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TO: **Board of Directors, HSA of Northern Virginia**
Project Review Committee, HSANV
Interested Parties

FROM: **Dean Montgomery**

SUBJECT: **Inova Fairfax Hospital**
Expand Cardiac Catheterization Service
(COPN Request # VA-8747)

I. Background and Summary of the Proposal

A. Background

Cardiovascular disease is the leading cause of disability and death, locally and nationwide. Cardiac catheterization is used to diagnose and treat some forms of the disease, notably coronary heart disease (also called coronary artery disease) which accounts for about half of cardiovascular disease. It is a diagnostic procedure that is used to confirm the presence of coronary artery disease, to deliver therapeutic agents to disease sites, and to evaluate the results of cardiac surgery. It involves inserting catheters (thin plastic tubes), into peripheral veins or arteries (usually those of the legs or arms) and threading them through these vessels back to the heart where their position is determined using fluoroscopy (continuous motion X-ray). Contrast media, drugs and other therapeutic agents may be delivered to the heart and coronary arteries in this way, permitting physicians to evaluate the heart and its blood vessels.

Advanced coronary artery disease is associated with increased probability of heart attack (acute myocardial infarction or AMI) and sudden death. Physicians use information obtained by cardiac catheterization in deciding whether to recommend medical or surgical therapy. Cardiac surgery may be an "open heart" or a "closed heart" procedure. Open heart refers to surgical procedures in which a mechanical pump temporarily performs the function of the patient's heart, allowing the surgeon to repair a lesion within the heart or the coronary arteries. Closed heart procedures do not require the use of a mechanical pump.

Initially used largely to confirm and evaluate coronary artery disease, cardiac catheterization increasingly is used therapeutically. In therapeutic catheterization, often referred to as coronary angioplasty or percutaneous coronary interventions (PCI)[1], catheters are used to deliver drugs and mechanical implements to the heart and its blood vessels.

The increasing utility of therapeutic catheterization has expanded the range of treatment options available to those with coronary artery disease. Use of this treatment alternative has reduced reliance on cardiac surgery, eliminating the need for surgery for many patients. The percentage of those having cardiac surgery shortly after diagnostic catheterization has decreased, as the percentage of those receiving therapeutic catheterization has grown. The number and percentage of catheterization patients receiving therapeutic procedures have increased over the last couple of decades. Therapeutic catheterizations of all types now constitute about one-third of the cardiac catheterizations performed in northern Virginia.

Specialized cardiac services are now offered at eight of Northern Virginia's eleven acute care community hospitals. Inova Fairfax Hospital and Virginia Hospital Center offer cardiac catheterization and cardiac surgery. [2] Inova Alexandria Hospital, Inova Loudoun Hospital, Prince William Medical Center, Sentara Northern Virginia Medical Center, Reston Hospital Center, and Stone Springs Hospital Center offer cardiac catheterization but not cardiac surgery.

Table 1 and Table 2 below show the capacity and use of Northern Virginia cardiac catheterization services between 2016 and 2022.

B. Summary of the Proposal

Inova Fairfax Hospital (IFH) seeks COPN authorization to expand its cardiac catheterization service, to add an eighth laboratory. The new lab would be placed in renovated space within the existing catheterization service.

Projected capital costs are $6,254,596. About $3.62 million would be direct construction expenses and about $1.96 million for equipment. The remainder, about $682,000, would be professional fee expenses. Capital costs would be paid from internal Inova Health System funds. There would be no project specific borrowing or other direct financing expense.

Table 1 and Table 2 below show recent capacity and service volumes of Northern Virginia cardiac catheterization services. Map 1 shows the locations of northern Virginia hospitals, with cardiac catheterization programs.

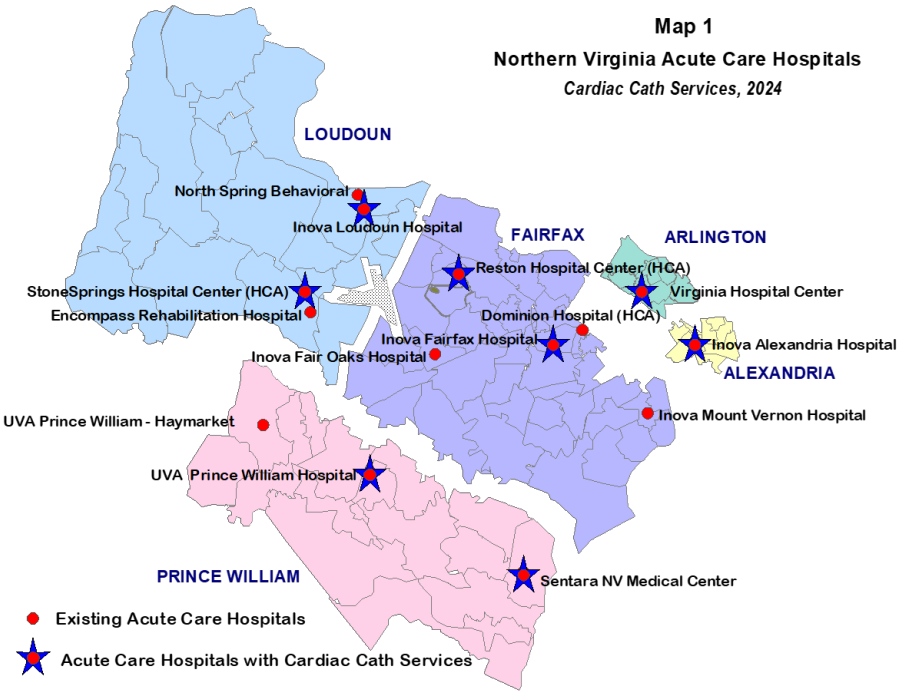
Inova Fairfax Hospital justifies the proposal on the grounds that:

- Inova Fairfax Hospital's cardiac catheterization laboratories are used heavily. Average annual caseloads are substantially above the service volume planning guidelines specified in the Virginia State Medical Facilities Plan (SMFP).

[1] The term PCI as used here includes percutaneous transluminal coronary angioplasty (PTCA).
[2] Reston Hospital Center obtained COPN approval for an open-heart surgery program in 2023. That service is expected to open soon.

- There is no excess or unused capacity within Inova Health System that can be used or reallocated to respond to increasing demand at Inova Fairfax Hospital.
- The project will permit Inova Fairfax Hospital to operate more efficiently and respond to current and near-term demand.
- There is no indication that adding catheterization capacity at Inova Fairfax Hospital to meet current and near-term demand, would affect competing services negatively.
- The project is consistent with applicable provisions of the Virginia SMFP, notably the institutional need provision (Section 12VAC5-230-80) of the plan.

If authorized on schedule, the new laboratory is expected to be placed in service in September of 2025.



II. Discussion

A. Community Need

Specialized cardiac services are widely available in northern Virginia and the Washington, D. C. metropolitan area. Eight of northern Virginia's eleven acute care community hospitals have cardiac catheterization programs. Two hospitals, Inova Fairfax Hospital and Virginia Hospital Center (VHC), offer both cardiac catheterization and open-heart surgery. These hospitals have the higher cardiac catheterization caseloads. In 2022 they served nearly two-thirds (63%) of those obtaining heart catheterizations at local programs (Table 1).

Table 1
Cardiac Catheterization Services
Northern Virginia Hospitals, 2016 - 2022

Hospital	Cath Labs (2023)	2016	2017	2018	2019	2020	2021	2022	Change 2016- 2022	Visits per Lab (2022)
Inova Alexandria Hospital	2	1,295	1,329	1,290	1,281	951	1,214	1,103	-14.8%	552
Inova Fairfax Hospital	7	4,335	4,414	5,097	5,170	4,465	6,113	6,232	43.8%	890
Inova Loudoun Hospital	2	785	829	872	800	772	968	1,176	49.8%	588
Reston Hospital Center	2	686	773	839	877	703	789	712	3.8%	356
Sentara Northern Virginia Medical Ce	2	772	994	1,003	1,075	888	1,024	935	21.1%	468
Stone Springs Hospital Center[1]	1	20	34	44	46	31	-	1	-95.0%	1
UVA Prince William Medical Center	2	667	865	1,050	951	888	958	946	41.8%	473
Virginia Hospital Center	4	1,535	2,046	2,336	2,198	2,336	2,900	2,199	43.3%	550
Total	22	10,095	11,284	12,531	12,388	11,034	13,966	13,304	31.8%	605

Source: VHI, ALSD, 2016 - 2022

[1] The StoneSprings cardiac catheterization laboratory is a replacement for the laboratory operated by Northern Virginia Community Hospital (NVCH) which closed in 2006 and was replaced by StoneSprings Hospital Center in 2015. The NVCH catheterization service was established in the early 1990's when major medical equipment was temporarily removed from COPN regulation. The serivce never has had significant use.

Six local hospitals, Inova Alexandria Hospital, Inova Loudoun Hospital, UVA Prince William Medical Center, Reston Hospital Center, Sentara Northern Virginia Medical Center, and StoneSprings Hospital Center offer cardiac catheterization but not cardiac surgery.[3] After more than a decade of relative stability in cardiac catheterization service volumes, demand increased by about 32% between 2016 and 2022 (Table 1), a compound annual growth rate of 4.7%. About 80% of the increase was at Inova Fairfax Hospital and Virginia Hospital Center, 59% at Inova Fairfax and 21% at VHC.

Inova Fairfax Hospital's catheterization caseload grew by about 44% during this period, a gain of 1,897 cases. The hospital reported serving 4,232 cardiac catheterization patients in 2022, a regional market share of 47%.

Table 2. Northern Virginia Cardiac Catheterization Services
Capacity and Service Volumes, 2022

Hospital	Cath Labs (2023)	*Cardiac Catheterization Patient Visits*	*Patient Visits/ Catheterizations per laboratory*	*Diagnostic Equivalent Catheterizations (DEPs)*[3]	*Other Visits/ Procedures*[1]	*Total Caseload (Cardiac Cath and Other Procedures)*	*Catheterization Patients/Cases per laboratory*	*Diagnostic Equivalent Catheterization Procedures per Laboratory*	*Total Cases/Procedures per Catheterization Laboratory*
Inova Alexandria Hospital	2	1,103	552	1,654	283	1,937	552	827	969
Inova Fairfax Hospital	7	6,232	890	11,693	843	12,536	890	1,670	1,791
Inova Loudoun Hospital	2	1,176	588	1,885	488	2,373	588	943	1,187
Reston Hospital Center	2	712	356	1,230	228	1,458	356	615	729
Sentara Northern Virginia Medical Center	2	935	468	1,291	101	1,392	468	646	696
StoneSprings Hospital Center[2]	1	1	0	2	1	3	1	2	3
UVA Prince William Medical Center	2	946	473	1,300	437	1,737	473	650	869
Virginia Hospital Center	4	2,199	550	5,222	1,331	6,553	550	1,306	1,638
Total	22	13,304	605	24,277	3,712	27,989	605	1,104	1,272

Source: VHI, ALSD, 2022; Tabulations, HSANV.

[1] Includes procedures such as cardiac pacemaker implantation and electrophysiological studies.

[2] The StoneSprings cardiac catheterization laboratory is a replacement for the laboratory operated by Northern Virginia Community Hospital (NVCH) which closed in 2006 and was replaced by StoneSprings Hospital Center in 2015. The NVCH catheterization service was established in the early 1990's when major medical equipment was temporarily removed from COPN regulation. The serivce never has had significant use.

[3] "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.) same session procedure (diagnostic and therapeutic) equals 3 DEPs, and a pediatric procedure equals 2 DEPs.

[3]The low-volume Inova Alexandria Hospital open-heart service closed in 2018. Reston Hospital Center obtained COPN authorization to establish an open heart surgery service in 2023. It is expected to open soon.

The mix of cardiac catheterization procedures reported by Inova Fairfax Hospital in 2022 equates to 1,670 diagnostic equivalent catheterization procedures (DEPs) per laboratory.[4] This workload is about 140% of the nominal service volume standard of 1,200 DEPs per laboratory. Combined with non-cardiac catheterization procedures performed in its laboratories (e.g., electrophysiological studies), the total Inova Fairfax DEP count was 1,791 per laboratory, roughly 149% of the planning standard (Table 2). Inova Fairfax reported 890 patient visits per lab, the highest use in the region and about 47% more than the northern Virginia average.

Planning Guidance

Virginia State Medical Facilities Plan (SMFP) planning guidance addresses the question of community (regional) need for cardiac catheterization services. The applicable plan sections read:

Criteria and Standards for Cardiac Catheterization Services

"12VAC5-230-390. 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; and

3. The utilization of existing services in the health planning district will not be significantly reduced.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such 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.

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." **Source: Virginia SMFP, p, 18**

[4] The Virginia COPN program definition of DEP reads: "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)". **Source: Virginia COPN Regulations, Definitions**

12VAC5-230-400. Expansion of services.

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

1. 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

2. 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." **Source: Virginia SMFP, pp, 18-19**

Section 12VAC5-230-400.1 applies to the Inova Fairfax proposal. As shown in Table 2, recent regional cardiac catheterization service volumes, measured against Virginia State Medical Facilities Plan (SMFP) service volume guidelines, indicate there is no regional need for additional cardiac catheterization services or an additional cardiac catheterization laboratory The average annual DEP workload per authorized laboratory in recent years has been below the target minimum service volume of 1200 catheterizations per laboratory.[5]

Inova Fairfax Hospital Perspective and Rationale

Inova does not assert, or otherwise suggest, that there is a regional need for additional cardiac catheterization capacity, but rather that the Inova Fairfax Hospital, the most heavily used local facility has an "institutional need" for additional capacity as permitted under section (12VAC5-230-80) of the Virginia SMFP. That provision reads:

"12VAC5-230-80. 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 exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.

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.

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

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

Inova cites the high catheterization laboratory use at Inova Fairfax Hospital (IFH), substantially higher than the nominal 1200 DEPs per laboratory specified in the Virginia SMFP, as justification for the

[5] The regional average in 2022 was reported to be 1,104 DEPs, about 8% below the nominal regional service volume/workload guideline of 1200 DEPs per laboratory. If the problematic StoneSprings Hospital Center service is set aside, the 2022 regional average was about 5% below the minimum service volume threshold.

proposal. It also emphasizes that the IFH catheterization caseload continues to grow, and that additional capacity is needed now to serve the existing caseload. Inova Fairfax catheterization service volumes will remain above the planning guidelines, even with the additional laboratory requested.

The institution specific need claim is well documented. Inova Fairfax qualifies for consideration to add a catheterization laboratory based on its recent service volumes, and its service volume growth rate, regardless of the capacity and use levels at other services.

B. Access Considerations

Northern Virginians have good access to specialized cardiac care services. Existing cardiac catheterization programs are widely distributed. Multiple services are available to most residents within 30 minutes of travel. The Inova Fairfax service, which has one-third of the region's supply (seven of the twenty-one active labs), serves about one-half of regional demand, 47% in 2022. It offers the widest array of services. Inova Fairfax's stability and efficiency are key to assuring access to advanced cardiovascular care in the region.

Inova Health System has acceptable charity care policies and practices. It serves patients equitably regardless of their ability to pay or source of payment. As an expansion of its current service, adding a catheterization laboratory at Inova Fairfax would not change appreciably geographic or economic access to cardiovascular care. It would contribute to maintaining access and current service offerings.

It would reinforce Inova Fairfax Hospital's dominant market position, but this is no indication that the project would affect other services negatively.

C. Cost Considerations

Inova Fairfax Hospital proposes a capital outlay of $6,254,596 to add a cardiac catheterization laboratory. About $3.62 million would be direct construction expenses. New equipment and technology would cost an additional $2.10 million. All development costs, including an additional $682,000 in professional fees, would be paid from internal Inova Health System funds. There would be no direct borrowing or other program specific financing expense.

The capital investment is substantial but not unusually high. It is within the capital expense range seen for comparable projects locally and elsewhere in Virginia. Projected costs and charges for cardiac catheterization at Inova Fairfax are competitive with those of other cardiac catheterization services, locally and elsewhere in Virginia. The project would not change the competitive landscape in a noticeable or measurable way.

Cardiac catheterization services are costly, both to develop and to maintain. They are also highly profitable even at low service volumes. The *proforma* budget for the project shows a profit of about $3.8 million in year one and about $5.5 million in year two. These are extraordinary returns on the $6.3 million investment. These estimates assume that the laboratory added would be used largely to perform complex therapeutic catheterization procedures.[6]

[6] The Virginia COPN program definition of complex therapeutic catheterization reads: "Complex therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of correcting or

D. Health System Considerations

Though there is unused capacity at several northern Virginia cardiac catheterization programs, there is no true excess capacity. Seven of the region's eight services have two or more catheterization laboratories. These services added a laboratory when their caseload exceeded the nominal service planning standard of 1200 DEPs per laboratory. All capacity added over the last two decades has been authorized based on institutional need, rather than a general regional need. Capacity increases is this manner builds into the system reserve capacity at each facility.

The Virginia SMFP planning guidelines treat these large stepwise increases in capacity as fungible, authorized to serve the regionwide population and demand. They are not. Most of the capacity added in this way remains unused until organic growth at that facility catches up with the capacity increase.

In short, other than the superfluous StoneSprings Hospital Center catheterization laboratory, there is no significant excess or surplus cardiac catheterization capacity in the region.

III. Conclusions and Alternatives for Agency Action

A. Conclusions

Cardiac catheterization services are available throughout Northern Virginia. Only three local hospitals, Inova Fair Oaks, Inova Mount Vernon Hospital, and UVA Prince William Haymarket do not offer the service. Northern Virginia cardiac catheterization use rates are inherently low. Though demand has increased significantly over the last five years, average use of existing services is less than two-thirds of recommended service volume standards. As defined by the Virginia SMFP catheterization laboratory algorithm, there is no demonstrated public need for additional cardiac catheterization services or catheterization laboratories. There is no indication of suppressed demand for, or limited access to, cardiac care.

Inova Fairfax Hospital's cardiac catheterization service is the largest and most heavily used in the region. It serves about half of those obtaining catheterization each year. Current and projected service volumes exceed substantially region service planning guidelines. The hospital has a documented internal need for additional capacity to accommodate current and projected demand.

Inova Fairfax Hospital qualifies for consideration to add cardiac catheterization capacity in accordance with the institutional need provision of the Virginia SMFP. There is no indication that adding a laboratory at IFH is likely to affect other service providers negatively.

B. Alternatives for Agency Action

1. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a certificate of public need authorizing the project be granted.

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improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart, specifically catheter-based procedures for structural treatment to correct congenital or acquired structural or valvular abnormalities.

A recommendation for approval could be based on concluding:

- The Inova Fairfax Hospital cardiac catheterization service is the largest and most heavily used service in the region. It consistently has caseloads substantially above the nominal service volume planning guidelines, with the highest DEP per laboratory count in the region.
- It is evident that additional capacity is needed to respond to current demand.
- Inova Fairfax Hospital has an institution specific need for additional capacity as that SMFP provision has been applied locally and elsewhere in Virginia.
- It is evident that the laboratory requested would be used efficiently upon installation.
- Given the nature and location of the project it is not likely to affect other cardiovascular services programs negatively.

2. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need authorizing the project not be granted.

A recommendation for denial could be based on concluding:

- There is no regional need for an additional cardiac catheterization laboratory.
- Inova Fairfax Hospital's qualification for consideration to expand its service does not equate to a community (regional) need for additional capacity.
- The proposed capital outlay is unnecessary given the availability of unused capacity at other cardiac catheterization programs, two of which are within Inova Health System.

IV. Checklist of Required Considerations

1. Maintain or Improve Access to Care

Adding cardiac catheterization capacity at Inova Fairfax Hospital is warranted to maintain access to the service at IFH and to permit efficient operations. Arguably, adding needed capacity at IFH would help assure continued access.

Inova Health System has acceptable charity care policies and practices. There would be no change in this policy or practice. Economic access to care among uninsured and low-income residents would not change.

2. Meet Needs of Residents

Inova Fairfax Hospital is an established provider of acute care hospital services, including cardiac catheterization. It is the major provider of cardiovascular services in the region. It has a well-defined service area and service delivery profile.

There is no indication or suggestion that the hospital is not trying to meet the identified needs of the communities and populations it serves. The project will not alter this commitment or practice. Arguably, it is necessary to permit the hospital to maintain an efficient, responsive cardiovascular service.

3. Consistency with Virginia State Medical Facilities Plan (SMFP)

The public need algorithm specified in the Virginia State Medical Facilities Plan does not indicate a regional need for an additional cardiac catheterization laboratory. Nevertheless, it is evident that Inova Fairfax Hospital needs additional capacity to respond to current and near-term demand. It has demonstrated an institutional need for additional cardiac catheterization capacity as that provision has been applied to similar proposals over the last two decades.

4. Beneficial Institutional Competition while Improving Access to Essential Care

The project would not introduce a new service provider. There is no indication, or reason to believe, that expanding the Inova Fairfax cardiac catheterization program would affect meaningfully or measurably the intraregional competition. It is essentially a maintenance of effort proposal.

5. Relationship to Existing Health Care System

Inova Fairfax Hospital is the major provider of cardiovascular care in the region. It is the largest, and by most measures the most efficient, local provider of catheterization services. Expanding the service to meet current demand is not likely to have noticeable health system effects. There is no indication, or expectation, that expanding the program as proposed would negatively affect any other service.

6. Economic, Financial Feasibility

Though relatively expensive at about $6.3 million, the project is financially feasible. Capital costs would be paid for from internal Inova Health System funds. The implied financing costs are roughly equivalent to the commercial bond rate for creditworthy borrowers. It is likely that the project would be profitable immediately, with a high rate of return on the investment.

7. Financial, Technological Innovations

The proposal does not entail innovative technologies, practices, or economic elements that warrant special consideration.

8. Research, Training Contributions and Innovations

The project does not have notable research or training elements that warrant special consideration.