

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2023

COPN Request No. VA-8689

McLean Ambulatory Surgery Center

McLean, Virginia

Expansion through the addition of a third OR

Applicant

McLean Ambulatory Surgery, LLC (MAS) is a limited liability company formed in 2014 under the laws of the Commonwealth of Virginia. MAS is owned by Inova Health Services, a 501 (c)(3) Virginia nonstock corporation (54% ownership) and multiple physician investors (46% ownership, in aggregate). Gastroenterology Associates of Northern Virginia, LLC, d/b/a Gastro Health holds a 6% membership interest and each other physician investor has less than 5% membership interest. Both Inova Health Care Services' and Gastro Health's offices are in Fairfax, Virginia. MAS is located in McLean, Virginia in Fairfax County, Virginia which is in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Table 1 displays data for operating rooms (ORs) in PD 8 as reported to Virginia Health Information (VHI) for 2021, the most recent year for which such data are available. Of the 185 General Purpose ORs (GPORs) authorized/operational in 2021, 132 are in acute care hospitals and the remaining 53 are in outpatient surgical hospitals (OSH). **Table 1** does not include open heart or trauma ORs, only general and ambulatory ORs. The overall utilization of PD 8 GPORs in 2021, based on hours of use, was 103.7% of the threshold of 1,600 hours per OR set forth in the State Medical Facilities Plan (SMFP). The hospital based ORs had an average utilization of 108.2% of the SMFP standard and the OSH sites averaged 92.5% utilization.

According to Division of Certificate of Public Need (DCOPN) records, there are currently 212 total authorized ORs in Planning District PD 8 (**Table 2**). This total includes eight open heart ORs (seven adult and one pediatric), two trauma ORs and 202 General and Ambulatory ORs. DCOPN notes that, of the 202 General and Ambulatory ORs in the current PD8 inventory, two are restricted to ophthalmic procedures and two are restricted to vascular access. Since 2021, a net of 17 (202-185) additional GPORs have been added in PD 8.

Surgical services at MAS include general, orthopedic, plastic, urology, gastroenterological and otolaryngology/Ear, Nose and Throat (ENT) surgical procedures.

Table 1. Operating Rooms, VHI 2021, Planning District 8

Facility Name	Operating Rooms	Total Cases	Total Hours	Average Hours per OR	Percent of SMFP Threshold
Acute Hospital					
Inova Alexandria Hospital	11	7,677	18,842	1,713	107.1%
Inova Fair Oaks Hospital	12	10,558	23,838	1,987	124.2%
Inova Fairfax Hospital	4	2,459	7,726	1,932	120.7%
Inova Fairfax Hospital	43	30,306	80,145	1,864	116.5%
Inova Loudoun Hospital	8	6,652	15,926	1,991	124.4%
Inova Mount Vernon Hospital	7	4,328	10,898	1,557	97.3%
Prince William Hospital	1	1,256	3,128	3,128	195.5%
Reston Hospital Center	12	13,241	22,862	1,905	119.1%
Sentara Northern Virginia Medical Center	9	4,598	8,570	952	59.5%
Stone Springs Hospital Center	7	2,580	4,866	695	43.4%
UVA Haymarket Medical Center	1	1,350	4,803	4,803	300.2%
Virginia Hospital Center	17	12,624	26,836	1,579	98.7%
Actue Hospital	132	97,629	228,440	1,731	108.2%
Outpatient Surgical Hospital					
Fairfax Surgical Center	6	8,615	11,186	1,864	116.5%
Haymarket Surgery Center	2	3,255	4,705	2,353	147.0%
HealthQare Services ASC, LLC	2	2,341	2,340	1,170	73.1%
Inova Ambulatory Surgery Center at Lorton	2	26	56	28	1.8%
Inova Loudoun Ambulatory Surgery Center	5	5,183	8,020	1,604	100.3%
Inova Surgery Center @ Franconia-Springfield	5	4,440	7,191	1,438	89.9%
Kaiser Permanente Tysons Corner Surgery Center	10	6,556	10,477	1,048	65.5%
Lake Ridge Ambulatory Surgical Center	1	747	664	664	41.5%
McLean Ambulatory Surgery Center	2	1,560	4,208	2,104	131.5%
Northern Virginia Eye Surgery Center, LLC	2	4,915	2,570	1,285	80.3%
Northern Virginia Surgery Center	4	4,515	5,237	1,309	81.8%
Pediatric Specialists of Virginia Ambulatory Surgery Center	2	2,041	2,250	1,125	70.3%
Prince William Ambulatory Surgery Center	4	4,847	8,838	2,210	138.1%
Reston Surgery Center	6	7,199	10,683	1,781	111.3%
	53	56,240	78,425	1,480	92.5%
Totals and Average, PD 8	185	153,869	306,865	1,659	103.7%

Source: VHI 2021, filtered on General and Ambulatory Surgical Class

Table 2: PD 8 COPN Authorized Operating Room Inventory

Facility	Total	Unrestricted	Ophthalmic	Vascular	Trauma	Cardiac	
						Adult	Ped
Inpatient Hospital							
Inova Alexandria Hospital	11	11	--	--	--	--	--
Inova Fair Oaks Hospital	12	12	--	--	--	--	--
Inova Fairfax Medical Campus	53	47	--	--	--	5	1
Inova Loudoun Hospital ¹	10	10	--	--	--	--	--
Inova Mount Vernon Hospital	7	7	--	--	--	--	--
UVA Prince William Medical Center d/b/a UVA Health Haymarket Medical Center	4	4	--	--	--	--	--
UVA Prince William Medical Center d/b/a UVA Health Prince William Medical Center	4	4	--	--	--	--	--
Reston Hospital Center	17	16	--	--	1	--	--
Sentara Northern Virginia Medical Center	9	9	--	--	--	--	--
Stone Springs Hospital Center	6	6	--	--	--	--	--
Virginia Hospital Center	16	13	--	--	1	2	--
Total Inpatient Hospital	149	139	0	0	2	7	1
Outpatient Surgical Hospital							
Fairfax Surgical Center	6	6	--	--	--	--	--
Haymarket Surgery Center	2	2	--	--	--	--	--
Healthqare Associates	2	0	--	2	--	--	--
Inova Ambulatory Surgery Center at Lorton	2	2	--	--	--	--	--
Inova Loudoun Ambulatory Surgery Center	5	5	--	--	--	--	--
Inova McLean Ambulatory Surgery Center	2	2	--	--	--	--	--
Inova Oakville Ambulatory Surgery Center ²	3	3	--	--	--	--	--
Inova Surgery Center at Franconia-Springfield	5	5	--	--	--	--	--
Kaiser Permanente Tysons Corner Surgery Center ³	7	7	--	--	--	--	--
Kaiser Permanente Woodbridge Surgery Center ⁴	4	4	--	--	--	--	--
Lake Ridge Ambulatory Surgical Center	1	1	--	--	--	--	--
Northern Virginia Eye Surgery Center, LLC	2	0	2	--	--	--	--
Northern Virginia Surgery Center	4	4	--	--	--	--	--
Pediatric Specialists of Virginia	2	2	--	--	--	--	--
Prince William Ambulatory Surgery Center	4	4	--	--	--	--	--
Reston Surgery Center	6	6	--	--	--	--	--
Stone Springs Surgery Center	2	2	--	--	--	--	--
VHC Ambulatory Surgery Center	4	4	--	--	--	--	--
Outpatient Surgical Hospital Total	63	59	2	2	0	0	0
Total Authorized Operating Rooms	212	198	2	2	2	7	1

Source: DCOPN Records

¹ COPN No. VA-04771 authorized Inova Loudoun Hospital's 9th and 10th ORs, expected to be operational 09/01/23.

² COPN No. VA-04770 authorized the establishment of Inova Oakville Ambulatory Surgery Center with three ORs, expected to be operational by 4/30/2024

³ Kaiser Permanente Tyson's Corner reported 10 ORs to VHI, 2021.

⁴ COPN No. VA-04691 authorized Kaiser Permanente Woodbridge Surgery Center, last reported to be completed 11/1/21.

Proposed Project

MAS proposes to add one GPOR to its two existing GPORs based on an institution-specific need for additional OR capacity. MAS currently occupies approximately 12,700 square feet with two minor procedure rooms, pre-operative and post-anesthesia care areas, sterile supply, sterilization room, staff locker rooms, patient registration and waiting, offices and lounge, in addition to two existing GPORs. If the proposed project is approved, MAS intends to lease an additional 3,039 square feet on a different floor and relocate selected support services to accommodate the additional GPOR as well as a minor procedure room, expanded sterile supply area and more prep/recovery rooms in space contiguous to existing surgical space. This plan would not result in the interruption of services at MAS during construction.

The projected capital costs of the proposed project are \$7,523,598 with 39% of these for direct construction costs. Approximately 65% of total capital costs will be financed. Including financing costs of \$1,026,258, capital and financing costs of the proposed project are \$8,549,856 (**Table 3**). Should the proposed project be approved, MAS has a target opening date of February 15, 2025.

Table 3. Capital and Financing Costs: McLean Ambulatory Surgery Center

Direct Construction Costs	\$2,934,623
Equipment Not Included in Construction Contract	\$1,610,202
Site Acquisition Costs	\$2,299,356
Architectural and Engineering Fees	\$320,860
Construction Loan Interest	\$358,557
Total Capital Costs	\$7,523,598
Conventional Loan Financing	\$1,026,258
TOTAL CAPITAL AND FINANCING COSTS	\$8,549,856

Source: COPN Request No. VA-8689

Project Definition

§32.1-102.1:3 of the Code of Virginia (the Code) defines a project, in part, as “An increase in the total number of...operating rooms in an existing medical care facility described in subsection A.” Medical care facilities are further defined, in part, as “Any facility licensed as a hospital, as defined in § 32.1-123.” The definition of “Hospital” in § 32.1-123 includes “hospitals known by varying nomenclature or designation such as...outpatient surgical...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 project will provide or increase access to healthcare services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

The proposed project is at an existing site accessible to public and private transportation. It represents an expansion of a facility already providing surgical services, so it would not increase geographic access within PD 8. The two existing ORs at MAS have approached and exceeded the SMFP standard during the past several years for which data are available from VHI. In 2021 MAS operated at 131.5% of the SMFP standard (**Figure 1**). The applicant states that MAS has had utilization at 147% of the SMFP standard for 2022.

The population in PD 8 is projected to grow 1.28% on average annually between 2020 and 2030 adding 350,128 people to the PD over the decade. This is a substantially faster rate of growth than that of Virginia overall at 0.76% annually. Fairfax County, in which MAS is located, is projected to grow 0.96% annually, more than Virginia, but not at pace with the growth rate of PD 8 overall. The population over age 65 utilizes surgical services at a higher rate than the overall population and is projected to grow faster, an average of 3.24% annually in PD 8 during the same decade, compared with a 2.45% average annual growth across Virginia (**Table 4**).

Technology advances and payor pressure due to the generally lower cost of outpatient surgical hospitals will continue to drive procedures to outpatient settings such as MAS. Shifting appropriate procedures to the outpatient surgical hospital setting will free up general hospital based ORs for more complex procedures appropriate to a higher level of care. Letters of support from surgeons indicate that they would like to move more procedures to MAS but lack of OR availability prevents this. The applicant states that additional physicians would like to perform surgeries at MAS as well but have been hindered by high utilization of its ORs. From the perspective of existing and growing demand for surgeries at MAS, an additional OR would increase access at a highly utilized ambulatory facility.

Figure 1. McLean Ambulatory Surgery Center Volumes and Utilization

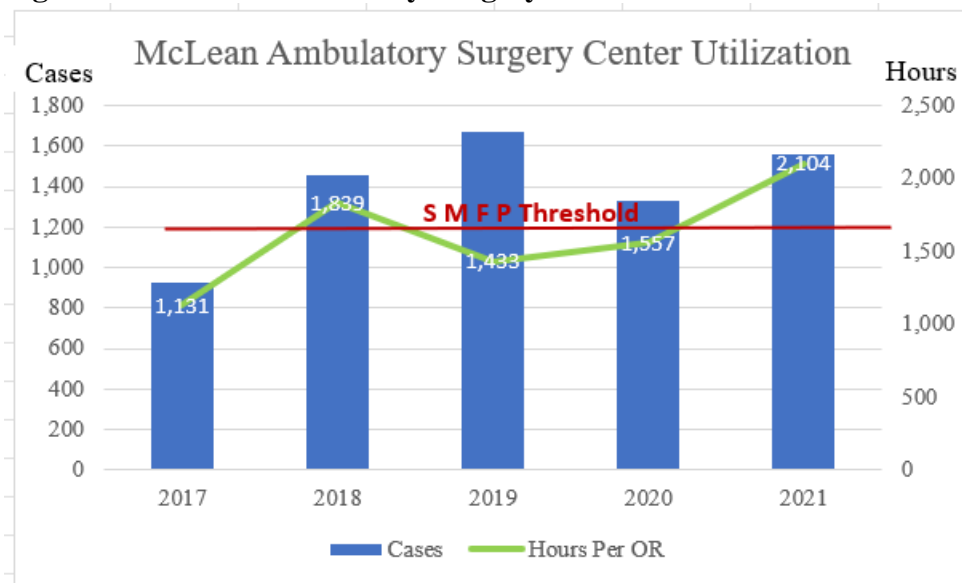


Table 4. Population Projections for PD 8, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Arlington	139,966	166,261	18.79%	1.69%	182,067	9.51%	0.91%
Fairfax County	207,627	249,298	20.07%	1.80%	274,339	10.04%	0.96%
Loudoun	22,565	25,047	11.00%	1.02%	26,397	5.39%	0.53%
Prince William	1,081,726	1,162,504	7.47%	0.71%	1,244,025	7.01%	0.68%
Alexandria City	12,332	14,988	21.54%	1.92%	17,032	13.64%	1.29%
Fairfax City	312,311	430,584	37.87%	3.18%	554,808	28.85%	2.57%
Falls Church City	37,821	43,099	13.96%	1.28%	46,332	7.50%	0.73%
Manassas City	14,273	17,086	19.71%	1.77%	20,284	18.72%	1.73%
Manassas Park City	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 (August 2019) and DCOPN (interpolations)

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

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

DCOPN received four letters of support from physicians currently performing surgeries at MAS: two general surgeons, an orthopedic surgeon (chief of foot and ankle surgery for Inova) and an ENT head and neck surgeon, Inova’s ENT section chief. Together, these letters expressed the following points in support for the proposed project:

- Ambulatory surgery centers are a convenient, efficient, and cost-effective option for surgical care.
- Physicians are making efforts to shift less invasive surgeries from hospitals to ambulatory surgery sites to provide the best options for surgical care for patients.
- Shifting surgeries to MAS as they would like has been hindered by lack of space/time to accommodate additional procedures.
- Due to technology advances, payor pressure and decreased availability of hospital based ORs, the number of surgical cases appropriate for an ambulatory surgery center will continue to grow.
- An additional OR at MAS would enhance throughput and improve access for existing and future demand for outpatient surgeries.

Public Comment

DCOPN provided notice to the public regarding this project on March 13, 2023. The public comment period closed on April 27, 2023. On April 17, 2023, the Health Systems Agency of

Northern Virginia (HSANV) held a public hearing. No public comment was presented aside from the letters of endorsement included with the application.

DCOPN is not aware of any opposition to the proposed project.

- (ii) The availability of reasonable alternatives to the proposed project that would meet the needs of people in the area to be served in a less costly, more effective manner;**

MAS had the highest hours per OR of any of Inova's facilities in 2021 and as an outpatient facility poised for additional growth, there is not a reasonable alternative to adding capacity at MAS. The proposed project appears to be the best option for meeting the demand already realized at MAS. Ideally, in a PD with a surplus of ORs, resources would be reallocated to correct the maldistribution of ORs. This option was explored.

Inova Ambulatory Surgery Center at Lorton ("Lorton ASC") has operated at less than 50% of the SMFP threshold since 2019, with utilization of less than 3% the past two years, according to VHI data. Though many of the facilities in PD 8 exceeded 100% of the SMFP standard in 2021, Lorton ASC reported OR hours equivalent to only 1.8%. As of 2020, Inova is the sole member of the LLC that owns Lorton ASC, and Inova is also the majority owner of MAS. The two OSHs are, however, separate legal entities.

Interestingly, this type of re-allocation has occurred before when one of the ORs from Lorton ASC was reallocated to Inova Surgery Center at Franconia-Springfield ("F-S ASC"), authorized per COPN No. VA-04690 on December 16, 2019. This occurred as the physicians that were members of the LLC that owned Lorton ASC gave up that ownership and became members of the LLC that owns F-S ASC. Inova received COPN No. VA-04747 on July 8, 2021, to replace the second OR at Lorton ASC as a means to decompress hospital based ORs at Inova Fairfax Hospital. The applicant states that the shifting of appropriate cases from Inova Fairfax Hospital to the Lorton ASC has begun and the ORs at Lorton ASC may approach full utilization by the end of calendar year 2023. GPORs at Inova Fairfax have operated above the SMFP threshold for three of the past five years. Relocating an OR from Lorton ASC would move capacity from one area of need to another but not correct OR maldistribution.

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

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed at its April 17, 2023, board meeting the COPN application filed by MAS. The board voted seven in favor, and none opposed to recommend approval of the project. The recommendation was based upon the following findings and conclusions:

- Northern Virginia surgery service volumes have grown steadily for several decades, with an ongoing shift from inpatient to outpatient service delivery. Currently, about 80% of

local surgery cases are outpatient. Regional surgery facility service volumes are likely to continue to increase at about the rate of population growth.

- The rapid growth at MAS reflects this evolution and trend in the local market.
- Application of the Virginia SMFP need determination methodology suggests there may be a small regional operating room surplus (e.g., four rooms) in 2028.
- There are no unused operating rooms within Inova Health System that can be used to accommodate increasing demand at MAS. The location and nature of unused surgery capacity elsewhere in the region are such that it is not an alternative to the McLean project.
- The high and growing service volumes at MAS qualifies the service for consideration to expand in accordance with the institutional need provision of the Virginia State Medical Facilities Plan.
- Adding an operating room at MAS would not affect other surgery services negatively.

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

Table 3 shows the projected capital and financing costs of the proposed project, \$8,549,856, of which \$358,557 is for a construction loan and \$1,026,258 is conventional loan financing. Even excluding financing costs, the capital costs of \$7,523,598 are extraordinarily high. COPN No. VA-04772 authorized the additional of two operating rooms at Reston Hospital Center in PD 8 at a cost of \$4,507,000, or \$2,253,500 per OR. Last year, COPN No. VA-04770 authorized the establishment of Inova Oakville Ambulatory Surgical Center with three GPORs at a capital cost of \$20,013,530, less than \$7 million per OR in a new facility. The most recent authorized projects to add a single OR at an established facility (VA-04816 and VA-0479) projected capital costs of \$351,391 and \$1,509,700, respectively.

There are benefits to the project, as it is a highly utilized, outpatient facility and is poised for growth. In 2021, MAS had a utilization of 131.5% and the applicant states that additional physicians on the medical staffs of Inova Fairfax and Inova Fair Oaks Hospitals have expressed interest in performing surgeries there. As more procedures become appropriate for the less costly outpatient setting, it is advantageous to transition them to OSHs for more convenient, less expensive care for patients, and to free up hospital based ORs for patients that require acute care services.

(v) The financial accessibility of the proposed project to people in the area to be served, including indigent people; and

According to 2020 VHI data on charity care, the latest year for which such data are available, Inova hospital provided charity care, in aggregate, in the amount of 4.3% of gross patient revenue. This exceeds the mean charity care contributions in HPR II for that year, 3.4% (**Table 5**).

Table 5. HPR II Charity Care Contributions 2020*

2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	\$949,158,182	\$57,879,875	6.10%
Inova Mount Vernon Hospital	\$499,398,426	\$29,342,493	5.88%
Inova Loudoun Hospital	\$817,869,692	\$35,123,877	4.29%
Novant Health UVA Health System Prince William Medical Center	\$530,326,336	\$21,923,014	4.13%
Inova Fairfax Hospital	\$3,855,962,450	\$147,813,100	3.83%
Sentara Northern Virginia Medical Center	\$823,831,674	\$29,925,512	3.63%
Inova Fair Oaks Hospital	\$649,476,560	\$21,302,369	3.28%
Virginia Hospital Center	\$1,491,327,243	\$29,205,595	1.96%
Novant Health UVA Health System Haymarket Medical Center	\$284,391,247	\$4,747,340	1.67%
Reston Hospital Center	\$1,535,959,085	\$19,925,030	1.30%
StoneSprings Hospital Center	\$247,806,370	\$1,302,439	0.53%
Total Facilities			11
Median			3.6%
Total \$ & Mean %	\$11,685,507,265	\$398,490,644	3.4%

Source: VHI 2020 Charity Care Contributions Data

*2020 data is the most recent data available

MAS is an LLC owned by both Inova and multiple physician investors. The proforma for the proposed project projects a provision for charity at 2% (**Table 6**), far lower than charity provided by Inova hospitals, and may indicate an intention to choose patients at MAS to maximize payment.

	Year 1	Year 2
Total Gross Revenue	\$ 54,865,669	\$ 57,623,285
Contractual Discounts	\$ 36,054,444	\$ 37,966,103
Provision for Charity	\$ 1,115,086	\$ 1,174,209
Net Revenue	\$ 17,696,139	\$ 18,482,973
Total Operating Expenses	\$ 13,965,654	\$ 13,961,914
Income from Operations	\$ 3,730,485	\$ 4,521,059

Source: COPN Requestw No. VA-8689

Recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. McLean Ambulatory Surgery, LLC falls under Inova’s systemwide charity condition of 4.1%, so the proposed project, if approved, will be subject to a 4.1% charity care condition, to be derived from total gross patient services revenues.

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

DCOPN did not identify any other factors, not previously discussed in this staff report, to bring to the Commissioner’s attention with respect to determining a public need for the proposed project.

3. The extent to which the proposed project is consistent with the State Health Services Plan;

§ 32.1-102:1 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 SMFP.

Part V of the SMFP contains criteria and standards for the addition of operating rooms. They are as follows:

**Part V
 General Surgical Services**

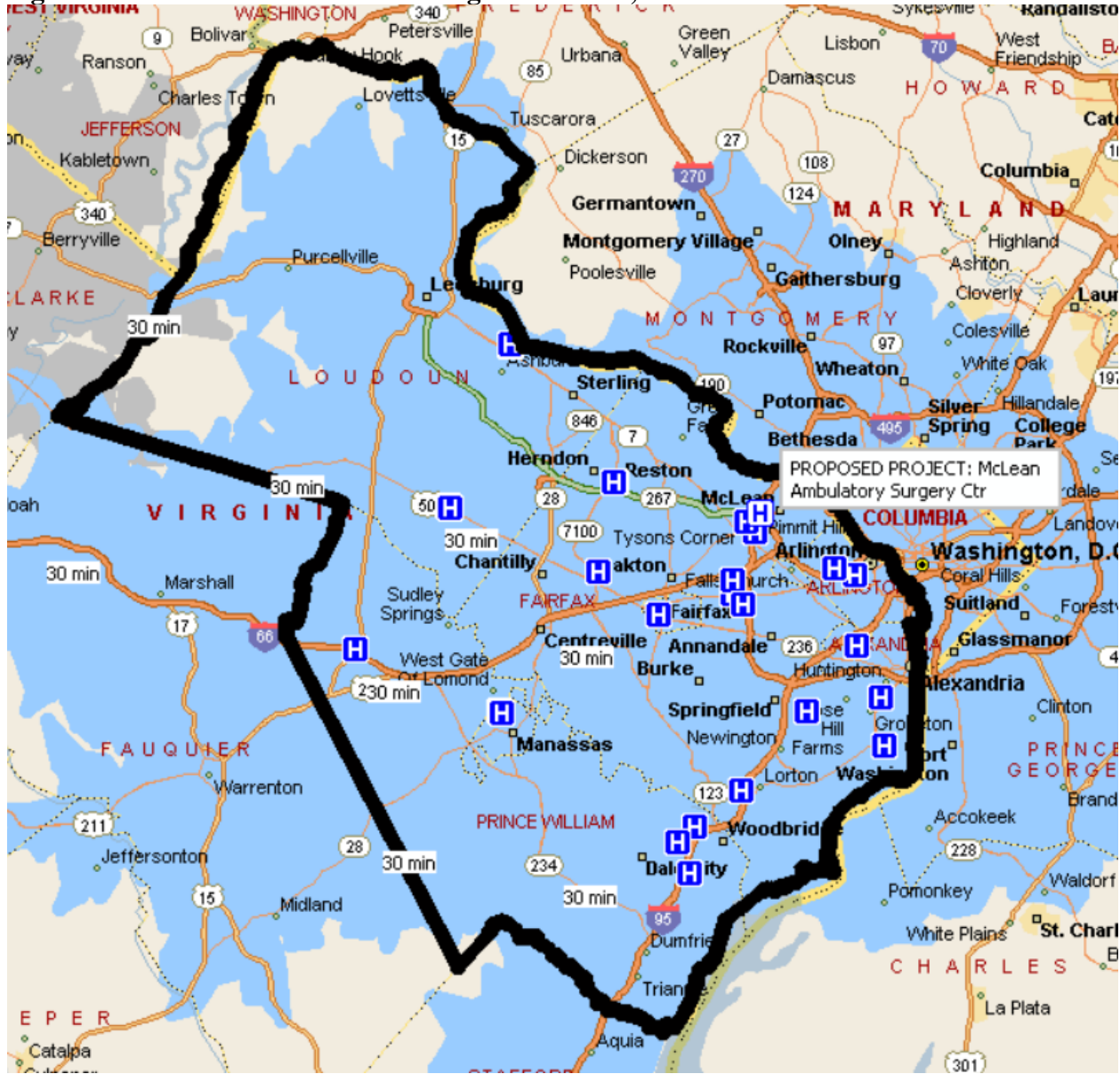
12VAC5-230-490. Travel time.

Surgical services should be available within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

The light blue shaded area in **Figure 2** shows the area that is within 30 minutes driving time from an existing provider of surgical services in PD 8. Parts of Purcellville and Lovettsville are not within this driving time nor are they within 30 minutes from Virginia surgical providers outside of PD 8. The total population of both of these cities is 11,600, only 0.45% of the total population of PD 8, indicating that certainly less than 1% of the PD 8 population is outside of the 30-minute

driving time criteria. The proposed project is at an existing site and will not expand geographical access to surgical services.

Figure 2. Authorized Providers of Surgical Services, PD 8



12VAC5-230-500. Need for new service.

A. The combined number of inpatient and outpatient general purpose surgical operating rooms needed in a health planning district, exclusive of procedure rooms, dedicated cesarean section rooms, operating rooms designated exclusively for cardiac surgery, procedures rooms or VDH-designated trauma services, shall be determined as follows:

$$\text{FOR} = \frac{((\text{ORV} / \text{POP}) \times (\text{PROPOP})) \times \text{AHORV}}{1600}$$

Where:

ORV = the sum of the total inpatient and outpatient general purpose operating room visits in the health planning district in the most recent five years for which general purpose operating room utilization data has been reported by VHI; and

POP = the sum of total population in the health planning district as reported by a demographic entity as determined by the commissioner, for the same five-year period as used in determining ORV.

PROPOP = the projected population of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

AHORV = the average hours per general purpose operating room visit in the health planning district for the most recent year for which average hours per general purpose operating room visits have been calculated as reported by VHI.

FOR = future general purpose operating rooms needed in the health planning district five years from the current year.

1600 = available service hours per operating room per year based on 80% utilization of an operating room available 40 hours per week, 50 weeks per year.

- B. Projects involving the relocation of existing operating rooms within a health planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a health planning district; (ii) result in the provision of the same surgical services at a lower cost to surgical patients in the health planning district; or (iii) optimize the number of operations in the health planning district that are performed on an outpatient basis.**

Not applicable. The applicant is not seeking approval for a new service or to relocate an existing operating room. For the sake of completeness, the OR need in PD 8 is calculated as follows:

Based on GPOR utilization data submitted to and compiled by VHI for the five-year period 2017-2021, which is the most recent five-year period for which relevant data are available, the number of inpatient and outpatient OR visits (ORV) was **703,141** (an average of **140,628** cases each year). This excludes visits in open heart and trauma ORs.

Based on actual population counts derived as a result of the 2010 U.S. Census, the population projections as compiled by Weldon Cooper, the U.S. population estimates for PD 8 for the five years 2017-2021 (POP) are **12,699,646** (2,539,929 average population each year). The projected population in five years, 2028 (PROPOP) is **2,861,022**.

The average hours per GPOR visit in PD 8 for 2021, the most recent year for which average hours per GPOR visit (AHORV) has been calculated using information collected by VHI is **1.99**

Using these figures in the GPOR need calculation indicates the number of GPORs needed in PD 8 in five years:

$$\frac{((703,141 / 12,699,646) \times 2,861,022)) \times 1.99}{1600} = 197.02 \text{ (198) ORs needed in PD 8}$$

Number of licensed GPORs in PD 8, excluding C-section, Open Heart (8) and Trauma ORs (2)
=202

There is a surplus of 4 GPORs in PD 8.

12VAC5-230-510. Staffing.

Surgical services should be under the direction or supervision of one or more qualified physicians.

The applicant has provided assurances that surgical services will be under the direction or supervision of one or more qualified physicians.

Part 1

Definitions and General Information

12VAC5-230-30. When Competing Applications Received.

In reviewing competing applications, preference may be given to an applicant who:

- 1. Has an established performance record in completing projects on time and within the authorized operating expenses and capital costs;**
- 2. Has both lower capital costs and operating expenses than his competitors and can demonstrate that his estimates are credible;**
- 3. Can demonstrate a consistent compliance with state licensure and federal certification regulation and a consistent history of few documented complaints, where applicable; or**
- 4. Can demonstrate a commitment to serving his community or service area as evidenced by unreimbursed services to the indigent and providing needed but unprofitable services, taking into account the demand of the particular service area.**

No application has been accepted for review that competes with the proposed project.

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.

MAS had OR hours in 2021 equal to 131.5% of the SMFP threshold for adding an OR. Though there is a surplus of four GPORs in PD 8, MAS has institutional need to expand capacity.

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.

Lorton ASC has underutilized capacity, operating at only 1.8% utilization of its two ORs in 2021. Lorton ASC is a separate legal entity from MAS, but currently Inova is the sole member of the LLC that owns Lorton ASC, as well as the majority owner of MAS. The second OR at Lorton ASC has been reallocated (COPN No. VA-04690) and replaced again (COPN No. VA-04747) within the past four years as Inova has worked to address over utilization and maldistribution of its ORs across PD 8. Lorton ASC is 19 miles and 42 minutes from the proposed project. Reallocating it to MAS could hinder the decompression of GPORs at Inova Fairfax Hospital, which was the reason the second OR at Lorton ASC was authorized for replacement. In a PD with a small surplus (four ORs) it is most appropriate to leave the Lorton ASC ORs in place.

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

The proposed project does not involve a nursing facility.

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

The proposed project is not a new service but an expansion of an existing facility.

Eight Required Considerations Continued

4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;

Inova owned or partially owned 56.8% of the GPORs in PD 8, and those Inova-affiliated ORs performed 51.8% of the cases in PD 8 in 2021, according to VHI data. HCA had 17% of the ORs in PD 8 (21% of the cases) followed by Sentara (5% of ORs and 3% of cases). If the proposed project is approved, it would add an OR to the dominant market leader to provide capacity for existing and future demand at a single outpatient surgical hospital, but it would not foster beneficial competition.

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

Inova has the largest presence in the surgical services market across PD 8 and these services are highly utilized. In 2021, PD 8 GPORs had an average utilization at 103.7% of the SMFP threshold of 1,600 hours per OR (**Table 1**), while Inova facilities had an average utilization of 109.7% (**Table 7**) across its GPORs. Since the 2021 VHI report, Inova has been authorized for two additional GPORs at Inova Loudoun Hospital (COPN No. VA-04771) and for three additional GPORs (COPN No. VA-04770) at Inova Oakville Ambulatory Surgery Center. These

are included in the current inventory (**Table 2**). Had these five new ORs been in service in 2021, Inova’s average hours per OR would still have been 105% of the SMFP threshold.

Table 7. Inova GPORs, Aggregated

Facility Name	Operating Rooms	Total Cases	Total Hours	Average Hours per OR	Percent of SMFP Threshold
Acute Hospital					
Inova Alexandria Hospital	11	7,677	18,842	1,713	107.1%
Inova Fair Oaks Hospital	12	10,558	23,838	1,987	124.2%
Inova Fairfax Hospital	4	2,459	7,726	1,932	120.7%
Inova Fairfax Hospital	43	30,306	80,145	1,864	116.5%
Inova Loudoun Hospital	8	6,652	15,926	1,991	124.4%
Inova Mount Vernon Hospital	7	4,328	10,898	1,557	97.3%
Actue Hospital	85	61,980	157,375	1,851	115.7%
Ambulatory Surgical Hospital					
Inova Ambulatory Surgery Center at Lorton	2	26	56	28	1.8%
Inova Loudoun Ambulatory Surgery Center	5	5,183	8,020	1,604	100.3%
Inova Surgery Center @ Franconia-Springfield	5	4,440	7,191	1,438	89.9%
Northern Virginia Surgery Center	4	4,515	5,237	1,309	81.8%
Pediatric Specialists of Virginia Ambulatory Surgery Center	2	2,041	2,250	1,125	70.3%
McLean Ambulatory Surgery Center	2	1,560	4,208	2,104	131.5%
	20	17,765	26,962	1,348	84.3%
Totals and Average, PD 8	105	79,745	184,337	1,756	109.7%

Source: VHI 2021

General and Ambulatory Surgical Operating Rooms

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

Though projected capital and financing costs are exceptionally high for the addition of a single OR, at \$8,549,856 (**Table 3**), the proposed project appears to be wholly feasible. The applicant anticipates the need for three full-time equivalent employees to operate the additional GPOR. Though health care staffing is a statewide challenge, this modest number appears achievable without significant impact on existing providers. The proforma summarized in **Table 6** demonstrates a projected positive new income for MAS from its first year after implementation. This is \$345,000 higher than the net income projected in year one in the absence of the proposed project, and \$832,000 higher in year two.

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

The proposed project does not represent innovations in the financing and delivery of health care services but does add capacity for surgical services on an outpatient basis.

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

Not applicable. The applicant has not presented any documentation of an affiliation with a teaching hospital, medical school or institution of higher education.

DCOPN Staff Findings and Conclusions

The proposed project will not improve geographic access in PD 8. Though there is a surplus of four GPORs in PD 8, MAS exceeded the SMFP threshold for average hours per OR in 2021, demonstrating an institution-specific need for an additional OR. The proposed project is generally consistent with the eight Required Considerations of the Code of Virginia and the relevant provisions of the SMFP. The proposed project would improve access for patients seeking care at MAS and decompress overutilized ORs at area hospitals.

Population growth in PD 8 exceeds Virginia's, payor pressures and technology improvements driving shifts to the outpatient setting, as well as demand by additional physicians for more OR time at MAS support the conclusion that growth in utilization will continue at MAS. There is no alternative to adding OR capacity at MAS. Status quo would result in worsening access issues both at MAS and in hospital based ORs.

The projected costs of the proposed project are extraordinarily high and include over \$1 million in financing costs; however, the benefits of the project to expand capacity in a high and growing demand facility and to shift surgeries appropriately to the outpatient setting are significant. The proposed project is wholly feasible in the short and long term from the perspective of staffing and expected return.

There is a surplus of four GPORs in PD 8, with a net addition of seventeen newly authorized ORs in PD 8, since the latest VHI report in 2021. Inova's ORs in the aggregate, however, operated above the SMFP threshold and would continue to surpass the threshold even including newly authorized ORs not yet operational. There is only one Inova-affiliated ambulatory surgery center that reported very poor utilization in 2021, but reallocation to the proposed project would not save capital costs and would exacerbate resource constraints elsewhere.

The regional health services agency, HSA NV recommended approval and there is no known opposition.

DCOPN Staff Recommendation

DCOPN recommends **conditional approval** of McLean Ambulatory Surgery, LLC's COPN Request number VA-8689 to add one general purpose OR for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia.
2. McLean Ambulatory Surgery, LLC has demonstrated an institutional need for additional surgical capacity.
3. The proposed project is more beneficial than the status quo.
4. The Health Systems Agency of Northern Virginia recommended approval of the proposed project and there is no known opposition.
5. The proposed project is financially viable in both the short and long term.

DCOPN's recommendation is contingent upon McLean Ambulatory Surgery LLC's agreement to the following charity care condition. McLean Ambulatory Surgery, LLC falls under Inova's systemwide charity condition, 4.1%:

McLean Ambulatory Surgery LLC will provide surgical 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 4.1% of McLean Ambulatory Surgery LLC's gross patient revenue derived from surgical 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. McLean Ambulatory Surgery LLC 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. 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.

McLean Ambulatory Surgery LLC will provide surgical care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally McLean Ambulatory Surgery LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.