

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

November 19, 2019

COPN Request No. VA-8461

Loudoun Hospital Center

Loudoun County, Virginia

Add a Second Cardiac Catheterization Laboratory on the Inova Loudoun Hospital Campus

Applicant

Inova Loudoun Hospital (ILH) is a 501(c) (3) Virginia nonstock corporation organized in 1988. ILH is an incorporated division of Inova Health Care Services, Inc. (which does business as Inova Health System), which is also a 501(c)(3) Virginia nonprofit, nonstock corporation. The sole member of Inova Health System is the Inova Health System Foundation, Inc. The Inova Health System's offices are located in Falls Church, Virginia. ILH is located in Leesburg (Loudoun County), Virginia, which is in Planning District (PD) 8 of Health Planning Region (HPR) II.

Background

ILH operates a 183-bed community hospital in the suburbs of Loudoun County in Leesburg, Virginia. ILH provides a full range of services, including a designated trauma center, pediatric emergency room, comprehensive women's care, a Level III neonatal intensive care unit, and comprehensive cardiovascular services. ILH has been providing cardiac catheterization services since 2005, pursuant to COPN No. VA-03890.

According to the 2017 Virginia Health Information (VHI) data, the most recent year for which such data is available, and DCOPN records, there are 19 stationary cardiac catheterization laboratories in PD 8 (Table 1). Of the 19 cardiac catheterization laboratories, 18 are currently operating and one is expected to open within two weeks. In July 2018, Novant Health UVA Health System Prince William Medical Center received COPN No. VA-04604 to add a second cardiac catheterization laboratory in PD 8. The expected date of completion is December 1, 2019. As such, the current total PD 8 cardiac catheterization laboratory inventory is effectively 19. As shown in Table 2, utilization of cardiac catheterization laboratories in PD 8 ranged from a high of 84% of the State Medical Facilities Plan (SMFP) standard in 2017 to a low of 74% in 2014. In 2017, utilization of these laboratories reached 84% of available capacity.

Table 1. Cardiac Catheterization Laboratory Inventory and Utilization by Facility in PD 8

Facility	Cardiac Catheterization Labs	Total DEPs	Utilization
Inova Alexandria Hospital	2	2,321	97%
Inova Fairfax Hospital	7	6,457	77%
Inova Loudoun Hospital	1	1,429	119%
Novant Health UVA Health System Prince William Medical Center*	2	1,434	120%
Reston Hospital Center	1	1,399	117%
Sentara Northern Virginia Medical Center	2	1,432	60%
Stone Springs Hospital Center	1	45	4%
Virginia Hospital Center	3	3,607	100%
Total	19	18,124	84%

Source: VHI (2017)

*In July 2018, Novant Health UVA Health System Prince William Medical Center received COPN No. VA-04604 to add a second cardiac catheterization laboratory. The expected date of completion is December 1, 2019.

Table 2. Cardiac Catheterization Utilization in PD 8, 2013-2017

Diagnostic Equivalent Procedures						
Year	Cath Labs	Diagnostic	Therapeutic	Same Session	Total DEPs	Utilization
2013	16	6,284	2,342	6,987	15,613	81%
2014	16	5,776	1,222	7,239	14,237	74%
2015	16	5,918	1,346	7,302	14,566	76%
2016	17	6,701	1,576	8,082	16,359	80%
2017	18	7,315	2,196	8,613	18,124	84%

Source: VHI (2013-2017)

Note: Utilization rate based on SMFP expansion standard of 1,200 cardiac catheterization Diagnostic Equivalent Procedure (DEP) per laboratory.

As shown in Table 3, in the five-year period ending in 2017, total Cardiac Catheterization diagnostic equivalent procedures (DEPs) at ILH increased by 11%, with an increase of 14% when you also consider the increase in non-cardiac catheterization procedures performed in the catheterization laboratory.

Table 3. Adult Cardiac Catheterization Utilization (in DEPs) at ILH, 2013-2017

	2013	2014	2015	2016	2017	% Change
Diagnostic	354	361	381	397	515	45%
Therapeutic	106	24	10	32	56	-47%
Same Session	822	804	840	1,116	858	36%
Total Cardiac Cath DEPs	1,282	1,189	1,231	1,545	1,429	11%
Utilization /Lab	107%	99%	103%	129%	119%	
Non Cardiac Cath Procedures	274	265	292	349	353	29%
Total	1,556	1,454	1,523	1,894	1,782	14%

Source: VHI (2017)

Note: Non-Cardiac Cath procedures have not been converted to DEPs.

Proposed Project

ILH is requesting authorization to expand its cardiac catheterization service by converting its existing 678 square foot electrophysiology (EP) laboratory to a dual purpose EP and cardiac catheterization laboratory. This would result in two cardiac catheterization laboratories at ILH. ILH currently provides EP service in a dedicated EP laboratory using a Philips FD10 fluoroscopy unit, which was acquired in 2017, and is cardiac catheterization capable. ILH proposes to commence using the existing EP laboratory and equipment to perform cardiac catheterization services immediately upon COPN approval. The applicant asserts that no equipment, software, construction or renovations are needed. Consequently, there are no capital costs for the proposed project.

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 of care.**

Geographically, ILH is located just off VA SR 7, which intersects with US 495, approximately twenty minutes by car from the facility. Public transport to the facility is readily available. Public bus transportation is available near the main patient entrance and metro rail is available at the West Falls Church Metro Station via the Fairfax Connector and Loudoun Commuter bus services.

According to the SMFP, reasonable access to cardiac catheterization services is determined on an HPR basis. Therefore, access is determined by the availability of cardiac catheterization services within 60 minutes driving time under normal conditions of 95% of the population living in HPR II. Note that HPR II consists of a single planning district, PD 8.

The heavy black line in **Figure 1** identifies the boundaries of PD 8. The light blue shading illustrates the area that is within a 60-minute driving time under normal driving conditions of existing cardiac catheterization services. The dark blue line illustrates the area that is within a 60-minute driving time of ILH. DCOPN concludes that **Figure 1** clearly illustrates that cardiac catheterization services are already well within a one-hour drive under normal conditions for all residents of the planning district. While traffic congestion is a regular complaint of those attempting to navigate the major travel arteries of HPR II, because the proposed project

Population also plays a major role in determining the need for certain medical services in a planning district. Table 4 shows projected population growth in PD 8 through 2030.

Table 4. Population Projections for PD 8, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Chg	2030	% Change 2020-2030	Avg Ann % Chg 2020-2030
Alexandria City	139,966	166,261	18.79%	1.69%	182,067	9.51%	0.91%
Arlington County	207,627	249,298	20.07%	1.80%	274,339	10.04%	0.96%
Fairfax City	22,565	25,047	11.00%	1.02%	26,397	5.39%	0.53%
Fairfax County	1,081,726	1,162,504	7.47%	0.71%	1,244,025	7.01%	0.68%
Falls Church City	12,332	14,988	21.54%	1.92%	17,032	13.64%	1.29%
Loudoun County	312,311	430,584	37.87%	3.18%	554,808	28.85%	2.57%
Manassas City	37,821	43,099	13.96%	1.28%	46,332	7.50%	0.73%
Manassas Park City	14,273	17,086	19.71%	1.77%	20,284	18.72%	1.73%
Prince William County	402,002	478,134	18.94%	1.71%	571,844	19.60%	1.81%
Total PD 8	2,230,623	2,587,000	15.98%	1.46%	2,937,128	13.53%	1.28%
PD 8 65+	192,589	300,491	56.03%	4.44%	413,269	37.53%	3.24%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

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

As depicted in Table 4, Weldon-Cooper projects that the total population of PD 8 will increase by approximately 16% from 2010 to 2020 and by approximately 14% from 2020 to 2030. Overall, the planning district is projected to add an estimated 356,377 people in the 10-year period ending in 2020—an increase of approximately 35,638 people annually. Regarding the 65+ age group for PD 8, Weldon-Cooper projects a more rapid increase in population growth (an approximate 56% increase from 2010 to 2020 and approximately 38% from 2020 to 2030). This is significant as this population group typically uses health care resources, including cardiac services, at a rate much higher than those individuals under the age of 65 do. When compared to statewide population projections for the same period, it is evident that the population of PD 8 is increasing a much faster rate than Virginia as a whole. Weldon-Cooper projects that statewide, the total population will increase by approximately 8% from 2010 to 2020 and by another

approximately 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.

Most of the population increase in PD 8 is attributed to Fairfax County, Prince William County, and Loudoun County. With a projected population of 430,584 in 2020, up from 312,311 in 2010, Loudoun County, where the proposed project would be located, has the third largest population base in the Planning District. It is projected that by 2020, nearly 17% of the population of PD 8 will live in Loudoun County, which is projected to grow at a rate of 3.18% annually. According to the applicant, 75% of its cardiac catheterization patients originate from Loudoun County and expansion of cardiac catheterization services is necessary to add much needed capacity to support existing and future demand for adult cardiac catheterization services.

DCOPN did not identify any other unique geographic, socioeconomic, cultural, transportation, or other barriers to care in the planning district.

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;

The applicant provided four letters of support for the proposed project from physicians associated with the Inova Healthcare System. Collectively, these letters discussed the importance of decompressing overutilization of ILH's existing lab, providing timely diagnoses and the effect that continued population growth will have on the need for cardiac catheterization services. Additionally, the letters articulated the need to decrease delays in patient care, eliminate prolonged workdays for staff and prevent longer stays in intake and recovery areas.

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

A public hearing for the proposed project was held by the Health Systems Agency of Northern Virginia (HSANV) on October 7, 2019. Representatives for Inova Health System presented the project. No members of the public provided testimony. The minutes of this public hearing are included in the HSANV record for the proposed 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;

As stated above, ILH, which is part of the Inova Health System, has experienced a noticeable increase in total cardiac catheterization laboratory utilization in the past five years. DCOPN recognizes that one possible alternative would be to transfer cardiac catheterization services from Inova Alexandria Hospital (IAH) or Inova Fairfax Hospital (IFH). However, in 2017, IAH performed 2,231 DEPs in its two cardiac catheterization laboratories, operating at a utilization of

97%. Also in 2017, IFH performed 6,457 DEPs in its seven cardiac catheterization laboratories, operating at a utilization of 77%. DCOPN notes that if IFH were to transfer one of its cardiac catheterization laboratories to ILH, IFH's utilization would reach approximately 90%, likely creating an institutional need for expanded cardiac catheterization services at IFH. Therefore, DCOPN concurs with the applicant, that it is not appropriate to reallocate services from IAH or IFH because the cardiac catheterization laboratories at those facilities are appropriately utilized.

DCOPN also observes that in 2017, the 18 cardiac catheterization laboratories in PD 8 were operating at 84% utilization and that maintaining the status quo could be an alternative to the proposed project. However, while underutilized capacity of other cardiac catheterization laboratories in PD 8 could accommodate any increase in cardiac catheterization procedures for the foreseeable future, the status quo would not allow for the decompression on the utilization of the one cardiac catheterization laboratory at ILH. Furthermore, HSANV notes and DCOPN concurs, ILH proposes to increase catheterization capacity in a prudent and cost-effective way. The additional capacity requested would come from converting the hospital's EP laboratory to dual use, for both EP and catheterization patients. Therefore, DCOPN concludes that the proposed project is more advantageous 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 Board of Directors of the HSANV at its meeting on October 14, 2019, voted nine in favor and none opposed to recommended approval of the proposed project for the following reasons:

1. Inova Loudoun Hospital has relatively high and increasing demand for cardiac catheterization and related cardiovascular procedures.
2. Current and projected cardiac catheterization service volumes are higher than the nominal service volume planning standard specified in the Virginia State Medical Facilities Plan.
3. The size and composition of ILH's primary service area is such that demand for cardiovascular services and procedures is likely to continue to grow as the population increases.
4. Though there is no general regional need for additional cardiac catheterization services or capacity, Inova Loudoun Hospital has documented an internal service specific need for additional cardiac catheterization capacity.
5. ILH proposes to increase catheterization capacity in a prudent and cost-effective way. The additional capacity requested would come from converting the hospital's electrophysiological (EP) laboratory to dual use, for both EP and catheterization patients.
6. The request does not entail additional capital expense. The capital outlay for the electrophysiology laboratory has been incurred. Use of the EP laboratory to respond to cardiac catheterization demand should result in more efficient use of this resource.
7. The proposal is consistent with the institutional need provision of the Virginia State Medical Facilities Plan.

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

(iv) Any costs and benefits of the project;

The applicant asserts that no equipment, software, construction or renovations are needed. Consequently, there are no capital costs for the proposed project and the target date of opening is immediately upon COPN approval. The applicant further states that the benefits of the proposed project include the following: (1) decompressing high utilization of ILH's one existing cardiac catheterization laboratory; (2) improving timely access to much-needed services for residents of ILH's service area; and (3) alleviating scheduling complications, capacity concerns, and extended patient wait times currently experienced by ILH.

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

The Pro Forma Income Statement (Table 5) provided by the applicant proposes the provision of 3.4% charity care (reflected in the "Provision for Charity" line item) based on gross patient services revenue. According to regional and statewide data regularly collected by VHI, for 2017, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 4.3% of all reported total gross patient revenues (Table 6). In that same year, ILH provided 3.97% of its gross patient revenue in the form of charity care. Should the Commissioner approve the request, ILH is expected to provide a level of charity care for total gross patient revenues at least equal to the Inova Health Care Services system-wide charity care condition of 4.1%, as set forth in COPN No. VA-04381.

Table 5. ILH's Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Revenue	\$32,406,209	\$34,554,881
Provision for Charity	(\$1,094,531)	(\$1,167,104)
Contractual Discounts	(\$17,691,308)	(\$18,864,3319)
Net Patient Revenue	\$13,620,369	\$14,523,459
Expenses		
Salaries, Wages and Benefits	\$3,560,211	\$3,793,305
Supplies and Pharmaceuticals	\$1,305,720	\$1,391,209
Other Expenses	\$1,926,842	\$2,052,996
Depreciation and Amortization	\$630,365	\$645,620
Bad Debt	\$486,093	\$518,323
Indirect Expenses	\$1,117,224	\$1,190,371
Total Operating Expenses	\$9,026,455	\$9,591,824
Net Income	\$4,593,914	\$4,931,635

Source: COPN Request No. VA-8461

Table 6. HPR II 2017 Charity Care Contribution

Health Planning Region II			
2017 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Novant Health UVA Health System Prince William Medical Center	\$486,755,131	\$41,131,289	8.45%
Sentara Northern Virginia Medical Center	\$843,733,000	\$48,798,667	5.78%
Inova Mount Vernon Hospital	\$459,731,206	\$25,268,629	5.50%
Inova Alexandria Hospital	\$882,503,794	\$48,235,851	5.47%
Inova Fairfax Hospital	\$3,200,076,133	\$155,686,282	4.87%
Inova Loudoun Hospital	\$695,206,726	\$27,592,571	3.97%
Inova Fair Oaks Hospital	\$642,557,622	\$21,275,398	3.31%
Novant Health UVA Health System Haymarket Medical Center	\$237,376,864	\$7,661,395	3.23%
Virginia Hospital Center	\$1,240,732,950	\$33,068,670	2.67%
Reston Hospital Center	\$1,153,120,639	\$12,648,498	1.10%
StoneSprings Hospital Center	\$156,479,524	\$1,021,413	0.65%
Total Facilities			11
Median			4.0%
Total \$ & Mean %	\$9,841,794,065	\$422,388,663	4.3%

Source: VHI (2017)

(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 discretionary 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.

The State Medical Facilities Plan (SMFP) contains standards and criteria for the addition or expansion of 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.

As discussed above and **Figure 1**, cardiac catheterization services are already well within a 60 minute drive under normal conditions for all residents of the planning district. While traffic congestion is a regular complaint of those attempting to navigate the major travel arteries of HPR II, because the proposed project would be located in a facility that already offers cardiac catheterization services, it would likely have little impact on geographic access to this service in HPR II.

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 would expand an existing service.

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 laboratory would be part of a stationary 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 illustrated in Table 3 above, utilization of the cardiac catheterization services at ILH have increased by 11% with regard to total DEPs between 2013 and 2017. The cardiac catheterization service reached a utilization level of 129% in 2016 and 119% in 2017 based on 1,200 DEPs per laboratory as outlined by the SMFP expansion standard for the applicant’s existing cardiac catheterization service. Based on data provided by the applicant, for 2018, ILH’s cardiac catheterization lab performed 1,544 cardiac DEPs, 128% of the expansion threshold. DCOPN concludes that ILH meets this standard.

- 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.**

Table 7 shows the applicant’s projected utilization (based on diagnostic equivalent procedures) of cardiac catheterization services at ILH for the first two full years of operation with two cardiac catheterization laboratories. ILH projects 835 DEPs per cardiac catheterization laboratory in the first 12 months of operation of the expanded cardiac catheterization service and an average of 869 DEPs per cardiac catheterization laboratory in the second 12 months of operation. Therefore, the proposed second laboratory is within the SMFP standard for expansion of a cardiac catheterization service provided the applicant’s projections are on target. Given the utilization trends of ILH’s cardiac catheterization service, it would appear that the applicant’s projections are reasonable.

Table 7. ILH Projected Utilization

Year	Cath Labs	Diagnostic DEPs	Therapeutic DEPs	Same Visit DEPs	Total	Utilization
Year 1	2	566	56	1,048	1,670	139%
Year 2	2	588	58	1,090	1,737	145%

Source: COPN Request No. VA-8461

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. ILH is not proposing to provide pediatric cardiac catheterization procedures.

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

Proposals to provide elective interventional cardiac procedures such as PTCA, transeptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic pericardiocentesis or therapeutic procedures should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed non-emergent cardiac service will be located.

Not applicable.

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 ILH's cardiac catheterization services, Dean Pollock, M.D., FACC, is board-certified in Internal Medicine, Interventional Cardiology, and Cardiovascular Disease and has experience in performing physiologic and angiographic procedures.

- 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.**

Not applicable. ILH is not proposing to provide pediatric cardiac catheterization procedures.

- 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 ILH 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.**

Not applicable. ILH is not proposing to provide pediatric cardiac catheterization procedures.

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.**

ILH has asserted an institutional need to expand its cardiac catheterization services based on the overutilization of ILH's one cardiac catheterization laboratory. The SMFP standard for expansion of an existing cardiac catheterization service requires the applicant to perform an average of 1,200 DEPs per laboratory annually. In 2017, ILH's cardiac catheterization service performed 1,429 DEPs, and as such, operated at 119% of the 1,200 DEPs advocated by the SMFP as the minimum utilization level required for justifying an institution specific need to expand a cardiac catheterization service. Additionally, the applicant has stated that in 2018, ILH performed 1,544 cardiac DEPs. This is 129% of the SMFP expansion standard of 1,200 DEPs. The applicant has stated that these high volumes hinder ILH's ability to deliver timely care to its patients and to efficiently operate its catheterization lab. Accordingly, ILH has demonstrated an institutional need to expand.

- 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.**

ILH proposes expansion of its cardiac catheterization services based on institutional need. While there are two other hospitals in the Inova Health System that provide cardiac catheterization services, Inova Alexandria Hospital (IAH) and Inova Fairfax Hospital (IFH), the applicant asserts, and DCOPN concurs, that neither of these hospitals has underutilized cardiac catheterization services and it is not reasonable to reallocate a cardiac catheterization laboratory from IAH or IFH to ILH. In 2017, IAH performed 2,231 DEPs in its two cardiac catheterization laboratories, operating at a utilization of 97%. Also in 2017, IFH performed 6,457 DEPs in its seven cardiac catheterization laboratories, operating at a utilization of 77%. DCOPN notes that if IFH were to transfer one of its cardiac catheterization laboratories to ILH, IFH's utilization would reach approximately 90% utilization, likely creating an institutional need for expanded cardiac catheterization services at IFH. Therefore, DCOPN agrees with the applicant that it is not appropriate to reallocate services from IAH or IFH.

- 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 ILH 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.**

ILH is an established provider of cardiac catheterization services. HSAHV asserts, and DCOPN agrees, that the proposed project would not introduce a service provider or new service delivery site and that there is no indication to believe that the proposed project would affect competition among providers of cardiac catheterization services in PD 8.

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.**

ILH is part of the Inova Health System and is an established provider of cardiac catheterization services in PD 8. A review of the 2017 utilization data for ILH (Table 3) reveals ILH's cardiac catheterization laboratory operated at 119% utilization. As such, ILH has asserted an institutional need to expand its cardiac catheterization services. The SMFP standard for expansion of an existing cardiac catheterization service requires the applicant to perform an average of 1,200 DEPs per laboratory annually. In 2017, ILH's cardiac catheterization service performed 1,429 DEPs, and as such, operated at 119% of the 1,200 DEPs advocated by the SMFP as the minimum utilization level required for justifying an institution specific need to expand a cardiac catheterization service. Expansion of cardiac catheterization services at ILH is unlikely to have a noticeable effect on existing services or facilities, apart from the decompression of the volumes on the one existing cardiac catheterization laboratory at ILH.

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

As previously discussed, the applicant asserts that no equipment, software, construction or renovations are needed. Consequently, there are no capital costs for 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 seek to introduce new technology, but rather to expand an already existing cardiac catheterization laboratory. Most cardiac catheterizations and related procedures are performed on an outpatient basis. The applicant did not cite any cooperative efforts by ILH to meet regional health care needs. DCOPN did not identify any other factors which have not been discussed elsewhere in this staff 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; and
 - (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for the citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Staff Findings and Conclusions

Inova Loudoun Hospital proposes to expand its cardiac catheterization service by adding a second catheterization laboratory through converting ILH's existing 678 square foot EP laboratory to a dual purpose EP and cardiac catheterization laboratory. ILH currently provides EP service in a dedicated EP laboratory using a Philips FD10 fluoroscopy unit, which is also cardiac catheterization capable. ILH proposes to commence using the existing EP laboratory and equipment for cardiac catheterization services immediately upon COPN approval. The applicant asserts that no equipment, software, construction or renovations are needed to convert the EP laboratory to a dual purpose laboratory. Consequently, there are no capital costs for the proposed project. Based on the pro forma profit and loss statement provided by the applicant (Table 5), the addition of a second cardiac catheterization laboratory at ILH would add to the profitability of the hospital's cardiac catheterization service. The pro forma provided by the applicant projects a net income of \$4,593,914 in the first year of operation and \$4,931,635 in year two.

In the five-year period ending in 2017, utilization of the cardiac catheterization service at ILH grew from 1,282 diagnostic equivalent procedures DEPs to 1,429 DEPs, for a total change percentage of 11%. The service is projected to reach 1,737 DEPs by the second year of operation. The proposed cardiac catheterization laboratory would increase the existing cardiac catheterization laboratory inventory in PD 8 to 20 laboratories. The SMFP standard advocates at least 1,200 DEPs per cardiac catheterization laboratory per year. The service at ILH operated at 119% utilization in 2017. This utilization level does not include non-cardiac catheterization procedures; although as much as 20% of the procedures performed in the hospital's cardiac catheterization laboratory qualify as such. Nonetheless, based on cardiac catheterization DEPs alone, ILH has an institutional need for one additional cardiac catheterization laboratory.

ILH proposes to increase catheterization capacity in a prudent and cost-effective way. The additional capacity requested would come from converting the hospital's EP laboratory to dual use, for both EP and catheterization patients. Therefore, DCOPN concludes that the proposed project is more advantageous than the status quo. Finally, DCOPN did not receive any opposition to the proposed project, either in writing or at the public hearing.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Inova Loudoun Hospital's COPN Request No. VA-8461 to add a second cardiac catheterization laboratory by converting ILH's existing 678 square foot EP laboratory to a dual purpose EP and cardiac catheterization laboratory. DCOPN's recommendation is based on the following findings:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Conditions of the Code of Virginia.
2. There are no capital costs for the proposed project and the proposed project is financially feasible in the immediate and the long-term.
3. The applicant has demonstrated an institutional need to add one cardiac catheterization laboratory.
4. The project is more favorable than the status quo.
5. DCOPN has not received any letters of opposition to the proposed project and no opposition was expressed at the public hearing.
6. The Health Systems Agency of Northern Virginia recommends approval of the proposed project.

DCOPN's recommendation is contingent upon ILH's agreement to the following indigent care condition:

Inova Health Care Services d/b/a Inova Health System must provide charity care consistent with the 4.1% system-wide condition placed on the previously conditioned COPN No. VA-04381 (issued April 2, 2013). Inova Health System 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 facilitate cardiac catheterization services to medically underserved persons in an aggregate amount equal to at least 4.1% of Inova Health System's total patient services revenue derived from cardiac catheterization services provided at Inova Loudoun Hospital as 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.. 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. In respect of this condition on Inova Health System's provision of cardiac catheterization services, Inova Health System 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.