	<b>10.9%</b>	<b>306,701</b>	<b>404,555</b>	<b>97,854</b>	<b>31.9%</b>
<i>Virginia, Statewide</i>	<i>8,631,393</i>	<i>9,129,002</i>	<i>497,609</i>	<i>5.8%</i>	<i>1,395,291</i>	<i>1,762,641</i>	<i>367,350</i>	<i>26.3%</i>

Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

Utilization of cardiac catheterizations is higher in age groups 60 and older than it is in the population overall,<sup>6</sup> so the older population is an important segment to examine when assessing access. The number of people over 65 is expected to grow by nearly 98,000 people in PD 8 between 2020 and 2030, through in-migration and aging. This is 32% growth, compared to Virginia’s projected growth of 26.3% for the 65+ segment during the same period (**Table 4**). Though the growth rates in Falls Church, Fairfax County and Arlington County for the 65 and older population are lower than that of the state, the number of people over 65 in this area surrounding the proposed project is projected to grow by nearly 40,000 from 2020 to 2030 (**Table 4 & Figure 3**).

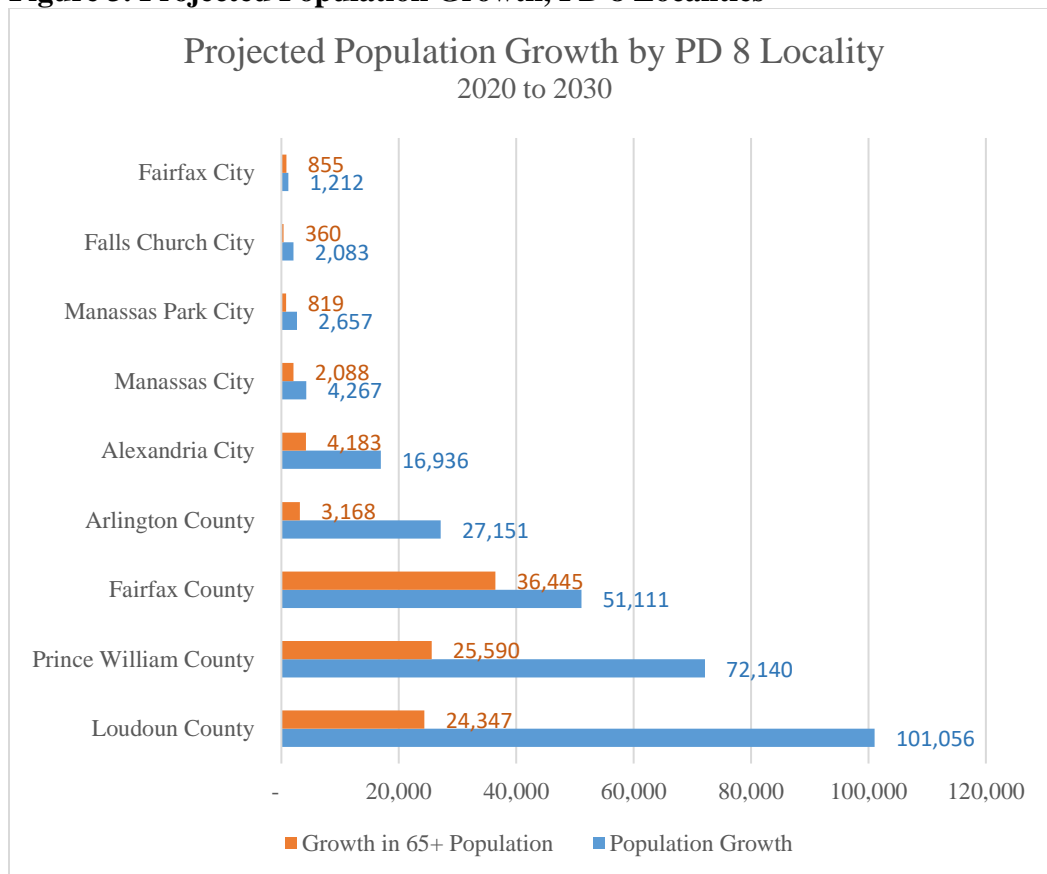
**Figure 2. Portion of PD 8 by Locality**



Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

<sup>6</sup> <https://www.ahdbonline.com/issues/2021/september-2021-vol-14-no-3/3171-characterizing-cardiac-catheterization-utilization-in-a-us-population-with-commercial-or-medicare-advantage-health-plans>

**Figure 3. Projected Population Growth, PD 8 Localities**



Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

Poverty rates in PD 8 are lower in each locality than that of Virginia, indicating relatively less socio-economic barriers to address. IFH is accessible through private and public transportation, located a quarter mile from the Capital Beltway (Interstate 95). It is accessible from the north and south by Interstates 95 and 495 and from east and west via Interstate 66 and Route 50. Public bus transportation is available at the hospital’s main entrance and Metro-rail with a shuttle service is available within three miles at the Dunn Loring Metro station.

**Table 5. 2022 Poverty Rates, PD 8**

<b>Locality</b>	<b>% in Poverty</b>
Arlington County	6.8%
Fairfax County	5.9%
Loudoun County	3.8%
Prince William County	6.9%
Alexandria city	9.0%
Fairfax city	7.6%
Falls Church city	4.1%
Manassas city	9.1%
Manassas Park city	8.9%
<b>PD 8</b>	<b>6.1%</b>
<b>Virginia</b>	<b>10.6%</b>

Source: US Census Bureau, Small Area Income and Poverty Estimates

**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 a statement of endorsement from IFH’s medical staff and three additional letters of support from interventional cardiologists practicing at IFH. These letters, in aggregate, expressed the following:

- IFH provides the full spectrum of interventional cardiology, cardiovascular surgery, advanced heart failure and cardiac critical care capabilities.
- IFH serves as the destination center to over 30 hospitals across the region for patients experiencing cardiogenic shock.
- Regional network protocol is to identify cardiogenic shock quickly, stabilize patients, manage as they can and transfer those that require more advanced treatments and expertise (to hub hospitals).
- Cardiac ICU and its multidisciplinary shock team of specialists are available at IFH around the clock.
- IFH’s current cardiac catheterization labs are at capacity.
- There is a need for an additional cardiac catheterization lab at IFH.
- The Co-Director of Inova Schar Heart and Vascular’s Complex Coronary Therapeutics and Cardiogenic Shock Programs has seen tremendous growth in volumes and complexity of patients at IFH.
- As the quaternary hospital for cardiovascular care in its area, adequate capacity for the region’s sickest patients is critical.
- Expected population growth and corresponding demand for cardiac catheterization services will place additional burden on the existing service, already at full capacity.



- Decompression of existing cardiac catheterization labs will be required to avoid a decrease in access for patients and physicians.
- Addition capacity is needed to ensure IFH can continue to provide excellent and timely care for patients.
- The expansion of IFH's cardiac catheterization service will ensure IFH is able to meet the public need.
- The Executive Committee of the Medical Staff of IFH agree to support an additional cardiac catheterization laboratory fully and actively.

### Public Comment

DCOPN provided notice to the public regarding this project inviting public comment on March 8, 2024. The public comment period closed on April 22, 2024. On May 6, 2024, the Health Systems Agency of Northern Virginia (HSANV) held a public hearing. The proposed project was presented by Elizabeth Breen, Counsel for Inova Health System; Andrew Gill, Vice President & Administrator IHSV; and Benham Tehrani, MD, Director, Inova Fairfax Hospital Cardiac Catheterization Laboratory. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to the project.

**(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.**

There is no reasonable alternative to the addition of capacity at IFH. The applicant states that IFH is the largest and busiest hospital in the Commonwealth. IFH serves as the hub for Inova's cardiac and vascular services "with the most advanced technologies and facilities focused on prevention, diagnosis and treatment of heart disease." IFH has received numerous awards over the past three years in cardiovascular care. IFH performs both simple and complex cases for adults and pediatrics. Emergent cases are performed 24 hours a day, 7 days a week with scheduled cases Monday through Friday from 7 a.m. to 5 p.m. IFH has demonstrated an institutional need for an additional cardiac catheterization lab, with high utilization in its seven existing cardiac catheterization labs in 2022 at 146% of the SMFP threshold and 148% of the threshold in 2023. The proposed project is more beneficial than the status quo.

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

The HSANV Board of Directors reviewed at its May 6, 2024, board meeting the COPN application filed by IFH to add one cardiac catheterization laboratory. The board voted 13 in favor, and none opposed to recommend approval of the project. The recommendation was based upon the following findings and conclusions:

- Inova's claim of an institution specific need for additional cardiac catheterization capacity at Inova Fairfax Hospital is well documented. There does not appear to be a practical alternative to the project described.

- IFH's dominant role in the local cardiovascular services market has evolved organically, with considerable public benefit. There is no evident public interest or benefit in limiting its natural growth and development.
- Given the state of the regional cardiovascular services market, and established medical referral patterns, there is no indication that expansion of the IFH cardiac catheterization service would affect other catheterization services negatively.
- Approval of the project would be consistent with the treatment of similar COPN proposals, locally and statewide.

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

Total projected capital costs for the proposed project are \$6,254,596, funded entirely with accumulated reserves, so there are no financing costs involved in the proposed project. The estimated costs are consistent with other recently approved projects to add a cardiac catheterization lab at an established facility. For example, COPN No. VA-04820 was authorized in 2023 to add a catheterization lab at VCU Medical Center in Richmond at a projected cost of \$6.2 million.

The applicant has described several benefits to the proposed project, primarily the decompression of its seven existing cardiac catheterization labs, which have demonstrated utilization of 114.3% adjusted to 146%, including complex therapeutic catheterizations (148% in 2023). The applicant is one of two programs in PD 8 that offer open heart surgery, also making them eligible to perform complex therapeutic cardiac catheterization procedures. As a referral hub for complex cardiac cases, capacity is essential to meeting needs of the referral network in the region.

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

IFH provided charity care in the amount of 3.14% of its gross patient revenue in 2021, the latest year for which such data are available. This is above the HPR II mean of 2.63% for inpatient hospitals (**Table 6**). The applicant's proforma for the proposed project includes charity care at 1.0% of gross revenue; however, the proposal, if approved, is subject to Inova Health Care Services' systemwide condition of 3.9%.

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from cardiac catheterization. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

**Table 6. HPR II Charity Care Contributions: 2021**

Inpatient Hospitals	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	\$1,099,098,713	\$48,200,302	4.39%
Inova Mount Vernon Hospital	\$586,328,215	\$23,515,873	4.01%
Encompass Health Rehab Hospital of Northern Virginia	\$44,352,947	\$1,727,170	3.89%
Inova Loudoun Hospital	\$1,063,559,182	\$34,808,182	3.27%
Inova Fairfax Hospital	\$4,579,299,978	\$143,761,495	3.14%
UVA Health Prince William Medical Center	\$620,916,889	\$19,226,771	3.10%
Inova Fair Oaks Hospital	\$756,218,384	\$23,149,143	3.06%
Sentara Northern Virginia Medical Center	\$943,730,551	\$25,008,347	2.65%
Virginia Hospital Center	\$1,828,402,362	\$35,153,100	1.92%
UVA Health Haymarket Medical Center	\$334,178,317	\$3,397,874	1.02%
Dominion Hospital	\$173,930,124	\$1,370,987	0.79%
Reston Hospital Center	\$1,743,343,281	\$11,983,844	0.69%
StoneSprings Hospital Center	\$352,270,979	\$1,575,166	3.60%
North Spring Behavioral Healthcare	\$65,581,626	\$215,233	0.33%
<b>Total Inpatient Hospitals:</b>			<b>14</b>
<b>HPR II Total Inpatient \$ &amp; Mean %</b>	<b>\$14,191,211,548</b>	<b>\$373,093,487</b>	<b>2.63%</b>

Source: VHI (2021)

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop 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 State Medical Facilities Plan (SMFP).

The State Medical Facilities Plan (SMFP) contains the criteria and standards for cardiac catheterization services. They are as follows:

## Part IV. Cardiac Services

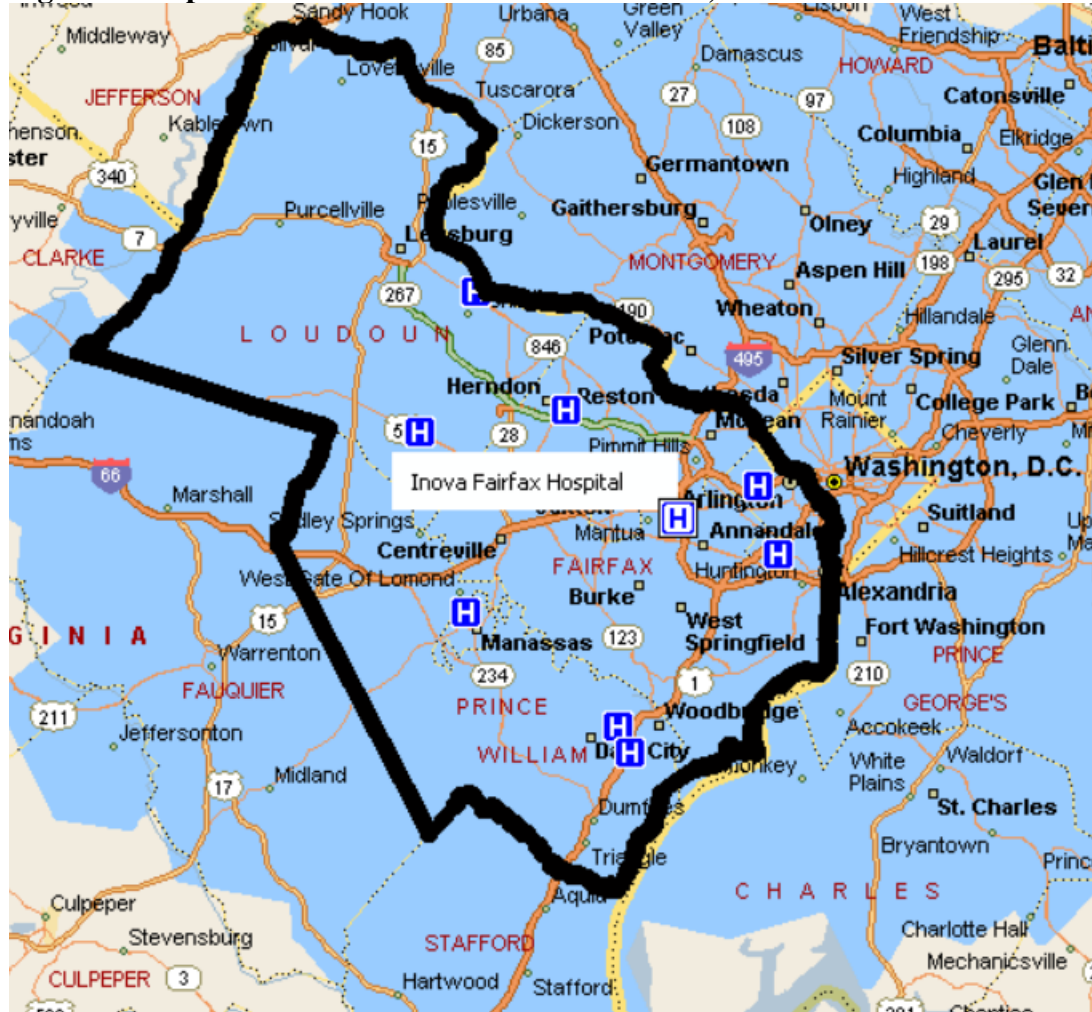
### Article 1. Criteria and Standards for Cardiac Catheterization Services

#### 12 VAC 5-230-380. Travel Time.

Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the Commissioner.

The black outline in **Figure 4** is the border of PD 8. The H symbols represent authorized providers of cardiac catheterization services in the PD, and the white symbol with the blue H is the location of the proposed project at IFH. The blue shading represents the area within 60 minutes' drive time of a PD 8 cardiac catheterization provider and demonstrates that over 95% of the population in PD 8 is already within 60 minutes of cardiac catheterization services.

**Figure 4. Map of Cardiac Catheterization Facilities, PD 8**



**12 VAC 5-230-390. Need for New Service.**

**A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:**

- 1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;**
- 2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation;**
- 3. The utilization of existing services in the health planning district will not be significantly reduced.**

Not applicable. The proposed cardiac catheterization laboratory is an expansion of an existing service rather than a new service. With available data, existing providers in PD 8 operated at 86.8% of the 1,200 DEP threshold in 2022, as described with **Tables 1 & 2**, above; however, data on complex therapeutic cardiac catheterizations performed at VHC are unavailable. It is unlikely that the proposed project will significantly reduce utilization of existing services.

**B. Proposals for mobile cardiac catheterization laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.**

Not applicable. The proposed cardiac catheterization lab is not a mobile service.

**C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPS in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.**

Not applicable. The proposal is for the expansion of an existing cardiac catheterization program.

**12 VAC 5-230-400. Expansion of Services.**

**Proposals to increase cardiac catheterization services should be approved only when:**

**A. All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and**

As reported to VHI in 2022, IFH had a utilization of 1,371 DEPs per cardiac catheterization lab, 114% of this 1,200 DEP threshold (**Table 1**). In the detail that IFH provided in its application (**Table 2**), 243 of the 1,013 adult therapeutic cardiac catheterizations reported to VHI in 2022 were simple, while the remaining 770 were complex therapeutic cardiac catheterizations. Of

pediatric cases, only three of the 66 reported therapeutic catheterizations were simple, while the remaining 63 were complex. The DEP calculation for IFH, with this breakout and application of the updated relative values for the complex therapeutic procedures in the SMFP DEP definition, results in 12,281 DEPs for IFH in 2022. With complex therapeutic procedures broken out, IFH had 1,754 DEPs per cardiac catheterization lab, or 146.2% of this threshold (**Table 2**).

**B. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.**

With no change to IFH's 2022 DEP volume, 12,281 DEPs spread over eight cardiac catheterization labs (the seven existing and the proposed additional lab) is equal to 1,535 DEPs per lab, still 128% of the SMFP threshold. The proposal is unlikely to impact existing cardiac catheterization labs in the PD.

**12 VAC 5-230-410. Pediatric Cardiac Catheterization.**

**No new or expanded pediatric cardiac catheterization should be approved unless:**

- A. The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;**
- B. The applicant can demonstrate that the proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation; and**
- C. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.**

Not applicable. IFH is not proposing to expand pediatric cardiac catheterization services.

**12 VAC 5-230-420. Non-emergent Cardiac Catheterization.**

**A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.**

**The programs shall:**

- 1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;**
- 2. Adhere to strict patient-selection criteria;**
- 3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American**

**College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;**

- 4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;**
- 5. Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;**
- 6. Develop and maintain a quality and error management program;**
- 7. Provide PCI 24 hours a day, seven days a week;**
- 8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and**
- 9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.**

IFH is an established provider of simple therapeutic cardiac catheterization procedures and affirms compliance with each of the requirements in this subsection.

**B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.**

IFH is an established provider of complex therapeutic cardiac catheterization services and does have open heart cardiac services on-site. The applicant affirms that it participates in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

**12 VAC 5-230-430. Staffing.**

- A. Cardiac catheterization services should have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures;**

The medical director of IFH's cardiac catheterization services, Behnam Tehrani, MD, meets this standard.

- B. In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.**

The medical director for IFH's existing pediatric catheterization services is Catherine Tomasulo, MD, and she meets this criterion.

**C. Cardiac catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience performing physiologic and angiographic procedures.**

The applicant provided assurances that cardiac catheterization services at IFH are under the direct supervision of board-certified physicians with clinical experience in the performance of physiologic and angiographic procedures.

**D. Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.**

IFH has provided assurances that its existing pediatric catheterization direct supervision meets this requirement.

**12 VAC 5-230-80. When Institutional Expansion Needed.**

**A. Notwithstanding any other provisions of this chapter, the Commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceed its current services capacity to provide such service or on the geographic remoteness of the facility.**

IFH has demonstrated an institutional need to expand its cardiac catheterization service by adding an eighth cardiac catheterization lab, based on utilization exceeding the SMFP threshold of 1,200 DEPs in 2022. **Table 1** shows utilization at 114% of the threshold before applying the revised DEP definition that adds DEP multipliers for complex therapeutic cardiac catheterization procedures. Once the DEP calculation is updated with these multipliers, IFH's DEPs were 1,754 per catheterization lab in 2022 (**Table 2**) and 1,779 per catheterization lab in 2023.

**B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.**

IFH is part of Inova Health Care Services, and two other Inova facilities offer cardiac catheterization services in PD 8. Neither is underutilized. Inova Alexandria Hospital operated at 69.0% of the SMFP threshold for DEPs in 2022, and Inova Loudon at 78.6% (**Table 1**).

**C. This section is not applicable to nursing facilities pursuant to §32.1-102.3:2 of the Code of Virginia.**



Not applicable. The proposed project is not part of a nursing facility.

**D. Applicants shall not use this section to justify a need to establish new services.**

Not applicable. The cardiac catheterization service at IFH is an existing service.

**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.**

The proposal addresses an institutional need and does not foster institutional competition.

**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.**

IFH is the largest and busiest hospital in PD 8, offering tertiary/quaternary health services for adults and children. It is the referral hub for cardiac services from the other Inova hospitals as well as more than two dozen others in the regional network. Inova Health Care Services owns and operates eleven of the 22 cardiac catheterizations in PD 8. Of these Inova facilities, only IFH offers open heart surgical services and complex therapeutic cardiac catheterization services.

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

The proposed project is feasible in the immediate and long-term. Capital costs are reasonable and consistent with recently authorized, similar projects and will be funded with accumulated reserves. The proforma for the proposed additional catheterization lab (**Table 7**) shows that it will have an excess of revenue over expenses starting with year one. Though health care personnel are increasingly difficult to recruit, a modest 5.5 additional staff members will be needed to implement the proposal, which IFH is likely to accomplish with its stated recruitment strategies.

**Table 7. Proforma Inova Fairfax Hospital, Addition of one Cardiac Catheterization Lab (Project Only)**

	<b>Year 1</b>	<b>Year 2</b>
<b>Gross Revenue</b>	\$ 71,202,458	\$ 97,419,389
Charity Care	\$ 712,025	\$ 974,194
Contractual Deductions	\$ 41,719,276	\$ 57,086,593
<b>Net Revenue</b>	\$ 28,771,157	\$ 39,358,602
<b>Expenses</b>	\$ 25,011,859	\$ 33,823,136
<b>Income/Loss</b>	\$ 3,759,298	\$ 5,535,466

Source: COPN Request No. VA-8747

- 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 proposal does not provide innovations in the financing of health services nor propose the provision of cardiac catheterization services on an outpatient basis. IFH asserts that it has the most advanced technology in the region across a broad range of highly specialized, innovative cardiovascular techniques. It offers tertiary and quaternary services for adults and children and participates in clinical trials, “consistently among the first U.S. hospitals trusted to study the latest advances in heart and vascular disease treatments.”

- 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.**

Inova’s website states that IFH is “an independent academic medical center and serve as a regional medical school campus,” also providing residency and fellowship training programs for physicians, both independently and through multiple graduate medical education partnerships.

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

IFH is an important provider of services in PD 8 and the greater region and a hub for referrals to advanced cardiac services. The proposed project will not expand geographic access to cardiac catheterization services in PD 8 but will improve access to the highly utilized cardiac catheterization services at IFH. The location of the proposed project is highly populated and fast-growing, which is expected to drive additional demand for cardiac catheterization services in the future. The proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.

The proposed project has support from the public, especially its medical community. The HSANV recommended approval and there is no known opposition to the proposal. The applicant has demonstrated an institutional need for expansion of its cardiac catheterization services and there appears to be no reasonable alternative to the proposed project. The proposal is more beneficial than the status quo and it is unlikely to impact existing providers significantly.

Projected capital costs are reasonable and the proposal is wholly feasible in the immediate and long-term. Modest additional staffing is required.

**DCOPN Staff Recommendations**

The Division of Certificate of Public Need recommends conditional approval of Inova Fairfax Hospital's COPN Request number VA-8747 to expand its cardiac catheterization services with one additional cardiac catheterization lab in Falls Church, Virginia for the following reasons:

1. The proposal to add an eighth cardiac catheterization laboratory at Inova Fairfax Hospital is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. The applicant has demonstrated an institutional specific need for cardiac catheterization capacity and the proposal will improve access to highly utilized services in a populated and fast-growing area.
3. There is no reasonable alternative identified and the proposal is more beneficial than the status quo.
4. The projected capital costs of the proposed project are reasonable.
5. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of cardiac catheterization services in PD 8.
6. The proposed project appears to be wholly feasible in the immediate and long-term.
7. The Health Systems Agency of Northern Virginia recommended approval of the proposed project.
8. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Inova Health Care Services d/b/a Inova Fairfax Hospital's agreement to the following charity care condition. Inova Health Care Services d/b/a Inova Fairfax Hospital falls under Inova's systemwide charity condition, 3.9%.

Inova Health Care Services d/b/a Inova Fairfax Hospital will provide cardiac catheterization services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount equal to at least 3.9% of Inova Health Care Services d/b/a Inova Fairfax Hospital's gross patient revenue derived from cardiac catheterization 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. Inova Health Care Services d/b/a Inova Fairfax Hospital will accept the revised Inova systemwide charity condition based on 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. when it 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.

Inova Health Care Services d/b/a Inova Fairfax Hospital will provide cardiac catheterization services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Inova Health Care Services d/b/a Inova Fairfax Hospital will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.