

FAIRFAX COLON&RECTAL SURGERY

COLORECTAL / ANORECTAL PHYSIOLOGY & SURGERY

www.fairfaxcolorectal.com

P: (703) 280-2841

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July 30, 2025

VIA Email: copn@vdh.virginia.gov

VIA Email: karen.shelton@vdh.virginia.gov

Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Dr, Suite 401
Henrico, VA 23233

RECEIVED

JUL 31 2025

VDH/GLC

RE: COPN Request No VA-8833

Dear Commissioner Shelton:

Please accept this letter as the formal submission of the Certificate of Public Need (COPN) application for Fairfax Colon & Rectal Surgical Center, LLC. Our application seeks approval to convert our existing outpatient office-based surgery practice into a Medicare-certified ambulatory surgery center specializing in colorectal and anorectal surgical services.

Our facility has provided outpatient colorectal surgical services for over seventeen years, and this project will expand access to these specialized services for the Northern Virginia community, including government-sponsored insurance populations such as Medicare, Medicaid, and Tricare beneficiaries.

Enclosed please find the completed application, including all required documentation, plans, and supporting materials, on the attached external thumb drive. We respectfully request your review and approval of this application to allow us to proceed with this important project.

Should you require any additional information or have questions during the review process, please feel free to contact me directly at mdelac@fxcrs.com or by phone at (703) 650-2333.

We appreciate your attention to this matter and look forward to working with your office throughout the application process.

Sincerely,



Michael Delac, CMPE
Chief Operating Officer

Fairfax Colon & Rectal Surgery, PC & Fairfax Colon & Rectal Surgical Center, LLC

CCL: Erik Bodin III, Division of Certificate of Public Need
erik.bodin@vdh.virginia.gov

COMMONWEALTH OF VIRGINIA

APPLICATION FOR A

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

(CHAPTER 4, ARTICLE 1:1 OF TITLE 32.1,

SECTIONS 32.1 – 102.1 THROUGH 32.1 – 102.12 OF

THE CODE OF VIRGINIA OF 1950, AS AMENDED)

OUTPATIENT FACILITIES

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

- A. Fairfax Colon & Rectal Surgical Center, LLC
Official Name of Facility

2710 Prosperity Ave., Ste 200
Address

Fairfax VA 22031
City State Zip

(703) 280-2841
Telephone

- B. Fairfax Colon & Rectal Surgical Center, LLC
Legal Name of Applicant

2710 Prosperity Ave., Ste 200
Address

Fairfax VA 22031
City State Zip

- C. Chief Administrative Officer

Michael Delac
Name

2710 Prosperity Ave., Ste 200
Address

Fairfax VA 22031
City State Zip

(703) 650-2333
Telephone

- D. Person(s) to whom questions regarding application should be directed:

Michael Delac, Chief Operating Officer
Name

2710 Prosperity Ave., Ste 200
Address

<u>Fairfax</u>	<u>VA</u>	<u>22031</u>
City	State	Zip
<u>(703) 650-2333</u>	<u>(703) 712-8304</u>	
Telephone	Facsimile	

E. Type of Control and Ownership (Complete appropriate section for both owner and operator.)

Will the facility be operated by the owner? Yes

<u>Owner of the Facility</u> (Check one)	<u>Proprietary</u>	<u>Operator of Facility</u> (Check one)
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(1) _____	(1) Individual	(1) _____
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(2) _____	(2) Partnership-attach copy of Partnership Agreement and receipt showing that agreement has been recorded	(2) _____
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(3) _____	(3) Corporate-attach copy of Articles of Incorporation and Certificate of Incorporation	(3) _____
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(4) <u>X</u>	(4) Other <u>LLC</u>	(4) <u>X</u>
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- Articles of Organization attached

Non-Profit

(5) _____	(5) Corporation-attach copy of Articles of Incorporation and Certificate of Incorporation	(5) _____
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(6) _____	(6) Other _____ Identify	(6) _____
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Governmental

(7) _____	(6) State	(7) _____
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(8) _____	(8) County	(8) _____
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(9) _____	(9) City	(9) _____
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(10) _____ (10) City/County (10) _____
 (11) _____ (11) Hospital Authority or Commission (11) _____
 (12) _____ (12) Other _____ Identify (12) _____

F. **Ownership of the Site (Check one and attach copy of document)**

- (1) _____ Fee simple title held by the applicant
 (2) _____ Option to purchase held by the applicant
 (3) _____ leasehold interest for not less than _____ years
 (4) _____ Renewable lease, renewable every 10 years
 (5) _____ ☒ Other Master Service Agreement

- See attached *Master Service Agreement and Facilities Agreement* between Fairfax Colon & Rectal Surgical Center, LLC (ASC/Applicant) and Fairfax Colon & Rectal Surgery, PC, defining financial responsibility, including equal share in property lease costs.

G. **Attach a list of names and addresses of all owners or persons having a financial interest of five percent (5%) or more in the medical care facility.**

(a) In the case of proprietary corporations also attach:

- (1) A list of the names and addresses of the board of directors of the corporation.
 (2) A list of the officers of the corporation.

- See attached list of ownership structure and directorship positions, *FCRS & FCRSC Ownership Structure Eff 01.01.2023*

(3) The name and address of the registered agent for the corporation.

- Registered Agent, *Fairfax Colon & Rectal Surgical Center, LLC*, and *Fairfax Colon & Rectal Surgery, PC*:
 - Registered Agent: Kimberly A. Matzie, MD, FACS, FASCRS
 Home Address: 3123 Northwood Rd, Fairfax, VA 22031
 Work Address: 2710 Prosperity Ave, Ste 200, Fairfax, VA 22031

H. List all subsidiaries wholly or partially owned by the applicant.

- N/A

I. List all organizations of which the applicant is wholly or partially owned subsidiary.

- *Fairfax Colon & Rectal Surgical Center, LLC* (applicant) is a wholly owned subsidiary of *Fairfax Colon & Rectal Surgery, PC*.

J. If the operator is other than the owner, attach a list of the names(s) and addresses of the operator(s) of the medical care facility project. In the case of a corporate operator, specify the name and address of the Registered Agent. In the case of the partnership operator, specify the name and address of the general or managing partner.

- N/A

K. If the operator is other than the owner, attach an executed copy of the contract or agreement between the owner and the operator of the medical care facility.

- N/A

SECTION II ARCHITECTURE AND DESIGN

A. Location of the Proposed Project

1. Size of site: .93 acres
2. Located in Falls Church, Fairfax County City/County/Planning District
3. Address or directions 2735 Hartland Rd., Falls Church, VA 22043

4. Has site been zoned for type of use proposed:

X Yes (attach copy of zoning or use permit)

- See attached *FCRS-Outpatient Application Zoning Exhibit*

_____ No

If no, explain status _____

B. Type of project for which Certificate of Public Need is requested. (Check one)

- (1) _____ New construction
- (2) _____ Remodeling/modernization of an existing facility
- (3) _____ No construction or remodeling/modernization
- (4) X Other: Renovation and Modernization of an existing commercial office building into an outpatient ambulatory care facility on the first floor. (Identify)

C. Design of the facility

- (1) Does the facility have a long-range plan? If yes, attach a copy.

- *Fairfax Colon & Rectal Surgical Center's* long-range strategic plan and ultimate goal is to expand access to efficient, cost-effective, patient-centered colorectal care in a strategically located facility. The design incorporates space planning and infrastructure that will accommodate both current and projected volumes of colorectal surgical and procedural services.

The project includes two operating rooms and one procedure room, providing flexibility in surgical and procedural scheduling. The layout also features a dedicated waiting room, expanded sterile processing space, and increased medical supply storage to support anticipated clinical growth.

Administratively, the facility is designed to enhance workflow efficiency and includes adequate space for the addition of nursing, clerical, and administrative staff. The mechanical, medical gas, and electrical systems are sized to support future equipment upgrades, ensuring adaptability to evolving technology.

The facility design fully complies with current Facility Guidelines Institute (FGI) standards and anticipates future regulatory requirements.

- (2) Briefly describe the proposed project with respect to location, style and major design features, and the relationship of the current proposal to the long range plan.

- The proposed project involves repurposing an existing, underutilized commercial office building located near the intersection of Interstate 66 and I-495, a highly accessible location for patients across the Northern Virginia region. The site is also close in proximity to major healthcare facilities, including Inova Fairfax Hospital. The project will focus on renovating the building's interior to support high-quality outpatient colorectal surgical care, while preserving the existing exterior structure, with only minor modifications to meet the functional requirements of the new ambulatory surgery center. This renovation strategy aligns with Fairfax Colon & Rectal Surgical Center's long-range plan to expand access to efficient, cost-effective, and patient-centered colorectal care in a strategically located facility.

(3) Describe the relationship of the facility to public transportation and highway access.

- The facility location is highly accessible for patients across the Northern Virginia region, conveniently located near the intersection of Interstate 66 and I-495, adjacent to Hartland Green Park, on Hartland Road. Additionally, this facility is located in proximity to the following public transportation:

- Dunn Loring Metro Station: Approximately 1 mile away
- WMATA Bus Stop: Approximately .8 miles away
- Fairfax Connector Bus Stop: Approximately .5 miles away

(4) Relate the size, shape, contour and location of the site to such problems as future expansion, parking, zoning and the provision of water, sewer and solid waste services.

- The site of *Fairfax Colon & Rectal Surgical Center's* proposed ambulatory surgery center is well-suited to support both current operations and future needs. It is a previously developed, underutilized commercial office parcel with a size, shape, and topography appropriate for outpatient surgical use. The property is zoned for commercial/business purposes, fully complying with regulatory requirements for an ambulatory surgery center.

The existing building footprint and surrounding lot provide ample space for patient and staff access, safe ingress and egress, and all required code-compliant modifications. The site configuration supports efficient reuse of the structure, with only minor exterior renovations needed to accommodate its new surgical function. Although vertical or horizontal expansion is not currently planned, the layout allows for modest future interior reconfiguration as service volumes increase. Locating the surgery center on the ground floor further improves patient accessibility and operational efficiency.

Parking facilities are already in place and exceed local zoning requirements, ensuring ample capacity for patients, staff, and caregivers without the need for additional

construction. The site's zoning permits medical and surgical outpatient use, and no rezoning or variances will be required.

The facility will utilize existing public water and sewer infrastructure, both of which have sufficient capacity to support the proposed operations. Solid waste and regulated medical waste services will be provided by licensed third-party vendors in compliance with all applicable local, state, and federal requirements. No off-site infrastructure improvements are necessary to support the project.

- (5) If this proposal is to replace an existing facility, specify what use will be made of the existing facility after the new facility is completed.
- The current lease at *Fairfax Colon & Rectal Surgical Center, LLC*, an existing non-COPN facility, located at 2710 Prosperity Ave, Ste 200, Fairfax, VA 22031, terminates July 1, 2026, with optional month-to-month extensions, up to twelve months.
- (6) Describe any design features which will make the proposed project more efficient in terms of construction costs, operating costs, or energy conservation.
- The design of the proposed *Fairfax Colon & Rectal Surgical Center* emphasizes efficiency in construction costs, operational performance, and energy conservation. By repurposing an existing commercial office building, the project avoids the costs associated with new site development, structural construction, and major exterior work. The scope of renovation is focused primarily on the interior build-out, which significantly reduces overall construction time and expense.

The layout is designed for operational efficiency, with a compact floor plan that minimizes unnecessary travel distances for staff, centralizes sterile processing and supply areas, and optimizes patient flow from registration through recovery. The inclusion of two operating rooms and one procedure room provides scheduling flexibility while right sizing the space to match anticipated volumes, helping to control staffing and facility overhead costs.

Energy conservation measures include the use of modern HVAC systems with zone controls to manage energy use by area and occupancy, as well as LED lighting throughout the facility. The design takes advantage of existing insulation and window infrastructure, supplemented as needed to improve thermal performance. Low-flow plumbing fixtures and Energy Star-rated appliances will be used to reduce water and energy consumption.

Together, these features reflect a cost-conscious, environmentally responsible design that supports high-quality surgical care while managing long-term facility operating costs.

- D. Describe and document in detail how the facility will be provided with water, sewer and solid waste services. Also describe power source to be used for heating and cooling purposes. Documentation should include, but is not limited to:
- The proposed *Fairfax Colon & Rectal Surgical Center* will utilize existing municipal utility connections already in place at the project site, which previously served a commercial office building. These utility services are sufficient to support the scope of the new ambulatory surgical center without requiring any off-site upgrades.

Water and Sewer Services

Water and sanitary sewer services will be provided by *Fairfax Water Authority* and *Fairfax County Wastewater Management*, respectively. The site is already connected to the municipal water main and sanitary sewer lines, and system capacity has been confirmed as adequate for medical and surgical outpatient use. Plumbing upgrades within the building will include new medical-grade fixtures, backflow prevention devices, and low-flow faucets and toilets to improve efficiency and meet current health and building code requirements.

Solid Waste and Medical Waste Disposal

Solid waste services will be provided by the building's current waste disposal and recycling vendor, *Waste Management*. The design includes a designated indoor holding area for general solid waste and recyclable materials in compliance with Fairfax County regulations.

Medical and regulated waste will be collected, stored, and disposed of in accordance with all local, state, and federal regulations, including OSHA and EPA guidelines. Our licensed medical waste management provider, *Secure Waste*, will be contracted for regular pick-up and safe transport of biohazardous materials, sharps, and other regulated waste. The facility will include a secure, access-controlled medical waste storage area with appropriate ventilation and spill containment.

Power Source – Heating and Cooling

The facility will be served by *Dominion Energy*, which provides electric utility service to the area. The first-floor renovation for *Fairfax Colon & Rectal Surgical Center* will include a modern, high-efficiency electric HVAC system with zoned temperature controls, allowing for optimized climate control based on area usage. The HVAC system will support required air exchange rates for surgical environments and incorporate HEPA filtration in clinical areas as needed.

The system will be designed to comply with current *ASHRAE* and *FGI Guidelines* for ambulatory surgery centers. The electrical system will also be upgraded to meet the power demands of surgical equipment, medical devices, lighting, and IT infrastructure, and will include emergency backup capabilities.

- (1) Letters from appropriate governmental agencies verifying the availability and adequacy of utilities,
 - (2) National Pollution Discharge Elimination System permits,
 - (3) Septic tank permits, or
 - (4) Receipts for water and sewer connection and sewer connection fees.
- See attached Utility Receipts from Landlord, *Dominion Energy Invoice*, *Fairfax_Water_Invoice*, *Waste Management Invoice*

E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify:
 - a. The total number of square feet (both gross and net) in the proposed facility.
 - b. The total number of square feet (both gross and net) by department and each type of patient room (the sum of the square footage in this part should equal the sum of the square footage in (a) above and should be consistent with any preliminary drawings, if available).
 2. If Item #2 was checked in II-B, specify:
 - a. The total number of square feet (both gross and net) by department and each type of patient room in the existing facility.
 - b. The total number of square feet (both gross and net) to be added to the facility.
 - c. The total number square feet (both gross and net) to be remodeled, modernized, or converted to another use.
 - d. The total number of square feet (both gross and net) by department and each type of patient room in the facility upon completion. (The sum of square footage in this part should equal the sum of the square footages in parts (a) and (b) above and should be consistent with any preliminary drawings, if available. (The department breakdown should be the same as in (a) above.)
- Not applicable

3. Specify design criteria used or rationale for determining the size of the total facility and each department within the facility.
- The design of *Fairfax Colon & Rectal Surgical Center, LLC*, was guided by best practices for single-specialty ambulatory surgical centers and the specific procedural and operational needs of a high-volume colorectal surgery practice. The proposed ASC will be approximately 5200 square feet, sized to accommodate two operating rooms, one procedure room (built to operating room specifications), and the necessary pre-operative and post-anesthesia care units (PACU) to support safe, efficient patient throughput.

This configuration was determined based on:

- Historical case volume from the practice's 17-year record of outpatient anorectal procedures,
- Projected future demand from expanded access to Medicare, Medicaid, and Tricare patients,
- Procedure types typically performed (including hemorrhoidectomy, fissure repair, fistulotomy, HRA, colonoscopy, etc.), which are well-suited for outpatient settings with short recovery periods,
- Compliance with FGI Guidelines for Design and Construction of Outpatient Facilities, including room size minimums, sterile processing flow, and ADA accessibility,

Support spaces have been proportionally scaled to support full operations without excess square footage. The size of the facility balances patient care efficiency, staff workflow, and future growth while remaining cost-effective and code-compliant.

F. Attach a plot plan of the site which includes at least the following:

- See attached ALTA Survey 240806015 ALTA 08 22 2024 (24 x 36)
 1. The courses and distances of the property line.
- See attached ALTA Survey 240806015 ALTA 08 22 2024 (24 x 36)
 2. Dimensions and location of any buildings, structures, roads, parking areas, walkways, easements, right-of-way or encroachments on the site.
- See attached ALTA Survey 240806015 ALTA 08 22 2024 (24 x 36)

G. Attach a preliminary design drawing drawn to a scale of not less than 1/16"-1'0" showing the functional layout of the proposed project which indicates at least the following:

- See attached preliminary Drawing/Floor Plan *FCRS-OutpatientApplication-Floor Plan-Exhibit*

1. The layout of each typical functional unit.
2. The spatial relationship of separate functional components to each other.
3. Circulatory spaces (halls, stairwells, elevators, etc.) and mechanical spaces.

H. Construction Time Estimates

1. Date of Drawings:
Preliminary 03/27/2025 Final: 10/15/2025
2. Date of Construction:
Begin 12/09/2025 Completion 08/21/2026
3. Target Date of Opening: 09/01/2026

SECTION III

SERVICE DATA

A. In brief narrative form describe the kind of services now provided and/or the kind of services to be available after completion of the proposed construction or equipment installation.

- For the past seventeen years, *Fairfax Colon & Rectal Surgical Center, LLC* has provided, and will continue to provide, outpatient colorectal and anorectal surgical care at our existing non-COPN surgical facility. Our primary surgical services include:
 - **Hemorrhoidectomy** for *Grade III-IV hemorrhoids*, including conventional excision and Transanal Hemorrhoidal Dearterialization (THD)
 - **Fissurectomy/Sphincterotomy**, such as lateral internal sphincterotomy (LIS), for treatment of *anal fissures*
 - **Fistulotomy** procedures, including ligation of intersphincteric fistula tract (LIFT) and endorectal advancement flaps, for *anal fistulas*
 - **Pilonidal Cystectomy**, including cystotomy and Bascom techniques for *pilonidal cysts*
 - **Colonoscopy** with/without polypectomy for *diagnostic polyp detection and/or surveillance and colorectal cancer screening*
 - **Flexible sigmoidoscopy** for monitoring non-operative management of *rectal cancer*
 - **High-Resolution Anoscopy (HRA)** for the detection and surveillance of anal intraepithelial neoplasia (AIN) and early *anal cancer*
 - **Perirectal Abscess Incision & Drainage (I&D)** for surgical incision and drainage of perirectal abscess
 - **Sphincteroplasty** for *fecal incontinence*
 - **Excision of rectal lesions**, skin tags, and condyloma

Upon completion of this project, *Fairfax Colon & Rectal Surgical Center, LLC* will continue to provide the core outpatient colorectal and anorectal surgical services listed above. In alignment with our commitment to clinical excellence, we will also remain responsive to advancements in surgical techniques, technologies, and best practices. As innovations in outpatient colorectal care emerge, we will ensure that our providers are trained accordingly and that such advancements are appropriately integrated into our center to enhance patient outcomes and procedural capabilities.

Additionally, this project will enable us to significantly expand access to these essential services for patients across the entire Northern Virginia region, with a particular focus on improving access for individuals covered by government-sponsored health plans, including Tricare, Medicare, Medicare Advantage, and Medicaid.

B. Describe measures used or steps taken to assure continuity of care.

- To ensure continuity of care, *Fairfax Colon & Rectal Surgical Center, LLC* implements a comprehensive set of procedures and protocols designed to support seamless, safe, and coordinated patient care across all phases of the surgical experience. These measures include:
 1. Regular Clinical Oversight Meetings: Monthly and periodic meetings between the Medical Director and Clinical Director to review clinical protocols, address patient care concerns, and support continuous quality improvement.
 2. Governing Body Meetings: Monthly and annual meetings of the Governing Body to guide both business operations and clinical planning, ensuring alignment with regulatory and quality care standards.
 3. Emergency Preparedness Planning: Comprehensive emergency response plans are maintained and reviewed regularly, including drills and staff training to ensure patient safety and care continuity during unexpected events.
 4. Staff Training and Competency: New hires undergo structured competency evaluations at 30 days, 90 days, and annually, to ensure clinical readiness and adherence to facility protocols.
 5. Certified Electronic Health Record Use: The center uses a CEHRT-certified Electronic Medical Record (EMR) system to document, track, and share patient information securely and efficiently, facilitating coordination across providers.
 6. Clinical Staffing Standards: The facility maintains appropriate nursing and clinical staff-to-patient ratios to ensure high-quality, personalized care and timely response to patient needs.
 7. Credentialing and Privileging: All clinical staff undergo rigorous credentialing, recredentialing, and privileging processes to verify qualifications and maintain standards of care.
 8. IT and Data Security: Proactive monitoring of all IT systems ensures data integrity, security, and uptime of critical patient information systems.

9. **24/7 Provider Coverage:** A provider is on-call 24/7 with after-hours answering service support, ensuring patients and referring providers have access to clinical guidance outside of regular business hours.

Together, these measures support a coordinated and patient-centered approach to care, ensuring that each patient receives appropriate follow-up, communication, and support throughout their surgical experience.

C. What procedures are utilized in quality care assessment?

- To ensure *Fairfax Colon & Rectal Surgical Center, LLC* consistently delivers the highest standard of patient care, we implement a robust Quality Assurance and Performance Improvement (QAPI) program grounded in national best practices and regulatory guidelines. The following procedures and protocols are utilized at specified intervals to monitor, evaluate, and improve clinical quality and patient outcomes:

Risk Management & Clinical Oversight

1. Annual and periodic *Infection Control Risk Assessments*
2. Annual and periodic *Risk Management Assessments*
3. *Root Cause Analyses* conducted for any adverse events (as they occur)
4. *Near-Miss Reporting* with immediate review and mitigation strategies (as they occur)

Clinical Performance Review

5. *Monthly Clinical Chart Audits* with a *Quarterly Report Card* provided to each surgeon
6. *Internal and External Clinical Benchmarking* using AAAHC standards and comparative data
7. *Annual Quality Improvement Studies*, as required by AAAHC

Patient Experience & Outcomes Monitoring

8. *Real-time Patient Satisfaction Surveys*, reviewed with follow-up as needed; reported quarterly
9. *Daily Tracking* of transfers, adverse incidents, adverse events, and readmissions; summarized monthly
10. *Follow-up Protocols* for all patients requiring transfer, to ensure care continuity

Clinical Safety Monitoring

11. *Monthly Tracking and Reporting of Surgical Site Infections (SSIs)*
12. *Monthly Peer Review* of all transfers, adverse incidents, adverse events, and readmissions
13. *Daily Post-operative Follow-up* via phone call and/or secure EMR patient portal
14. *Pre-operative Nurse Phone Calls*, typically conducted seven days prior to the procedure

Emergency Preparedness & Accreditation

15. *Quarterly Scenario-Based Emergency Drills*, including simulations for disaster response, fire, patient emergencies, facility issues, and inclement weather
16. *AAAHC Certification and Recertification*, maintained continuously since the center's inception

These measures collectively support a proactive, data-driven approach to quality assessment and continuous improvement, ensuring safe, effective, and patient-centered care in an outpatient surgical setting.

- D. Describe the plan for obtaining additional medical, nursing and paramedical personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.

- Upon completion of the project, *Fairfax Colon & Rectal Surgical Center, LLC*, will obtain all additional clinical and administrative personnel necessary to ensure safe, efficient, and high-quality delivery of outpatient colorectal and anorectal surgical services.

To ensure timely staffing, *Fairfax Colon & Rectal Surgical Center, LLC* will initiate a hiring campaign several months prior to project completion utilizing our current new hire resources including local and regional nursing programs and existing workforce personnel. Competitive compensation, benefits, flexible scheduling, and opportunities for professional growth will be offered to attract and retain top talent.

2. Is this outpatient facility affiliated with or does it have a transfer agreement with a hospital?

☒ Yes (Give name of hospital) *Inova Fairfax Hospital*

☐ No

- See attached *Transfer Agreement ASC 10-2-06 Evergreen*

3. Is (will) there (be) an arrangement whereby medical records can readily be transferred between this outpatient facility and an inpatient facility (ies)?

☒ Yes

☐ No

4. Outpatient services are (will be) available from 7:30 a.m. to 4:30 p.m. five days of week.

5. Does (will) the facility operate scheduled clinics?

☐ Yes (Attach clinic schedule list) ☒ No

6. Are there other organized outpatient services in your primary service area?

☐ Yes ☒ No

7. The outpatient facility is (will be) staffed:

(a) Only by physicians on call: ☐ Yes ☐ No

(b) By full time physicians: ☒ Yes ☐ No

(c) By physicians who limit their practice to this outpatient service? ☐ Yes ☐ No

8. State specifically any limitations or restrictions for participation in the services of the facility.

- There are no general limitations or restrictions for participation in the services provided by *Fairfax Colon & Rectal Surgical Center, LLC*. The only exceptions involve *clinical contraindications*, where a patient's medical condition, anesthesia risk, or complexity of care would make treatment in a hospital setting more appropriate. In such cases, patients are referred to a higher-acuity facility to ensure their safety and receive the most appropriate level of care.

G. Please provide historical and/or project utilization statistics for the facility including number of patients, number of patient visits and number of patient services.

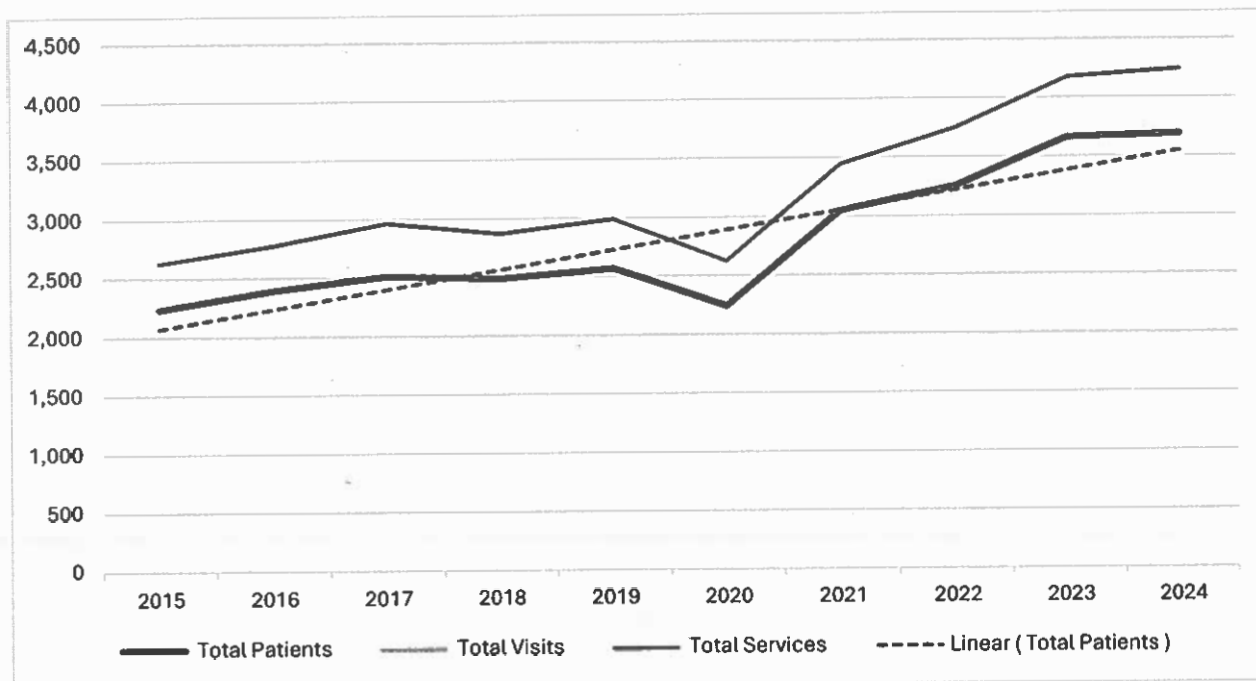
- Over the past ten years, *Fairfax Colon & Rectal Surgical Center, LLC* has experienced significant growth, with a 65% increase in *Total Annual Patient Visits* and *Total Unique Patients*, and a 62% increase in *Total Patient Services* performed (surgeries/procedures).

See the table and graph below for details:

Historical Utilization- 10- Year: 2015-2024

Year	Total Unique Patients	Total Visits	Total Patient Services
2015	2233	2240	2627
2016	2390	2396	2776
2017	2510	2519	2962
2018	2484	2490	2869
2019	2567	2572	2984
2020	2239	2245	2622
2021	3050	3060	3442
2022	3247	3252	3747
2023	3660	3662	4174
2024	3687	3690	4242

Historical Utilization-Ten Year: 2015-2024



- Over the past three years, during a period of significant growth, *Fairfax Colon & Rectal Surgical Center, LLC* has experienced a sustained increase in patient volume and procedural demand. Specifically, the center has seen an average annual growth rate of approximately 6.5% in total patient volume (measured by unique patients and total visits), and 7.2% in surgical and procedural volume (measured by total patient services).

This growth has been driven by increasing regional demand for outpatient colorectal surgical care, as well as our ability to accommodate that demand through more efficient use of our existing resources. Notably, we have expanded our clinical throughput by utilizing both of our surgical suites simultaneously on two days per week, resulting in an overall capacity utilization rate of approximately 68%. This demonstrates both operational efficiency and the need for additional capacity to meet future demand.

The table below summarizes the Average Annual Growth Rates in key service metrics over the past three years:

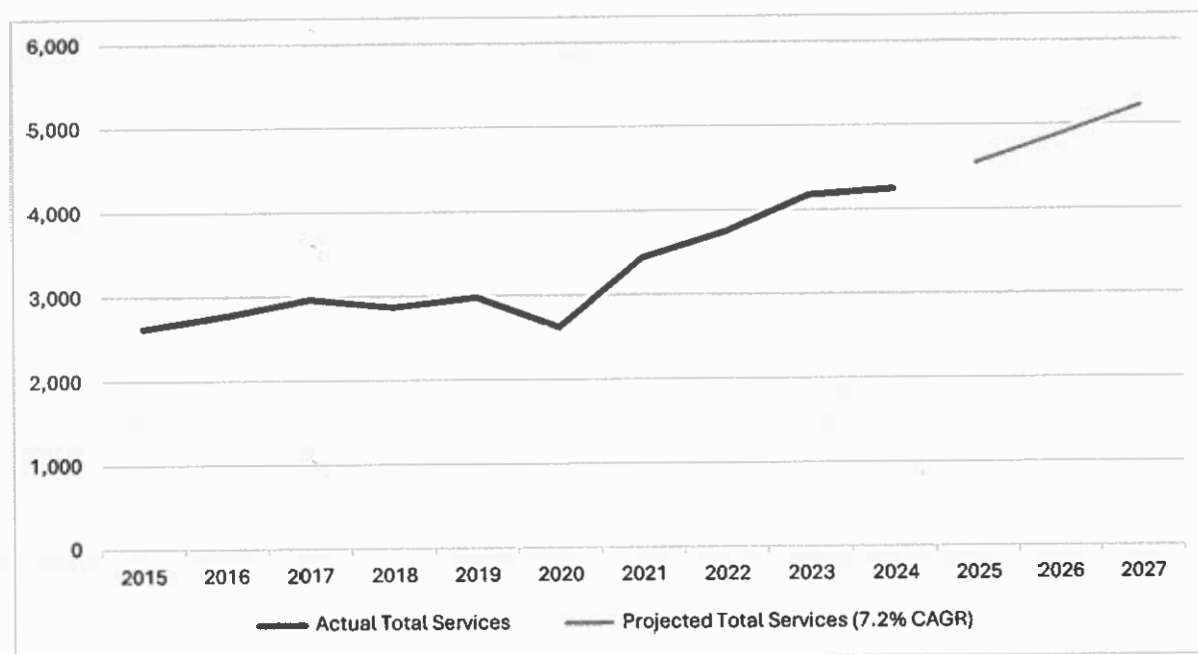
Average Annual Growth Rate (2021-2024)	
Total Patients:	6.5%
Total Visits:	6.4%
Total Patient Services (Surgeries/Procedures):	7.2%

- Based on our historical growth trajectory, current capacity constraints, and the additional procedural capacity that will result from this project, *Fairfax Colon & Rectal Surgical Center, LLC* projects an increase in surgical and procedural volume from 4,242 procedures in 2024 to over 5,200 by 2027. These projections are intentionally conservative and do not yet reflect the anticipated additional volume from addressing the unmet need among patients covered by government-sponsored health plans, including Medicare, Medicaid, and Tricare. Many of these patients currently experience extended delays in access to care due to limited capacity at existing facilities in the region.

The table and graph below summarize the projected utilization of patient services over the next three years, based on the Average Annual Growth Rates previously identified.

Projected Utilization (7.2% annual growth)	
Year	Projected Total Patient Services
2025	4,548
2026	4,876
2027	5,228

Projected Total Services (Actual & Projected)

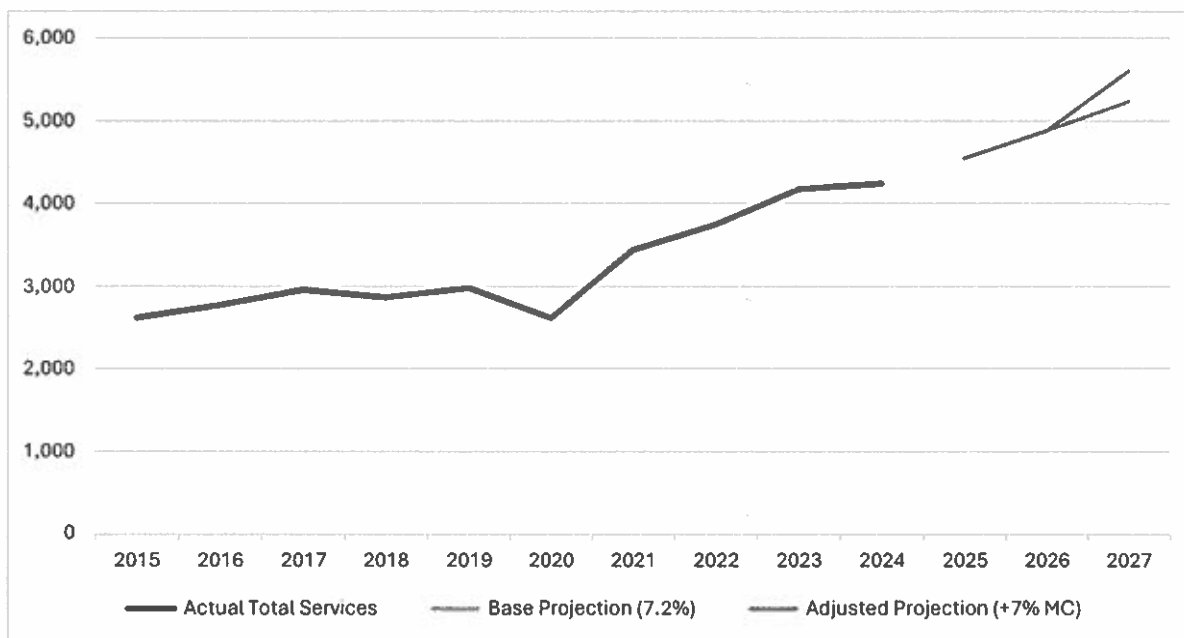


Upon COPN approval and Medicare certification, we anticipate further acceleration in growth due to newly accessible patient populations and continued demand for high-quality colorectal surgical services. *Fairfax Colon & Rectal Surgical Center, LLC* conservatively estimates an additional 7% increase in surgical volume beginning in 2027, the first full year after Medicare certification (actual government payer outpatient hospital surgery volume in 2024 was 476 individual cases, potentially representing an 11% increase if done in our center). This conservative projection reflects increased access for previously excluded Medicare beneficiaries and is consistent with observed unmet need, referral wait times, and public policy priorities favoring expanded access to outpatient surgical care.

The table and graph below represent a 7% Medicare-access bump applied starting in 2027:

Projected Total Patient Services (with Medicare Certification Impact)		
Year	Base Projection	Adjusted Projected (Medicare-access bump)
2025	4,548	4,548
2026	4,876	4,876
2027	5,228	5,594

Projected Total Services (with Medicare Certification Impact)



H. Staffing of Existing and/or Proposed Facility

In the following categories, indicate the number of full-time equivalent personnel (at least 35 hours per week).

		<u>Current</u>	<u>Additional</u>	<u>Needed</u>
	<u>Full</u>	<u>Vacant</u>	<u>Full</u>	<u>TOTAL</u>
	<u>Time</u>	<u>Positions</u>	<u>Time</u>	
Total number of Full-time staff	14	0	2	16
Administration-Business Office	3	0	0	3
Registered Nurses	7	0	1	8
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	4	1	1	6
Registered Medical Records Librarian	_____	_____	_____	_____
Registered Pharmacists	_____	_____	_____	_____
Laboratory Medical Technologists	_____	_____	_____	_____
ADA Dieticians	_____	_____	_____	_____
Radiologic Technologists	_____	_____	_____	_____
Occupational Therapists	_____	_____	_____	_____
Physical Therapists	_____	_____	_____	_____
Psychologists	_____	_____	_____	_____
Psychiatric Social Workers	_____	_____	_____	_____
Recreational Therapists	_____	_____	_____	_____
Inhalation Therapists	_____	_____	_____	_____
Medical Social Workers	_____	_____	_____	_____

Other Health

Professionals, Identify _____

All Other Personnel (Exclude Physicians and Dentists)

- I. Present a plan for obtaining all additional personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.
 - *Fairfax Colon & Rectal Surgical Center, LLC* has been fortunate to maintain its current FTE status over the years through its current recruiting and human resource strategies. Currently, we have only one available LPN position to fulfill to be considered “fully” staffed. We are confident we will be able to fill this position within the next month. Not listed in the FTE staffing table above, we currently have three PRN RN’s and one PRN LPN that we can call upon for coverage needs. Additionally, if there are periods of staffing shortages, *Fairfax Colon & Rectal Surgical Center, LLC* has an agreement with a nursing staffing agency called *Medely*, to support us.

Upon completion of the project, *Fairfax Colon & Rectal Surgical Center, LLC*, will obtain all additional clinical and administrative personnel necessary to ensure safe, efficient, and high-quality delivery of outpatient colorectal and anorectal surgical services. We currently anticipate adding three additional FTE’s to be considered fully staffed, including one Processing Technician, one Registered Nurse, and one Licensed Practice Nurse.

To ensure timely staffing, *Fairfax Colon & Rectal Surgical Center, LLC* will initiate a hiring campaign several months prior to project completion utilizing our current new hire resources including local and regional nursing programs and existing workforce personnel. Competitive compensation, benefits, flexible scheduling, and opportunities for professional growth will be offered to attract and retain top talent.

The table below represents our Staffing Timeline/Milestone Chart:

Staffing Timeline / Milestone Chart		
Timeframe	Milestone	Personnel Involved
6 months prior to open	Finalize staffing plan	Administrator/Clinical Director
5 months prior to open	Initiate recruitment/job postings	All ASC Personnel
4 months prior to open	Interviewing/candidate selection	All ASC Personnel
3 months prior to open	Job offers/onboarding/training begins	Administrator/Clinical Director
2 months prior to open	Continuous training	All ASC Personnel
1month prior to open	Continuous training	All ASC Personnel
Opening month	Facility opens/full staff operational	All ASC Personnel

J. Describe the anticipated impact that the project will have on the staffing of other facilities in the service area.

- *Fairfax Colon & Rectal Surgical Center, LLC* does not anticipate a significant impact on the staffing levels of other healthcare facilities in the service area. Given the robust and diverse healthcare labor market in Northern Virginia, we do not expect to draw a substantial number of personnel from area hospitals or existing ambulatory surgical centers.

This project represents a modest-scale, specialty-specific ambulatory surgery center with relatively limited staffing needs compared to large hospital systems. Staffing will be sourced through a combination of personnel transitioning from our existing office-based surgical practice, new graduates from local healthcare training programs, and targeted recruitment efforts via staffing agencies and online platforms.

While some degree of natural workforce mobility is expected with any new facility, the overall impact on the regional healthcare labor pool is expected to be minimal and carefully managed through proactive recruitment planning.

K. Attach the following information or documents:

1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers).
 - See Attached Business License *Fairfax Colon & Rectal Surgical Center Fairfax County Business License Ex 03.01.2026*
2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers).
 - See Attached AAAHC Accreditation Certificate & Report AAAHC OBS 74778 Certificate, and 74778 Ambulatory Accreditation Letter 301614
3. Roster of medical staff (existing facilities). Indicate their specialty, Board Certification, Board eligibility and staff privileges (active, associate, etc.).
 - See Attached Roster *FCRSC-Medical Staff Roster 2025*
4. Copies of letters of commitment or statement of intent from physicians indicating they will staff the proposed new facility or service upon completion (existing and proposed facilities).
 - See Attached Letters *FCRSC-Commitment Letter by Provider*

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

A. Please provide a comprehensive narrative description of the proposed project.

- *Fairfax Colon & Rectal Surgical Center, LLC* proposes to convert its existing office-based outpatient surgical practice—specializing exclusively in colorectal and anorectal procedures for the past seventeen years—into a dedicated, freestanding ambulatory surgery center (ASC). This conversion to a Medicare-certified facility will significantly expand access to timely, high-quality colorectal care for all residents of Northern Virginia, helping to address substantial unmet needs in one of the Commonwealth’s fastest-growing regions. The project involves the development of a state-of-the-art, single-specialty facility located in Fairfax County, Virginia, within Health Planning Region II (HPR II).

Fairfax Colon & Rectal Surgical Center, LLC is a physician-led organization formed by the board-certified colorectal surgeons of *Fairfax Colon & Rectal Surgery, PC*, a private, physician-owned practice that currently provides the majority of outpatient colorectal surgical services in the region. These surgeons are actively affiliated with the Inova Health System and UVA Haymarket Medical Center and bring deep regional experience and longstanding clinical leadership to this project.

The new ASC will include two operating rooms, one procedure room, and support areas specifically designed for high-efficiency, high-quality, outpatient colorectal surgical care. Procedures commonly performed at the center will include:

- Hemorrhoidectomy
- Anal fissure repair (fissurectomy)
- Fistulotomy and seton placement
- Incision and drainage of perirectal abscesses
- Pilonidal cyst excision
- High-resolution anoscopy
- Colonoscopy and flexible sigmoidoscopy
- Sphincteroplasty
- Excision of rectal lesions, skin tags, and condyloma

These services will be delivered in a Medicare-certified, AAAHC-accredited outpatient surgery center operated by the current team of board-certified colorectal surgeons of *Fairfax Colon & Rectal Surgery, PC*. The facility will be

staffed with a combination of experienced existing personnel, newly hired clinical and administrative support staff, and current contracted anesthesiologists. It will be equipped with advanced surgical and anesthesia equipment suitable for scheduled and same-day procedures requiring moderate to deep sedation or general anesthesia.

The proposed ASC will primarily serve adult patients with colorectal and anorectal conditions that are appropriate for outpatient surgical treatment. Currently, many of these patients are referred to hospital operating rooms or hospital-affiliated ASCs, or present to emergency departments due to prolonged wait times, limited access, or inefficient scheduling. These environments often result in higher costs, limited operating room availability, and delayed care.

By transitioning into a dedicated ASC, *Fairfax Colon & Rectal Surgical Center* will be able to offer more streamlined, patient-centered care in a high-volume, low-acuity setting, improving access for both privately insured and government-sponsored patients. This project directly addresses capacity limitations and will improve timely access to care, particularly for patients covered by Medicare, Medicaid, Tricare, and other government health plans.

B. Identification of Community Need

1. Describe the geographic boundaries of the facility's primary service area. (Note: Primary service area may be considered to be geographic area from which 75% of patients are expected to originate.)
 - The primary service area for *Fairfax Colon & Rectal Surgical Center, LLC* encompasses the geographic region from which approximately 75% of our patients have historically originated and are expected to continue to originate following the transition to a Medicare-certified ambulatory surgery center.

This area includes:

- **Fairfax County: 42%**
- **Prince William County: 10%**
- **Loudoun County: 12%**
- **Arlington County: 6%**
- **City of Alexandria: 5%**

Collectively, these localities represent the population core of Northern Virginia, specifically within Health Planning Region II (HPR II). These communities are contiguous, densely populated, and within a 30–45-minute drive time of the proposed ASC's location. The area's well-developed transportation

infrastructure, including I-66, I-495, and U.S. Route 50, supports timely and efficient patient access.

Secondary service areas, defined as areas contributing the remaining 25% of our patient population, include:

- **Spotsylvania County**
- **Stafford County**
- **City of Fredericksburg**
- **District of Columbia**
- **Montgomery and Prince George's Counties in Maryland**

These areas are home to many federal employees, veterans, and Tricare beneficiaries who currently travel into Fairfax County for specialty colorectal care due to limited availability of outpatient surgical options closer to home.

The proposed project will help meet rising regional demand and expand access to underserved populations, particularly government-sponsored health plan enrollees residing within this core service region.

2. Provide patient origin, discharge diagnosis or utilization data appropriate for the type of project proposed.

Patient Origin

- Excluding same-day urgent anorectal surgeries, patients are typically scheduled at *Fairfax Colon & Rectal Surgical Center* following an office consultation with a provider from *Fairfax Colon & Rectal Surgery*. Surgical intervention is recommended when the patient's condition cannot be safely or effectively managed in an office-based setting. Typically, patients treated at *Fairfax Colon & Rectal Surgery & Fairfax Colon & Rectal Surgical Center* are originally referred by their primary care provider, gastroenterologist, OB/GYN, oncologist, or self-referred.

Practice Utilization Data

The most common clinical conditions and corresponding CPT/ICD-10 codes treated at our existing office-based surgical center are outlined in the table below:

Condition/Procedure	% of Total Volume (2024)
Hemorrhoidectomy	28%
Anal Fissure Repair	4%
Fistulotomy	9%
Perirectal Abscess I&D	1%
Pilonidal Cyst Excision	1%
Colonoscopy/Flex Sigmoidoscopy	41%
High-Resolution Anoscopy	6%
Excision of Rectal Lesions	10%

Epidemiologic Justification and Demand Projections

The U.S. population aged 65 and older is projected to increase by over 90% between 2005 and 2025, fueling a 21.3% increase in outpatient colorectal procedures. This demographic shift underscores the urgent need for ambulatory services, especially in high-growth areas like Fairfax County. Most of the increased demand centers on screening and management of benign anorectal conditions—procedures best suited to ambulatory settings.

Clinical Efficacy & Utilization Trends

Hemorrhoidectomy

Hemorrhoidectomy represents a significant share of all anorectal surgical procedures and continues to be one of the most frequently performed operations in ambulatory surgical settings. According to national data, hemorrhoidectomy accounts for up to 69% of all ambulatory anorectal surgeries, underscoring its prominence in outpatient colorectal care.

The American Society of Colon and Rectal Surgeons (ASCRS) strongly supports excisional hemorrhoidectomy as the definitive treatment for patients with advanced hemorrhoidal disease, specifically Grade III and Grade IV internal hemorrhoids that are prolapsing and irreducible or refractory to non-operative management. Compared to office-based interventions (e.g., rubber band ligation or sclerotherapy), surgical hemorrhoidectomy provides superior long-term symptom relief and markedly reduces recurrence in patients with severe or circumferential disease.

Clinical outcomes associated with excisional hemorrhoidectomy are favorable. The procedure is generally well-tolerated in healthy patients and can be safely and efficiently performed in an outpatient setting under monitored anesthesia care. Complication rates remain low, with the most common adverse events being self-limited postoperative bleeding and transient urinary retention. Modern anesthesia techniques, improved surgical tools, and enhanced recovery protocols have further reduced post-procedural discomfort and shortened recovery time.

Utilization and Access Trends

The demand for surgical hemorrhoidectomy continues to rise, driven by:

- An aging population, which is more prone to advanced hemorrhoidal disease;
- Increased rates of chronic constipation, obesity, and sedentary lifestyle, contributing to hemorrhoid development;
- Limited access to specialized colorectal care in some outpatient settings, particularly for Medicaid and Medicare patients.

As a result, colorectal surgeons are increasingly performing these procedures in ASCs and office-based surgical suites. Shifting care to outpatient environments improves patient access, reduces overall costs, and frees hospital operating room resources for more complex inpatient cases.

Despite its outpatient suitability, patients often experience access barriers related to payer mix, facility constraints, and referral delays, especially in regions lacking Medicare-certified colorectal-focused ASCs. This can result in delayed care, worsening symptoms, and avoidable emergency department visits.

Project Relevance

Fairfax Colon & Rectal Surgical Center, LLC, has extensive experience in performing excisional hemorrhoidectomy in an office-based setting. The proposed conversion to a freestanding, Medicare-certified ambulatory surgery center will enable the facility to:

- Expand access to high-quality, guideline-supported hemorrhoidectomy for patients with government insurance (e.g., Medicare, Medicaid, Tricare);
- Increase procedure capacity to meet regional demand;
- Provide timely intervention for patients at risk of complications from delayed treatment.

Given its clinical efficacy, strong support from national surgical guidelines, and demonstrated outpatient suitability, surgical hemorrhoidectomy is a cornerstone procedure that highlights the necessity of expanded ASC capacity for anorectal care in the region.

Anal Fissure Repair

Anal fissures are a frequent source of severe anorectal pain and disability. While the majority of acute fissures resolve with conservative treatment, including stool regulation, sitz baths, and topical medications, up to 4% of patients develop chronic, non-healing fissures that ultimately require surgical management. These chronic fissures are typically characterized by persistent pain, bleeding, and sphincter spasm, often with visible hypertrophic papillae or sentinel skin tags.

The gold standard surgical intervention for chronic fissures is lateral internal sphincterotomy (LIS). This procedure involves partial division of the internal anal sphincter to reduce resting pressure, thereby facilitating blood flow and healing. LIS demonstrates consistently high success rates, with published healing outcomes ranging from 93% to 98%, and is strongly endorsed by the American Society of Colon and Rectal Surgeons (ASCRS) for patients who do not respond to medical therapy.

LIS is a brief and highly effective outpatient procedure that is routinely performed under regional or general anesthesia in ambulatory surgery centers. The procedure:

- Results in rapid pain relief and high patient satisfaction;
- Has low complication rates, with rare instances of minor postoperative bleeding or transient incontinence;
- Requires minimal recovery time and is associated with long-term durability of symptom resolution.

Utilization Trends and Patient Access Considerations

The demand for surgical fissure repair remains steady across demographic and clinical populations. In particular, increased utilization is seen among:

- Patients with chronic constipation, inflammatory bowel disease (such as Crohn's disease), and other conditions predisposing to fissure recurrence;
- Older adults, who have demonstrably lower rates of healing with conservative management;
- Medicaid and Medicare beneficiaries, who often face delays in accessing specialty colorectal care, leading to progression from acute to chronic fissures.

Given its high clinical efficacy, safety in outpatient settings, and cost-effectiveness, LIS has increasingly shifted to non-hospital environments. However, geographic and payer-related access barriers continue to limit the availability of this procedure for many patients in Northern Virginia—particularly those insured by government programs or requiring urgent evaluation and follow-up care.

Project Relevance

Through the proposed establishment of a Medicare-certified ambulatory surgery center, *Fairfax Colon & Rectal Surgical Center, LLC* will expand access to high-quality surgical fissure repair for patients across the region. With nearly two decades of experience treating fissures in an office-based surgery setting, the facility is uniquely positioned to:

- Deliver timely and effective surgical care to patients with chronic fissures;
- Accept publicly insured and underserved populations who currently face delays in referral and treatment;
- Reduce avoidable emergency department visits and hospital-based procedures for fissure-related pain and complications.

As part of its comprehensive suite of outpatient anorectal services, lateral internal sphincterotomy reflects both the clinical excellence and public health benefit of expanding access to specialized colorectal care in an ambulatory surgery setting.

Perirectal Abscess I&D (Incision & Drainage)

Perirectal abscess, also known as perianal abscess, is a common and potentially serious anorectal condition characterized by infection in the soft tissues surrounding the rectum or anus. These infections frequently originate from obstructed anal glands and can progress rapidly without appropriate surgical intervention. If not effectively treated, perirectal abscesses can lead to more complex conditions such as fistula-in-ano, systemic infection, or tissue necrosis.

The standard of care for perirectal abscess is timely surgical incision and drainage, which achieves resolution in the vast majority of cases. Clinical studies and national guidelines consistently demonstrate that >90% of patients experience complete symptom relief following prompt drainage. When performed early, surgical treatment is associated with low complication rates, reduced recurrence, and high patient satisfaction. Antibiotics are typically reserved for immunocompromised individuals or patients presenting with systemic signs of infection.

The American Society of Colon and Rectal Surgeons (ASCRS) and other professional bodies affirm that most perirectal abscesses can and should be managed in outpatient surgical settings, including ASCs when clinically appropriate. These settings provide equivalent outcomes to inpatient facilities for uncomplicated cases, while offering enhanced efficiency, lower costs, and greater patient convenience.

Utilization Trends and Demand

The national incidence of perirectal abscess is estimated at 68,000 to 96,000 new cases annually in the United States, with evidence of increasing frequency over the past decade. This growth correlates with rising rates of diabetes, obesity, immunosuppression, and inflammatory bowel disease—all of which are risk factors for abscess development. Additionally, urban and underserved populations experience

higher rates of emergency department visits for anorectal infections, many of which could be diverted to outpatient settings with proper access.

Over the last ten years, there has been a clear shift in the management of perirectal abscesses from inpatient hospital-based care to outpatient environments. This trend reflects broader efforts to improve care coordination, reduce unnecessary hospitalization, and expand access to timely surgical treatment. Notably, approximately 30–50% of patients with a perirectal abscess will develop a chronic anorectal fistula requiring additional surgical follow-up, such as fistulotomy or seton placement—further reinforcing the need for specialized and continuous outpatient colorectal care.

At present, patients requiring timely drainage of perirectal abscesses may face access barriers due to limitations in hospital operating room availability or payer-related restrictions, particularly for Medicaid or uninsured patients. These delays can result in worsening infection, emergency department overutilization, or prolonged morbidity.

Project Relevance

The proposed conversion of *Fairfax Colon & Rectal Surgical Center, LLC*, into a licensed freestanding ASC will directly address the increasing need for timely, outpatient management of perirectal abscesses and related anorectal conditions. By expanding access to surgical services under Medicare and Medicaid certification, the facility will:

- Improve timely access to high-efficacy surgical drainage procedures;
- Reduce emergency room burden and avoidable inpatient admissions;
- Ensure comprehensive follow-up care for fistula development;
- Serve high-risk, underserved, and government-insured populations more effectively.

Given the high clinical efficacy of outpatient abscess management and the documented trends toward increased incidence and outpatient utilization, the proposed project is both timely and aligned with regional and statewide healthcare delivery goals.

Anal Fistula Surgery/Fistulotomy

Anal fistulas are abnormal connections between the anal canal and perianal skin, most often arising as a chronic complication of a previously drained perianal abscess. These tracts can cause persistent drainage, pain, recurrent infection, and significant patient discomfort. Prompt and effective surgical management is necessary to achieve healing, prevent recurrence, and preserve continence.

The management of anal fistulas is highly individualized, depending on fistula anatomy, complexity, and relationship to the anal sphincter muscles. For simple, low-lying fistulas, fistulotomy, a procedure involving the careful unroofing of the tract remains

the gold standard. It is associated with greater than 90% success rates and a low risk of incontinence, particularly in patients without significant sphincter involvement.

For complex or high transsphincteric fistulas, newer sphincter-preserving techniques such as the Ligation of the Intersphincteric Fistula Tract (LIFT) procedure have shown excellent outcomes. Studies report healing rates as high as 99% for appropriately selected patients, with preservation of continence and reduced postoperative morbidity. Other advanced treatments—including advancement flaps, seton placement, and biologic plugs—are also utilized when indicated.

These procedures are safely and effectively performed in outpatient surgical settings. Advantages of managing fistulas in ambulatory environments include:

- Reduced anesthesia risk and same-day discharge;
- Low postoperative complication rates;
- High patient satisfaction due to rapid return to normal function and reduced pain;
- Efficient scheduling for follow-up care and staged interventions if required.

Utilization Trends and Patient Access Considerations

The need for surgical fistula management remains consistent across populations, with heightened demand among:

- Patients with prior perianal abscess;
- Those with Crohn's disease or other inflammatory bowel conditions, who are prone to complex fistulas;
- Working-age adults, for whom outpatient care and minimal downtime are critical;
- Medicare and Medicaid populations, who often face care delays and are more likely to experience disease progression.

Fistula care often requires ongoing coordination with primary care, gastroenterologists, and colorectal specialists. Access to prompt surgical evaluation is critical to avoid worsening infection, fistula tract extension, or formation of multiple external openings.

Project Relevance

Fairfax Colon & Rectal Surgical Center, LLC, has extensive experience managing anal fistulas, including simple fistulotomy, staged seton placement, and advanced sphincter-sparing procedures. The proposed conversion to a Medicare-certified ASC will:

- Expand access to timely and individualized fistula care;

- Reduce reliance on hospital operating rooms for non-complex anorectal procedures;
- Improve outcomes for publicly insured patients by streamlining referral and follow-up;
- Support long-term disease management for Crohn's patients and others requiring staged or repeat interventions.

Given the clinical effectiveness, safety profile, and efficiency of outpatient fistula surgery, this service represents a vital component of the center's commitment to comprehensive, accessible colorectal care in Northern Virginia.

Pilonidal Cyst Excision/Cystectomy

Pilonidal disease is characterized by painful, draining sinus tracts that often require surgical intervention after failure of conservative or antibiotic therapies. Without proper treatment, pilonidal disease may lead to recurrent infections, abscess formation, and significant impairment of daily activities, including school and work attendance.

Historically, treatment involved wide surgical excision with open or closed wound healing, often resulting in prolonged recovery, high recurrence rates, and considerable patient discomfort. In recent years, however, minimally invasive surgical techniques have gained traction due to their superior outcomes and improved patient experience. The most notable advancement is the Endoscopic Pilonidal Sinus Treatment (EPSiT), which allows for direct visualization and ablation of the sinus tract using a fistuloscope and electrocautery.

EPSiT and similar minimally invasive approaches are associated with:

- High healing rates (~95%);
- Low recurrence rates (5–6%), especially when compared to wide excision;
- Rapid return to normal activities, often within days;
- Minimal postoperative pain and excellent cosmetic outcomes.

These procedures are ideally suited for outpatient settings, where they can be performed under local or regional anesthesia with same-day discharge. As national standards evolve, the use of less invasive, tissue-sparing techniques is increasingly considered the preferred approach to surgical pilonidal disease management.

Utilization Trends and Patient Access Considerations

Pilonidal disease affects tens of thousands of young adults annually in the United States, resulting in a high cumulative burden of disease and productivity loss. This population—often without established primary care—frequently presents to urgent care centers or emergency departments during acute flare-ups. Many patients require

timely access to specialized surgical care for definitive treatment and to prevent recurrence.

Outpatient surgical management is essential to ensure:

- Reduced disruption to school and work schedules;
- Decreased reliance on emergency departments;
- Avoidance of extended wound care following traditional excision;
- Access to updated standards of care, such as EPSiT, which are not widely available in general hospital settings.

Access is especially limited for uninsured, underinsured, and publicly insured patients, who often experience longer delays and reduced continuity of care.

Project Relevance

As part of its comprehensive suite of colorectal and anorectal services, *Fairfax Colon & Rectal Surgical Center, LLC* has integrated minimally invasive techniques for pilonidal disease, including EPSiT and modified excision with off-midline closure when appropriate. With the proposed transition to a licensed ambulatory surgery center, the facility will:

- Expand access to up-to-date, minimally invasive surgical management;
- Serve a high-need, younger patient population, including those with Medicaid and no insurance;
- Reduce hospital and ER burden for an otherwise low-acuity but high-volume condition;
- Provide high-quality, evidence-based care with a focus on rapid recovery and patient-centered outcomes.

The inclusion of advanced pilonidal disease treatment within a dedicated outpatient surgery center represents a meaningful step forward in aligning regional care delivery with best practices and evolving clinical standards.

High-Resolution Anoscopy (HRA)

High Resolution Anoscopy (HRA) is a specialized diagnostic procedure used to detect anal intraepithelial neoplasia (AIN), the precursor to anal cancer. This technique is especially critical in high-risk populations, including:

- Individuals living with HIV/AIDS;
- Men who have sex with men (MSM);

- Patients with a history of HPV-related cervical, vulvar, or vaginal dysplasia;
- Solid organ transplant recipients and other immunosuppressed individuals.

Similar in concept to cervical colposcopy, HRA allows for direct magnified visualization of the anal canal and perianal skin using a colposcope after acetic acid and Lugol's iodine are applied. Suspicious lesions can then be biopsied under direct visualization. This procedure is crucial for early detection and prevention of anal cancer, which has seen rising incidence in recent years, particularly among immunocompromised patients.

National guidelines, including those from the Centers for Disease Control and Prevention (CDC), HIV Medicine Association (HIVMA), and Infectious Diseases Society of America (IDSA), support regular HRA screening for high-risk populations. The ANCHOR Study (2022), a landmark NIH-funded randomized controlled trial, demonstrated that treatment of high-grade anal dysplasia significantly reduces progression to anal cancer, affirming the value of HRA-guided surveillance and intervention.

Clinical Efficacy and Outpatient Suitability

High resolution anoscopy is a non-invasive outpatient diagnostic tool with the following advantages:

- Enables targeted biopsy of dysplastic lesions;
- Facilitates same-session diagnosis and planning for local ablation or excision;
- Is well-tolerated under local anesthesia or mild sedation;
- Offers early intervention opportunities to prevent progression to invasive anal cancer.

When coupled with follow-up ablative therapies—such as infrared coagulation, radiofrequency ablation, or surgical excision—HRA serves as the cornerstone of comprehensive anal dysplasia management in high-risk groups.

Utilization Trends and Gaps in Access

As awareness of anal cancer risk increases, demand for HRA continues to grow, particularly in regions with large urban and LGBTQ+ populations, as well as areas with a high prevalence of HIV. However, access to qualified HRA providers remains limited nationwide, with most care concentrated in academic centers.

In Northern Virginia and the surrounding region:

- There are very few providers trained to offer HRA, resulting in long wait times and geographic barriers;
- Many high-risk patients, including those with Medicaid, are unable to access this potentially life-saving surveillance;

- Primary care, HIV specialists, and gynecologists frequently refer patients for evaluation but lack local options for timely anoscopy and treatment.

Project Relevance

As part of its specialized surgical offerings, *Fairfax Colon & Rectal Surgical Center, LLC* currently performs HRA and anal dysplasia management for a growing network of community-based and referring providers. The transition to a Medicare-certified ambulatory surgery center will allow the facility to:

- Expand access to HRA for high-risk, underserved populations;
- Integrate surveillance with same-site treatment for anal dysplasia;
- Serve as a regional center of excellence for anal cancer prevention in collaboration with infectious disease, OB/GYN, and primary care colleagues;
- Reduce the burden on tertiary academic centers by offering community-based screening and management.

Given the strong clinical evidence supporting HRA and the growing need for equitable access to preventive anal cancer care, the inclusion of this service within the proposed ASC is fully aligned with public health priorities and best practices in colorectal disease management.

Colonoscopy & Flexible Sigmoidoscopy

Colonoscopy and flexible sigmoidoscopy are cornerstone procedures in the diagnosis, treatment, and prevention of lower gastrointestinal disease. These lower endoscopy services are vital for:

- Colorectal cancer (CRC) screening and surveillance;
- Evaluation of rectal bleeding, anemia, abdominal pain, chronic diarrhea, and weight loss;
- Diagnosis and monitoring of inflammatory bowel disease;
- Polyp detection and removal, with immediate therapeutic benefit.

Colonoscopy remains the gold standard for CRC screening, offering both diagnostic and therapeutic capabilities. The U.S. Preventive Services Task Force (USPSTF), American Cancer Society, and Centers for Medicare & Medicaid Services (CMS) recommend screening begin at age 45, reflecting the rising incidence of early-onset colorectal cancer.

Flexible sigmoidoscopy, though less comprehensive than a colonoscopy, remains valuable for targeted rectosigmoid evaluation, particularly in younger patients and when full colonoscopy is not immediately feasible. More recently flexible sigmoidoscopy has become central to surveillance strategies for patients

undergoing non-operative management of rectal cancer. Guidelines from the American Society of Colon and Rectal Surgeons (ASCRS), NCCN, and others recommend 3–6-month surveillance intervals, primarily via sigmoidoscopy or endorectal ultrasound, for up to five years post-treatment.

Clinical Efficacy and Preventive Value

Colonoscopy and flexible sigmoidoscopy have well-established clinical benefits:

- Colonoscopy reduces CRC mortality by up to 68% through early detection and polypectomy;
- Therapeutic endoscopy allows for real-time intervention—removing precancerous lesions, cauterizing bleeding, and performing biopsies;
- Both procedures are safe in outpatient settings, with low complication rates (<0.1% for serious adverse events);
- Recovery is rapid, and patients typically resume normal activities within 24 hours.

Outpatient colonoscopy is widely endorsed by payers and policy bodies as the most cost-effective and clinically impactful strategy for cancer prevention.

Utilization Trends and Unmet Need

Utilization of colonoscopy and flexible sigmoidoscopy has increased significantly in recent decades, driven by:

- Expanded screening guidelines and public awareness;
- Increased referrals from primary care and gastroenterology for diagnostic and surveillance needs;
- Rising incidence of CRC among patients under age 50.

Despite these trends, barriers to timely access persist, especially for patients who:

- Are uninsured or covered by Medicaid or Medicare;
- Lack a regular primary care physician or screening navigator;
- Live in areas where hospital outpatient departments prioritize higher-acuity cases.

In Northern Virginia, demand for timely outpatient colonoscopy and flexible sigmoidoscopy exceeds availability in many settings, particularly among:

- Medicaid and Tricare beneficiaries;
- Patients needing screening in conjunction with anorectal surgical evaluation;

- High-risk populations with positive fecal immunochemical test (FIT) or family history of colorectal cancer.
- Patients requiring frequent surveillance for non-operative management of rectal cancer

Project Relevance

The conversion of *Fairfax Colon & Rectal Surgical Center, LLC* to a licensed ASC center will support:

- Expanded capacity for screening and diagnostic colonoscopy for patients of all payers;
- Streamlined access for individuals with concurrent anorectal complaints, allowing for same-day evaluation and surgical intervention when indicated;
- Collaboration with primary care providers, OB/GYNs, and infectious disease specialists to close CRC screening gaps;
- Timely endoscopic surveillance for patients with inflammatory bowel disease, anal dysplasia, or prior colorectal polyps.

As demand continues to rise for lower endoscopy services, especially among aging and government-insured populations, providing these procedures in a dedicated, high-efficiency ASC setting will advance cancer prevention and enhance access to timely gastrointestinal care.

Sphincteroplasty

Sphincteroplasty remains a mainstay surgical treatment for fecal incontinence caused by traumatic or obstetric anal sphincter injuries, particularly in patients with identifiable sphincter defects on imaging (e.g., endoanal ultrasound or MRI). It is most commonly performed in middle-aged to older women with persistent incontinence symptoms despite conservative management.

Clinical Efficacy

- Over 70% of patients report significant symptom improvement following sphincteroplasty, with short-term continence rates of 70–90% in well-selected patients.
- Long-term success rates decline gradually over time, with studies showing sustained improvement in 50–60% of patients at 5 years post-surgery.
- Success is highest in those with discrete external sphincter defects, intact pudendal nerve function, and without significant coexisting pelvic floor disorders.

- Complication rates are relatively low, with rare risks of infection, wound breakdown, or recurrence of incontinence.
- It is endorsed by the American Society of Colon and Rectal Surgeons (ASCRS) as a first-line surgical treatment in appropriate candidates with external sphincter disruption.

Utilization Trends

- The number of sphincteroplasties performed annually has remained stable or slightly declined in recent years, largely due to:
 - Increased awareness and early repair of obstetric anal sphincter injuries (OASIS)
 - Wider adoption of nonsurgical alternatives such as sacral neuromodulation (InterStim) and injectable bulking agents
- Despite this, sphincteroplasty remains the most common surgical treatment for fecal incontinence in younger and midlife patients with structural defects.
- It is almost exclusively performed in the outpatient or ambulatory surgical setting, reflecting both safety and efficiency of care.
- As the population ages and awareness of pelvic floor disorders increases, demand for evaluation and surgical treatment of fecal incontinence is expected to grow modestly, particularly among Medicare and Medicaid populations, who often experience delayed diagnosis and limited access to specialty pelvic floor care.

Excision of rectal lesions, skin tags, and condyloma

Minor anorectal procedures, including excision of rectal polyps, skin tags, and anal condyloma—play a critical role in the management of benign and pre-malignant conditions, symptom relief, and cancer prevention. These procedures are routinely and safely performed in the outpatient setting, often under local or monitored anesthesia care.

Clinical Efficacy

- **Rectal Lesions:** Excision of rectal lesions such as adenomas or inflammatory polyps allows for both histopathologic diagnosis and definitive removal, often obviating the need for more invasive interventions. Endoscopic and transanal excisional techniques are associated with high diagnostic accuracy and curative intent for benign and low-grade dysplastic lesions.
- **Skin Tags:** Though benign, anal skin tags may cause hygiene issues, discomfort, or cosmetic concern. Surgical excision is definitive, with low recurrence and

high patient satisfaction, particularly among patients with prior hemorrhoidal disease or perianal trauma.

- Condyloma (Anogenital Warts): Caused by human papillomavirus (HPV), anal condyloma often recurs and may progress to high-grade dysplasia (AIN II/III) or squamous cell carcinoma in at-risk patients. Excisional treatment offers the benefit of:
 - Complete lesion removal
 - Pathologic evaluation for dysplasia or malignancy
 - Decreased recurrence when combined with immunologic or topical therapy
- Excision is often preferred over ablative or topical therapies for extensive, symptomatic, or recurrent cases, or when cancer cannot be ruled out clinically.

Utilization Trends

- Utilization of excisional procedures for anal lesions has increased modestly due to:
 - Rising HPV-related disease prevalence, especially in immunocompromised patients (e.g., HIV-positive individuals)
 - Greater use of High-Resolution Anoscopy (HRA) and anal cancer screening programs
 - Patient demand for definitive management of symptomatic tags or cosmetic concerns
- These procedures are frequently performed in freestanding ambulatory surgery centers, allowing efficient, high-volume care without occupying hospital ORs.
- Medicaid and Medicare patients, as well as uninsured individuals, often face delays in diagnosis and treatment due to limited access to anorectal specialists; expanding outpatient surgical capacity improves timely access to care and reduces progression to advanced disease.

C. 1. Is (are) the service(s) to be offered presently being offered by any other existing facility(ies) in the Health Planning Region?

- Yes: In addition to the surgical services currently provided by *Fairfax Colon & Rectal Surgical Center, LLC*, some of the proposed procedures can be performed at existing facilities within Health Planning Region II (HPR II), including local hospitals and their hospital-affiliated ambulatory surgery centers. However, the majority of these services are already being performed by

the surgeons of *Fairfax Colon & Rectal Surgery*, who currently operate at multiple locations throughout the region.

Despite the presence of other providers, access to these services—particularly for patients covered by government-sponsored health plans such as Medicare and Medicaid—is often limited. Hospital-based surgical settings frequently face constrained block time, resulting in prolonged waitlists, delayed care, and avoidable emergency department utilization. Moreover, the cost of delivering these procedures in hospital outpatient departments is significantly higher than in freestanding ambulatory surgery centers.

The proposed project does not represent a duplication of existing capacity. Rather, it expands access by establishing a dedicated, specialty-specific ambulatory surgical center focused solely on colorectal and anorectal procedures. This facility will provide timely, high-quality, and cost-effective care to a broader segment of the population, including individuals who are often underserved under the current hospital scheduling models—particularly Medicaid, Medicare, and uninsured patients.

In summary, although similar services are technically available in the region, meaningful access to timely, affordable, and specialized outpatient colorectal care remains inadequate. The proposed project is uniquely positioned to close this gap in an efficient, equitable, and sustainable manner.

2. If Yes,

a. Identify the facility(ies)

- The facilities include Inova Health System's regional locations, Virginia Hospital Center, Reston Hospital, and Sentara Northern Virginia Medical Center.

b. Discuss the extent to which the facility(ies) satisfy(ies) the current demand for the service(s).

- While several facilities within Health Planning Region II (HPR II) currently offer outpatient colorectal and anorectal surgical services, existing capacity is insufficient to meet current and projected demand—particularly for patients covered by Medicare, Medicaid, and other government-sponsored insurance plans.

Surgeons from *Fairfax Colon & Rectal Surgery* currently perform the majority of these procedures at multiple hospitals and surgery centers. However, limited availability of operating room block time at hospital-based and hospital-affiliated ambulatory surgery centers continues to constrain access. As a result, patients often experience:

- Prolonged wait times for both consultations and surgical procedures, particularly in cases involving government payers
- Delayed diagnosis and treatment, which may lead to disease progression and increased patient distress
- Inefficient use of emergency departments for issues that could be treated in a timely outpatient setting
- Increased cost of care, as procedures performed in hospital outpatient departments are significantly more expensive than those in freestanding ASCs

In many cases, patients insured by Medicare or Medicaid face more limited surgical scheduling options than commercially insured individuals. Even private pay patients may wait weeks to months for elective but necessary anorectal surgeries due to shared OR time with other specialties.

Furthermore, current facilities are not designed specifically for high-throughput, office-based anorectal care. Multispecialty ASCs prioritize a broad range of surgical services, which limits the efficiency and flexibility needed for the high-volume, same-day, low-acuity procedures that characterize outpatient colorectal practice.

While the services are technically available in the region, the current capacity does not adequately meet the demand, particularly for underserved patient populations and lower-acuity procedures. The proposed project of *Fairfax Colon & Rectal Surgical Center, LLC*, will relieve this bottleneck by offering dedicated, efficient, and affordable outpatient colorectal care, thereby enhancing access and outcomes across the region.

c. Discuss the extent to which the facility(ies) will satisfy the demand for services in five years.

- Current outpatient colorectal and anorectal surgical services in Health Planning Region II (HPR II) are operating near or at capacity, and demand is projected to increase steadily over the next five years due to demographic trends, rising prevalence of colorectal conditions, and expanded insurance coverage under government programs such as Medicare and Medicaid.

Existing facilities, including hospital outpatient departments and hospital-affiliated ambulatory surgery centers, will face ongoing challenges in expanding capacity because:

- *Limited operating room availability and block time* remain constraints within hospital-based and multispecialty ASC settings.
- *Competing priorities among surgical specialties* reduces flexibility to add colorectal cases, particularly lower-acuity outpatient procedures.

- *Rising demand from an aging population*, which is more susceptible to colorectal diseases, will further strain existing resources.
- *Increasing emphasis on cost containment and outpatient care* necessitates more efficient, specialty-specific centers.

Without additional dedicated outpatient surgical capacity, wait times for consultations and surgeries are expected to lengthen, disproportionately affecting patients covered by Medicare, Medicaid, and other government-sponsored plans.

The proposed *Fairfax Colon & Rectal Surgical Center* will address this projected shortfall by providing:

- *A specialty-specific, high-throughput ambulatory surgery center* focused exclusively on colorectal and anorectal procedures.
- Enhanced access for underserved patient populations through acceptance of Medicare, Medicaid, Tricare, and charity care.
- Efficient scheduling reduced wait times, and cost-effective outpatient care that cannot be fully met by existing hospital-based or multispecialty outpatient centers.

In five years, without the proposed facility, current providers will be unable to fully satisfy the anticipated demand for outpatient colorectal surgical services in the region. *Fairfax Colon & Rectal Surgical Center, LLC*, will play a critical role in closing this gap, ensuring timely, accessible, and affordable specialty care for the Northern Virginia population.

D. Discuss how project will fill an unmet need in the delivery of health care in the service area including, where applicable, geographic barriers to access.

- The proposed *Fairfax Colon & Rectal Surgical Center, LLC* will fill a clear and growing unmet need in the delivery of outpatient colorectal and anorectal surgical care in Health Planning Region II (HPR II).

While similar services are available within the region, access still remains limited, and these services are not available in a freestanding, specialty-dedicated facility that offers efficient, affordable, and timely access for all patients. The proposed project addresses this unmet need by creating a purpose-built setting where these patients can receive high-quality care without the following barriers:

Access Barriers

- *Government sponsored health plan beneficiaries*, such as Tricare, Medicare and Medicaid

- *Uninsured and underinsured patients*
- Patients requiring prompt care for non-life-threatening but functionally limiting anorectal conditions

Systemic Access Barriers

1. *Surgical Block Time Constraints*
Current hospital and ASC partners allocate limited surgical block time to colorectal surgeons, particularly for low-acuity, outpatient procedures. As a result, patients frequently wait weeks—or even months—for access to operating rooms.
2. *Disproportionate Impact on Government-Payer Populations*
Many facilities prioritize commercially insured patients due to reimbursement concerns, further limiting timely access for Medicare, Medicaid, and Tricare patients. This leads to delays in care, increased emergency department visits, and avoidable disease progression.
3. *Cost Barriers*
Hospital-based outpatient departments are significantly more expensive than freestanding ASCs. For uninsured or underinsured patients, these higher costs may limit their willingness or ability to proceed with needed care.
4. *Lack of Specialty-Focused Facilities*
Multispecialty ASCs lack the procedural focus, equipment, and scheduling flexibility required to efficiently manage the unique needs of colorectal and anorectal surgery patients.

Geographic Barriers

While Northern Virginia is a densely populated region, patients residing outside the immediate corridors of large hospital campuses—such as those in southern Fairfax County, Prince William County, and parts of Loudoun County—may face additional challenges accessing centralized hospital-based services due to:

- Traffic congestion and transportation challenges
- Limited availability of specialists in closer community-based settings
- Consolidation of surgical services to large urban medical campuses

The proposed facility in Fairfax County is strategically located to serve patients throughout Northern Virginia, with convenient access from multiple counties, and is easily reached via major commuter routes. It will bring dedicated colorectal surgical care into a community-based, lower-cost, outpatient environment, making care more geographically and financially accessible.

By offering timely, affordable, and specialized colorectal surgical care in a freestanding ASC, the project addresses systemic and geographic barriers that currently prevent many patients from receiving the care they need—especially those with government-sponsored coverage or limited financial resources. The proposed center will significantly improve equity, efficiency, and overall access in the regional healthcare system.

E. Discuss the consistency of the proposed project with applicable Regional Health Plan, State Health Plan, State Medical Facilities Plan, or other plans promulgated by State agencies.

- The proposed *Fairfax Colon & Rectal Surgical Center, LLC* is consistent with the goals and objectives outlined in the *Virginia State Medical Facilities Plan (SMFP)* and supported by historical planning positions of Health Planning Region II (HPR II) and the former Health Systems Agency of Northern Virginia (HSANV). The project also supports broader objectives of the Virginia State Health Improvement Plan (SHIP).

Under the SMFP's section on Ambulatory Surgical Services (12VAC5-230-310 through 370), the Plan encourages the development of ambulatory surgical services that:

- "Improve geographic and financial access to surgical services for all patients, including the medically underserved." [12VAC5-230-360]
- "Demonstrate that existing facilities are insufficient to meet current and projected demand." [12VAC5-230-320]
- "Support the efficient and appropriate use of surgical services, including a shift from inpatient to outpatient settings when clinically appropriate." [12VAC5-230-310]
- "Avoid unnecessary duplication of services." [12VAC5-230-340]

The *Fairfax Colon & Rectal Surgical Center* project complies with these provisions by:

- Expanding access to timely outpatient colorectal and anorectal surgery for underserved patients, particularly those covered by Medicare, Medicaid, and Tricare, as well as the uninsured.
- Addressing unmet demand caused by limited OR block time and long waitlists at hospital-based and multispecialty ASCs.
- Enhancing cost-efficiency by providing high-volume, low-acuity procedures in a lower-cost outpatient setting, rather than hospital outpatient departments.

- Avoiding duplication by focusing on a dedicated specialty that is underserved in current outpatient infrastructure.

Historically, previous HPR II reviews and HSNV recommendations have consistently supported projects that:

- Offload appropriate cases from inpatient settings to reduce hospital congestion and costs.
- Target specialty services that face scheduling bottlenecks or access delays.
- Support geographic distribution of care throughout Northern Virginia, not just around major hospital campuses.
- Ensure access for government payers, especially in high-cost markets like Northern Virginia.

This proposed project aligns with these regional planning priorities by:

- Creating new specialty-specific capacity where none currently exists in a freestanding form.
- Reducing pressure on hospital systems like Inova, Reston Hospital Center, and Virginia Hospital Center.
- Increasing geographic accessibility to patients in underserved or outlying areas of Fairfax, Prince William, and Loudoun counties.

The Virginia SHIP outlines statewide priorities including:

- Reducing disparities in access to care
- Increasing preventive and early-intervention services
- Expanding community-based care infrastructure

The project supports these objectives by offering:

- Expanded colorectal cancer screening and high-resolution anoscopy
- Early-stage surgical intervention for anorectal conditions
- Community-based outpatient care in a cost-effective, accessible environment

The proposed *Fairfax Colon & Rectal Surgical Center, LLC* is fully consistent with the SMFP's standards for non-duplicative, need-driven, specialty-based ambulatory surgical development. It also advances the goals of both the SHIP and prior HPR II planning efforts by expanding access, reducing delays, enhancing efficiency, and serving a broad and inclusive patient population across Northern Virginia.

F. Show the method and assumptions used in determining the need for additional beds, new services or deletion of service in the proposed project's service area.

- The need for the proposed freestanding ambulatory surgery center (ASC) was determined based on a combination of historical utilization trends, population growth, regional surgical demand, and system inefficiencies affecting patient access to timely care.

1. Historical Utilization and Growth Trends

Fairfax Colon & Rectal Surgical Center, LLC has operated a high-volume, office-based outpatient surgical practice for 17 years, focused exclusively on colorectal and anorectal conditions. Over the past three years (2021–2024), we have experienced an average annual growth rate of:

- 6.5% in total patient volume (unique patients and total visits), and
- 7.2% in surgical/procedural volume (total services rendered).

Despite operating two procedure rooms, our practice is now approaching 68% capacity utilization—even while offering outpatient surgeries only two full surgical days per week. This consistent year-over-year growth demonstrates strong, ongoing demand and limited remaining capacity under the current model.

2. Projected Demand for Services

Projections using the average annual growth rate (AAGR) of 7.2% applied to the current 2024 procedural volume (4,242 cases) indicate:

- Over 4,500 procedures projected in 2025
- More than 5,200 procedures by 2027, assuming no change in payer mix or referral sources.

These projections are conservative and do not yet account for the increased demand expected from the population currently underrepresented in our patient base, specifically Medicare, Medicaid, and Tricare beneficiaries, for whom we are currently unable to provide services in our non-COPN facility.

3. Population and Payer Growth in HPR II

Health Planning Region II (HPR II), including Fairfax County, is one of the fastest-growing areas in the Commonwealth of Virginia. According to state demographic data:

- The adult population in Fairfax County alone is projected to grow by more than 5% over the next five years.
- The Medicare-eligible population (65+) is growing at an even faster rate, especially within suburban and urban areas of HPR II.

- Colorectal conditions disproportionately affect adults over 50, making this population growth directly relevant to projected surgical need.

4. Access Barriers in Current System

Patients requiring outpatient colorectal surgery are frequently referred to hospital-based ORs or ASCs, where they encounter:

- Long wait times due to limited block scheduling availability
- Higher costs of care
- Inefficient surgical throughput in facilities not designed for low-acuity, high-volume outpatient surgery

The inability to accept Medicare, Medicaid, and Tricare patients at our current office-based facility creates a significant barrier to access, particularly for underserved or publicly insured patients, many of whom reside in Northern Virginia and are currently experiencing avoidable delays in care.

Based on sustained growth in historical utilization, projections of increasing surgical demand, documented barriers to access for publicly insured patients, and the population growth trends within HPR II, there is clear and compelling evidence for the need to expand our services into a Medicare-certified, freestanding ASC. This project will provide dedicated surgical access for all patients, including those covered by government-sponsored plans, while decompressing the burden on local hospital systems and improving the overall efficiency of care delivery in the region.

G. Coordination and Affiliation with Other Facilities.

Describe any existing or proposed formal agreements or affiliations to share personnel, facilities, services or equipment. (Attach copies of any formal agreements with another health or medical care facility.)

- *Fairfax Colon & Rectal Surgical Center, LLC* and *Fairfax Colon & Rectal Surgery, PC* do not currently have any formal agreements or affiliations to share personnel, facilities, or equipment: However, *Fairfax Colon & Rectal Surgical Center, LLC* and *Fairfax Colon & Rectal Surgery, PC*, have partnered with Inova over the past decade, including Professional Service Agreements for providing the following services for Inova:
 - Inova Schar Cancer Institute
 - Provide collaborative colon and rectal cancer evaluation management, consultation and surgical services in partnership with Inova Schar Cancer Institute multidisciplinary clinic.
 - Inova Executive Health/VIP 360

- Provide evaluation and management services Inova Executive Health/VIP360 concierge clientele
- Inova Juniper Program
 - Provide evaluation and management services for HIV and AIDS patients
- Inova Fairfax Medical Campus-Department of Surgery
 - Provide Surgical Resident training for their Colorectal Elective Rotation

Due to the Confidentiality clauses linked to these agreements, *Fairfax Colon & Rectal Surgical Center* will not be able to provide copies of such agreements.

Additionally, Dr. Lawrence Stern, MD, FACS, FASCRS, a managing director of both Fairfax Colon & Rectal Surgery and Fairfax Colon & Rectal Surgical Center, LLC, brings significant leadership and clinical expertise to the project. Dr. Stern has served as the Inova Health System Section Chief of Colorectal Surgery for several years, a role that underscores his reputation as a regional leader in colorectal care. His ongoing collaboration with area hospitals and demonstrated commitment to advancing surgical quality and outcomes further reinforce the project's clinical credibility and alignment with broader regional health care goals.

H. Attach copies of the following documents:

- I. A map of the service area indicating:
 - a. Location of proposed project.
 - Please see attached *Map of Service Area (Pinned Location)*
- b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).
- Locations include:

Inova Medical Campus Surgery Centers
3300 Gallows Road
Falls Church, VA 22042

Inova Loudoun Ambulatory Surgery Center
44035 Riverside Pkwy, Ste 200
Leesburg, VA 20176

Inova Fair Oaks Hospital Surgery Center
 3600 Joseph Siewick Dr.
 Fairfax, VA 22033

Inova Oakville Ambulatory Surgery Center
 400 Fannon St, 2nd Floor
 Alexandria, VA 22301

Inova Alexandria Hospital Surgery Center
 4320 Seminary Road
 Alexandria, VA 22304

Reston Hospital Surgery Center
 1860 Town Center Dr
 G100
 Reston, VA 20190

Virginia Hospital Surgery Center
 1851 N. George Mason Dr.
 Arlington, VA 22207

2. Any material which indicates community and professional support for this project, i.e. letter of endorsement from physicians, community organizations, local government, Chamber of Commerce, medical society, etc.
 - Please see attached *Letter of Support (By Name)*
3. Letters to other area facilities advising of the scope of the proposed project.
 - Please see attached *Facility Notification Letter (By Facility)*

SECTION V**FINANCIAL DATA**

It will be the responsibility of the applicant to show sufficient evidence of adequate financial resources to complete construction of the proposed project and provide sufficient working capital and operating income for a period of not less than one (1) year after the date of opening:

- A. Specify the per diem rate for all existing negotiated reimbursement contracts and proposed contracts for patient care with state and federal governmental agencies, Blue Cross/Blue Shield Plans, labor organizations such as health and welfare funds and membership associations.

- *Currently, Fairfax Colon & Rectal Surgical Center, LLC does not have any proposed or existing negotiated per diem contracts and is strictly fee-for-service.*

Utilizing 2024 data, our current fee-for-service rates can be calculated as follows:

- Per Procedure: \$ 678
- Per Patient:\$ 780
- Per Diem: \$ 11,552 (249 Operational Days)

- B. Does the facility participate in a regional program which provides a means for facilities to compare its costs and operations with similar institutions?

_____ Yes X No

If yes, specify program _____
Provide a copy of report(s) which provide(s) the basis for comparison.

- C. Estimated Capital Costs

Please see "Instructions for Completing Estimated Capital Costs" Section of the Certificate of Need application for detailed instructions for completing this question (attached)

Part I – Direct Construction Costs

1.	Cost of materials	\$ _____ 0
2.	Cost of labor	\$ _____ 0
3.	Equipment included in construction contract	\$ _____ 0
4.	Builder's overhead	\$ _____ 0

5.	Builder's profit	\$ <u>0</u>
6.	Allocation for contingencies	\$ <u>0</u>
7.	Sub-total (add lines 1 thru 6)	\$ <u>0</u>

Part II – Equipment Not Included in Construction Contract

If leasehold, lease expense over entire term of lease
(List each separately)

8. a. 2 x AMSCO FG 3085 Surgical Table w/accessories \$ 55,255

b. <u>AMSCO 600 Prevac Steam Sterilizer</u>	\$ <u>112,517</u>
c. <u>AMSCO 2532 Washer/Disinfector</u>	\$ <u>45,698</u>
d. <u>Furniture/Fixtures</u>	\$ <u>75,000</u>
e. _____	\$ <u>0</u>
9. Sub-total (add lines 8a thru 8e)	\$ <u>288,470</u>

Part III – Site Acquisition Costs

10. Full purchase price	\$ <u>0</u>
11. For sites with standing structures	\$ <u>0</u>
a. purchase price allocable to structures	\$ <u>0</u>
b. purchase price allocable to land	\$ <u>0</u>
12. Closing costs	\$ <u>0</u>
13. If leasehold, lease expense over entire term of lease	\$ <u>1,296,143</u>

- *Fairfax Colon & Rectal Surgical Center, LLC* has entered into a long-term, 10-year lease agreement with FCRS Real Estate, LLC, with an option to renew. As part of this agreement, the landlord has committed up to \$3 million in tenant improvement allowances to fund the buildout of the proposed ambulatory surgery center (ASC). Current buildout estimates range between \$2.75 million and \$2.99 million.

To finance this investment, *Fairfax Colon & Rectal Surgical Center, LLC* will repay the buildout costs in monthly installments of \$25,000, which will be made concurrently with monthly rent payments. These repayments will continue through the end of the initial 10-year lease term, providing a predictable and sustainable financing structure for the ASC development.

14. Additional expenses paid or accrued:

a. <u>Tenant Allowance/Buildout repayment to Landlord</u>	\$ <u>3,000,000</u>
b. _____	\$ <u>0</u>
c. _____	\$ <u>0</u>

15.	Sub-total (add lines 10 thru 14c)	\$ 4,296,143
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Part IV – Site Preparation Costs

16.	Earth work	\$	0
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17. Site utilities	\$	0
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18.	Roads and walks	\$	0
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19. Lawns and planting	\$	0
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20. Unusual site conditions:

a. _____ \$ _____ 0

b.	\$	0
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21. Accessory structures	\$	0
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22. Demolition costs	\$	0
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23.	Sub-total (add lines 16 thru 22)	\$	0
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Part V – Off-site Costs (List each separately)

24. _____ \$ 0

25. _____ \$ 0

26. _____ \$ _____ 0

27. _____ \$ _____ 0

28.	Sub-total (add lines 24 thru 27)	\$ 0
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Part VI – Architectural and Engineering Fees

29.	Architect's design fee	\$	0
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30.	Architect's supervision fee	\$	0
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31. Engineering fees	\$	0
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32. Consultant's fees \$ 0

33.	Sub-total (add lines 29 thru 32)	\$ 0
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Part VII – Other Consultant Fees (List each separately)

34.	a.	<u>Legal Fees</u>	\$ <u>1,850</u>
	b.	<u></u>	\$ <u></u>
	c.	<u></u>	\$ <u></u>
35.	Sub-total (add lines 34a thru 34c)		\$ <u>1,850</u>

Part VIII – Taxes During Construction

36.	Property taxes during construction	\$ <u>0</u>
37.	List other taxes:	
	a. <u></u>	\$ <u>0</u>
	b. <u></u>	\$ <u>0</u>
38.	Sub-total (add lines 36 thru 37b)	\$ <u>0</u>

Part IX-A – HUD Section 232 Financing

39.	Estimated construction time(in months)	<u>0</u>
40.	Dollar amount of construction loan	\$ <u>0</u>
41.	Construction loan interest rate	<u>0</u> %
42.	Estimated construction loan interest costs	\$ <u>0</u>
43.	Term of financing (in years)	<u>0</u>
44.	Interest rate on permanent loan	<u>0</u> %
45.	FHA mortgage insurance premium	\$ <u>0</u>
46.	FHA mortgage fees	\$ <u>0</u>
47.	Financing fees	\$ <u>0</u>
48.	Placement fees	\$ <u>0</u>

49. AMPO (non-profit only) \$ 0
50. Title and recording fees \$ 0
51. Legal fees \$ 0
52. Total interest expense on permanent mortgage loan \$ 0
53. Sub-total Part IX-A HUD Section 232 Financing
(add lines 42, 45, 46, 47, 48, 49, 50 and 51) \$ 0

**Part IX-B – Industrial Development Authority Revenue and General
Obligation Bond Financing**

(Circle selected method of financing)

54. Method of construction financing (construction loan, proceeds of bond sales, if other, specify) N/A
If construction is to be financed from any source other than bond sale proceeds, answer question 56 through 58. Otherwise, proceed to question 59.
55. Estimated construction time (in months) 8
56. Dollar amount of construction loan \$ 0
57. Construction loan interest rate 0 %
58. Estimated construction loan interest cost \$ 0
59. Nature of bond placement (direct, underwriter, if other, specify) N/A
60. Will bonds be issued prior to the beginning of construction? Yes X No
61. If the answer to question 60 is yes, how long before (in months)? N/A
62. Dollar amount of bonds expected to be sold prior to the beginning of construction \$ 0
63. Will principal and interest be paid during construction or only interest? N/A
64. Bond interest expense prior to the beginning of construction(in dollars) \$ 0
65. How many months after construction begins will last bond be sold? N/A
66. Bond interest expense during construction \$ 0
67. What percent of total construction will be financed from bond issue? \$ 0
68. Expected bond interest rate N/A %

86.	Interest rate on long term loan	<u>N/A</u> %	
87.	Anticipated mortgage discount (in dollars)	\$	<u>0</u>
88.	Feasibility study	\$	<u>0</u>
89.	Finder's fee	\$	<u>0</u>
90.	Legal fees	\$	<u>0</u>
91.	Insurance	\$	<u>0</u>
92.	Other fees (list each separately)		
		\$	<u>0</u>
93.		\$	<u>0</u>
94.	Total permanent mortgage loan interest expense (in dollars)	\$	<u>0</u>
95.	Sub-total Part IX_C (add lines 84 & 88 thru 93)	\$	<u>0</u>

Financial Data Summary Sheet

96.	Sub-total Part I	Direct Construction Cost (line 7)	\$	<u>0</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	\$	<u>288,470</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	\$	<u>4,296,143</u>
99.	Sub-total Part IV	Site Preparation Cost (line 23)	\$	<u>0</u>
100.	Sub-total Part V	Off-Site Costs (line 28)	\$	<u>0</u>
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	\$	<u>0</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	\$	<u>1,850</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	\$	<u>0</u>
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	\$	<u>0</u>

105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	\$ 0
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	\$ 0
107.	TOTAL CAPITAL COST (lines 96 thru 106)		\$4,586,463
108.	Percent of total capital costs to be financed <u>N/A</u> %		
109.	Dollar amount of long term mortgage (line 107 x 108)		\$ 0
110.	Total Interest Cost on Long Term Financing		\$ 0
	a.	HUD-232 Financing (line 53)	\$ 0
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	\$ 0
	c.	Conventional Loan Financing (line 94)	\$ 0
111.	Anticipated Bond discount		
	a.	HUD-232 Financing (line 53)	\$ 0
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 70)	\$ 0
	c.	Conventional Loan Financing (line 87)	\$ 0
112.	TOTAL CAPITAL AND FINANCING COST (ADD LINES 107, 110a, b or c AND 111a, b or c)		\$ 0
D.	1.	Estimated costs for new construction (excluding site acquisition costs)	\$ 0
	2.	Estimated costs of modernization and renovation (excluding site acquisition costs)	\$ 0
E.	Anticipated Sources of Funds for Proposed Project		<u>Amount</u>
	1.	Public Campaign	\$ 0

2.	Bond Issue (Specify Type) _____	\$ 0 _____
3.	Commercial Loans	\$ 0 _____
4.	Government Loans (Specify Type) _____	\$ 0 _____
5.	Grants (Specify Type) _____	\$ 0 _____
6.	Bequests	\$ 0 _____
7.	Private Foundations	\$ 0 _____
8.	Endowment Income	\$ 0 _____
9.	Accumulated Reserves	\$ 0 _____
10.	Other (Identify) _____	\$ 0 _____

- F. Describe in detail the proposed method of financing the proposed project, including the various alternatives considered. Attach any documents which indicate the financial feasibility of the project.

Proposed Finance Structure

The capital costs associated with the proposed conversion of *Fairfax Colon & Rectal Surgical Center, LLC*, into a Medicare-certified ambulatory surgery center (ASC) will be financed through a tenant improvement allowance provided by the landlord, FCRS Real Estate, LLC, under the terms of a long-term lease agreement.

Fairfax Colon & Rectal Surgical Center, LLC has entered into a 10-year lease with an option to renew, securing stable tenancy at the proposed facility site. As part of this agreement, the landlord has committed to providing up to \$3 million in tenant improvement (TI) funds to cover the full cost of the ASC buildout. Current construction and design estimates place total buildout costs between \$2.75 million and \$2.99 million, falling well within the committed allowance.

In return for this capital contribution, *Fairfax Colon & Rectal Surgical Center, LLC* will repay the full cost of the tenant improvement allowance through monthly installments of \$25,000, to be paid concurrently with the base rent over the initial 10-year lease term. This repayment structure provides a predictable, non-debt-based approach that ensures project stability without requiring external lending or equity financing.

Fairfax Colon & Rectal Surgical Center, LLC considered alternative financing options, including:

- Bank or commercial lending to fund construction independently
- Self-funding through capital reserves
- Partnership with a hospital or third-party ASC management firm

These alternatives were ultimately rejected due to factors such as:

- The favorable terms and reduced financial risk associated with the TI-based lease structure
- Avoidance of interest-bearing debt
- Retention of full ownership and operational control by the sponsoring colorectal practice (Fairfax Colon & Rectal Surgery, PC)
- The relationship between the tenant and landlord, which facilitated a collaborative buildout structure

Financial Feasibility and Sustainability

The repayment plan aligns with projected cash flow and operating margins, which are supported by:

- Existing surgical volumes from the longstanding, office-based surgery practice
- Projected growth following Medicare certification and expanded access for Medicaid and other government-insured patients
- Controlled capital costs and phased equipment acquisition

See attachment *FCRSC 10-Year Pro Forma*, which represents a detailed 10-year financial projection for *Fairfax Colon & Rectal Surgical Center, LLC*, reflecting the project's anticipated revenues, operating expenses, rent and buildout repayment obligations, and projected EBITDA. This financial model demonstrates the long-term financial feasibility and sustainability of the proposed project.

Projected revenues are conservatively estimated based on historical growth trends and adjusted to reflect increased surgical volume from newly accessible government payer patients, including Medicare, Medicaid, and Tricare. The pro forma also reflects a revised, blended reimbursement rate per procedure to account for the inclusion of these payers.

The pro forma includes the following conservative assumptions:

- **2026 Base Year Revenue:** \$2.89 million
- **Annual Revenue Growth Rate:** 5%
- **Operating Expenses:** 60% of revenue
- **Tenant Improvement Repayment Obligation:** \$300,000 annually for 10 years
- **Rent:** Based on executed lease terms, starting at \$197,805 in Year 1 and increasing modestly through Year 10

The result is a positive EBITDA each year, demonstrating that *Fairfax Colon & Rectal Surgical Center, LLC* will operate profitably while fulfilling its repayment and operating obligations.

- G. Describe the impact the proposed capital expenditure will have on the cost of providing care in the facility. Specify total debt service cost and estimated debt service cost per patient day for the first two (2) years of operation. (Total debt service cost is defined as total interest to be paid during the life of the loan (s). Estimate debt service cost per patient day by dividing estimated total patient days for year one into amount of debt service for that year. Repeat for year two.) Please attach an amortization schedule showing how the proposed debt will be repaid.

- The proposed capital expenditure, primarily consisting of tenant improvement (TI) buildout costs funded by the landlord and repaid through fixed monthly payments—will be managed through an internal lease-backed repayment structure rather than external financing. *Fairfax Colon & Rectal Surgical Center, LLC* will repay the buildout costs through monthly payments of \$25,000, totaling \$300,000 annually over the initial 10-year lease term.

While the buildout is not financed through a conventional interest-bearing loan, we estimate the equivalent cost of capital and track it as a debt-like obligation to assess the financial impact. For the purposes of this COPN application, the TI repayment obligation is treated as a proxy for debt service.

Estimated Patient Volume and Debt Service Per Patient Day

Year	Annual TI Repayment (Proxy Debt Service)	Estimated Patient Days	Debt Service Per Patient Day
2026	\$300,000	249	\$1,204.82
2027	\$300,000	262	\$1,145.04

- Year 1 Estimated Patient Days: 249**
- Year 2 Estimated Patient Days: 262**
- Note:* Patient days are based on historical surgical volume and anticipated growth following ASC certification.

This repayment obligation does not represent new borrowing but rather a fixed financial commitment embedded in the facility lease. The structure eliminates variable interest expense and supports predictable budgeting.

Amortization Schedule

See the below, *TI Repayment Amortization Schedule*, reflecting the \$300,000 annual payment for 10 years, totaling \$3 million in total repayment. Since no traditional loan interest is incurred, the amortization table reflects principal-only repayment with no interest component.

Year	Annual Payment	Principal Paid	Remaining Balance
2026	\$300,000	\$300,000	\$2,700,000
2027	\$300,000	\$300,000	\$2,400,000
2028	\$300,000	\$300,000	\$2,100,000
2029	\$300,000	\$300,000	\$1,800,000
2030	\$300,000	\$300,000	\$1,500,000
2031	\$300,000	\$300,000	\$1,200,000
2032	\$300,000	\$300,000	\$900,000
2033	\$300,000	\$300,000	\$600,000
2034	\$300,000	\$300,000	\$300,000
2035	\$300,000	\$300,000	\$0

H. Attach a copy of the following information of documents.

1. The existing and/or proposed room rate schedule, by type of accommodation.
- *Fairfax Colon & Rectal Surgical Center, LLC* is a freestanding outpatient ambulatory surgical center (ASC). No overnight accommodations are offered or billed. Therefore, there is no "room rate" schedule applicable to this facility.

All services are provided on a same-day outpatient basis and are billed as bundled facility fees by procedure type, consistent with CMS and commercial payer guidelines for ambulatory surgery.

2. The audited annual financial statements for the past two (2) years of the existing facility or/if a new facility without operating experience, the financial state of the owner (s). Audited financial statements are required, if available.

- See attached *ASC Profit & Loss 2022, ASC Balance Sheet 2022, ASC Profit & Loss 2023, and ASC Balance Sheet 2023*; 2024 financial statements are still under audit by *Fairfax Colon & Rectal Surgical Center's* accountant.

3. Copy of the proposed facility's estimated income, expense and capital budget for the first two years of operation after the proposed project is completed.

- See attached *Two Year Financial Projection*

Financial Projection Summary

Fairfax Colon & Rectal Surgical Center, LLC projects strong financial performance over the first two years of operation following the proposed project's completion. In the base year (2026), the center anticipates gross patient revenue of \$2.89 million, with a conservative 5% growth assumption leading to \$3.03 million in revenue by 2027. After accounting for a 2% adjustment for bad debt and contractual allowances, net operating revenue is projected at approximately \$2.83 million in 2026 and \$2.97 million in 2027.

Operating expenses, including salaries, medical supplies, facility rent, tenant improvement (TI) repayment, insurance, and general administrative costs, are projected to remain consistent at approximately 60% of revenue. Total operating expenses are estimated at \$1.80 million in each of the first two years. This yields an estimated EBITDA of \$1.03 million in 2026 and \$1.17 million in 2027, reflecting positive cash flow and operational sustainability from the outset.

Capital expenditures in 2026 include \$2.99 million for tenant improvements (funded by the landlord and repaid at \$300,000 annually) and \$213,470 in essential equipment. In 2027, projected capital costs drop to \$50,000 for supplemental equipment needs. Rent obligations in Year 1 are \$197,805 and decrease to \$130,650 in Year 2 due to transition from the existing office lease.


These projections demonstrate that the proposed ASC is financially feasible and sustainable, with sufficient margin to support ongoing operations and capital repayment obligations.

SECTION VI ASSURANCES

I hereby assure and certify that:

- a. The work on the proposed project will be initiated within the period of time set forth in the Certificate of Public Need; and
- b. completion of the proposed project will be pursued with diligence; and
- c. the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances.

I hereby certify that the information included in this application and all attachments are correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

<u></u>	<u>2710 Prosperity Ave, Ste</u>
Signature of Authorizing Officer	Address – Line 1
<u>Michael Delac</u>	<u>Suite 200</u>
Type/Print Name of Authorizing Officer	Address – Line 2
<u>Chief Operating Officer</u>	<u>Fairfax, VA 22031</u>
Title of Authorizing Officer	City/State/Zip
<u>Office: (703) 650-2333 Cell: (703) 600-9226</u>	<u>02/26/2015</u>
Telephone	Date

Copies of this request should be sent to :

- A. **Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233**
- B. **The Regional Health Planning Agency if one is currently designated by the Board of Health to serve the area where the project would be located.**

Revised 02/24/2015

FAIRFAX COLON & RECTAL SURGERY

COLORECTAL / ANORECTAL PHYSIOLOGY & SURGERY

www.fairfaxcolorectal.com

P: (703) 280-2841

F: (703) 280-4773

November 14, 2025

VIA Email: copn@vdh.virginia.gov / hsanvstaff@hsanv.org

Health Systems Agency of Northern Virginia
3040 Williams Dr. Suite 200
Fairfax, VA 22031

Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233

RE: COPN Request No VA-8833

To Whom It May Concern:

Please accept this letter as our formal response to the Virginia Department of Health's Division of Certificate of Public Need *Completeness Determination Letter*, dated August 11, 2025, in conjunction and alignment with the items clarified in Allison Kagle's email, dated August 25, 2025.

Section I (Allison's Email)

- 1. Please distinguish Fairfax Colon & Rectal Surgical Center, LLC (the applicant) from Fairfax Colon & Rectal Surgery Center, PC, (the landlord), and any other related parties (e.g., FGRSC real estate, that may be involved in the project. Are the members of these organizations the same, with a minority interest of 12.5%?***

Yes: *Fairfax Colon & Rectal Surgery, PC*, (owner of the applicant) currently consists of eight shareholder surgeons who function as Directors/Officers of the Professional Corporation; each shareholder owns 12.5% of the Professional Corporation (and its assets).

Fairfax Colon & Rectal Surgical Center, LLC, (the applicant), is a wholly owned subsidiary of *Fairfax Colon & Rectal Surgery, PC*, thus the eight shareholder surgeons own 12.5% of *Fairfax Colon & Rectal Surgical Center, LLC*.

FCRS Real Estate, LLC, (the landlord) currently consists of eight members, the same eight shareholder surgeons of *Fairfax Colon & Rectal Surgery, PC*. *FCRS Real Estate, LLC* is NOT a wholly owned subsidiary of *Fairfax Colon & Rectal Surgery, PC*; it is a completely separate entity.

In October 2024, *FCRS Real Estate, LLC*, acquired the property located at 2735 Hartland Rd, Falls Church, VA 22043.

As the landlord, *FCRS Real Estate, LLC* is financing the tenant improvement buildout for both *Fairfax Colon & Rectal Surgery, PC*, and *Fairfax Colon & Rectal Surgical Center, LLC* (the applicant). In consideration of this investment, the tenant entities have entered into a long-term lease agreement with *FCRS Real Estate, LLC*, under which they will pay both monthly rent and make monthly repayments toward the improvement costs. The lease term is set for ten (10) years, and the tenant improvement costs will be repaid over that ten-year term.

Section I (Allison's Email)

2. *Requesting a copy of the signed lease and the deed*

Emailed separately on September 8, 2025.

3. *Will the Prosperity Ave. location be closing?*

Yes

Upon completion of the buildout and tenant improvements and termination of our current lease at 2710 Prosperity Avenue on June 30, 2026, *Fairfax Colon & Rectal Surgical Center, LLC*, will relocate the ASC to the 1st floor of 2735 Hartland Rd, and *Fairfax Colon & Rectal Surgery, PC* will relocate its offices to the 2nd Floor.

Section III (Allison's Email)

1. *Do you currently have operating rooms or procedure rooms in the other facilities?*

Yes, but *with significant limitations*.

While *FCRSC* surgeons do utilize operating and procedure rooms at other facilities, our access is increasingly constrained by the reduction or complete elimination of monthly reserved operating room ("block") time. In multiple locations, previously assigned block time has been reduced, reassigned, or absorbed by hospital-employed surgeons, leaving *FCRSC* with inconsistent, unpredictable, and insufficient OR availability.

These limitations have a direct impact on patient care:

- Delays in scheduling occur when outpatient colorectal procedures cannot be accommodated within reasonable timeframes.

- Shared OR resources and system-level prioritization result in colorectal cases being deferred in favor of other service-line demands.
- Administrative restrictions and variable open-time release practices further reduce practical access for independent surgeons.

Currently, FCRSC performs hospital-based outpatient procedures only when required, either due to payer restrictions or because a patient's clinical situation necessitates a higher-acuity setting (e.g., significant comorbidities). For the majority of routine anorectal and ambulatory colorectal procedures, an independent ASC setting is more efficient, lower cost, and preferred by both patients and payers.

The establishment of FCRSC's ambulatory surgical center will provide:

- Dedicated, surgeon-controlled operating and procedure rooms
- Timely and reliable scheduling
- Improved workflow and operational efficiency
- Reduced overall cost of care
- Equitable access for Medicare, Medicaid, Tricare, and uninsured patients

By creating dedicated outpatient colorectal surgical capacity, FCRSC will eliminate the scheduling barriers inherent in hospital-based environments and significantly improve access and continuity of care for patients across Planning District 8.

2. Provide surgical data (if applicable) from other facilities to prove need:

Based on the information currently available to us, Planning District 8 (PD 8) has a total of 203 general-purpose operating rooms (GPORs). Four of these are specialty-restricted, two for ophthalmic procedures and two for vascular access, leaving 199 GPORs available for general and ambulatory surgery. Of these 199 GPORs:

- 140 are located in acute care hospitals
- 59 in ambulatory surgical centers (ASCs)

Although these GPORs provide a total estimated 334,600 annual operating room hours, practical access for outpatient colorectal procedures is substantially lower due structural, ownership, and operational constraints across the region.

Many ASCs are owned or operated by physician groups or joint ventures that may prioritize specific surgeons or payer mixes, further restricting access for independent providers. Fairfax Colon & Rectal Surgical Center, LLC (FCRSC) is independent of these existing groups and ventures.

Effective Outpatient Operating Room Availability in PD 8

Facility Type	Number of GPORs	Avg Annual Hours per GPOR	Total Annual Hours	% Available for Outpatient/Private Cases	Effective Outpatient Hours
Hospitals	140	1,800	252,000	25%	63,000
ASCs	59	1,400	82,600	80%	66,080
Total	199	–	334,600	–	129,080

Effective Outpatient Hours represent practical access—not theoretical licensed capacity.

- **Hospitals:** The majority of OR time is dedicated to inpatient surgery, emergency coverage, trauma, add-ons, and block time assigned to employed or high-volume specialists. As a result, only ~25% of hours are available for independent outpatient surgeons.
- **ASCs:** While ASCs are inherently outpatient-focused, many in PD 8 are physician-owned or part of joint ventures that prioritize specific surgical groups or payer mixes, leaving limited or no access for independent colorectal practices.

Impact on Access for FCRSC's Patients

Although PD 8 has 199 GPORs, FCRSC does not realistically have access to most ASC OR time due to restrictive ownership structures. Therefore, the 66,080 ASC outpatient hours listed above significantly overstate actual availability for FCRSC's patients.

Additional factors further restricting meaningful access include:

- *Hospital block time assignments* that favor employed surgeons and large service-line groups.
- *Open/shared OR time often released only seven days in advance*, which makes proactive scheduling for outpatient colorectal surgery nearly impossible.
- *Reduced reimbursement for government payers* (Medicare, Medicaid, Tricare), which discourages hospitals and ASCs from providing time for higher-complexity, lower-margin cases.
- *Independent office-based practices* like FCRSC are further constrained because they cannot perform key colorectal surgeries for government-insured or uninsured patients without ASC certification.

How FCRSC Will Address the Identified Capacity Gap

FCRSC will directly close this gap by establishing dedicated GPORs reserved exclusively for outpatient colorectal procedures. This model will:

1. Provide predictable, reliable OR access for all outpatient colorectal cases.
2. Ensure equitable access regardless of payer, including Medicare, Medicaid, Tricare, and uninsured patients.
3. Redirect appropriate outpatient colorectal cases away from overloaded hospital ORs, allowing hospitals to maintain existing volumes and focus on urgent, emergent, and inpatient needs.
4. Improve scheduling efficiency, reduce delays, and enhance continuity of care for colorectal patients across PD 8.

Despite 199 GPORs in PD 8, the practical outpatient surgical capacity available to independent colorectal surgeons is severely constrained by hospital prioritization, ASC ownership patterns, and payer-mix limitations. FCRSC's proposed ASC directly addresses this unmet need by creating new, dedicated outpatient colorectal surgical capacity, consistent with both the State Health Services Plan and the goals of improving access, efficiency, and cost-effectiveness within Planning District 8.

3. Do the other facilities not accept Medicare, Medicaid, or Tricare?

Yes. While other facilities *technically* accept Medicare, Medicaid, and Tricare, practical access for these patients is significantly limited due to structural, operational, and reimbursement-related factors. The barriers described below directly affect the ability of independent colorectal surgeons to schedule timely outpatient procedures for government-insured patients.

1. Hospital Block Time Restrictions

Hospitals prioritize block time for:

- Employed surgeons
- High-volume specialty groups
- Service-line priorities (orthopedics, cardiac, general surgery, etc.)

Independent surgeons—especially those treating a large proportion of lower-reimbursing government payers—receive little to no dedicated block time, which results in:

- Delayed scheduling
- Inability to plan elective cases efficiently
- Longer waits for Medicare, Medicaid, and Tricare patients

2. "Open Time" Availability is Not Operationally Usable

Although hospitals make a small amount of open/shared OR time available, it is generally:

- Released only seven days in advance, and
- Allocated on a first-come, first-served basis

For office-based practices, this forces physicians to:

- Cancel or reschedule full clinic days with <1 week's notice
- Rearrange preoperative workflows

- Create disruptions that are impractical for patients and staff

Therefore, “open time” does not provide meaningful capacity for timely outpatient colorectal surgery.

3. ASC Ownership Models Further Limit Access

Many ASCs in PD 8 are:

- Physician-owned
- Owned by specialty groups
- Joint-venture centers with hospitals
- Selective in case type and payer mix

These centers may accept government payers on paper, but access to OR time for independent surgeons is frequently limited or unavailable—particularly for high-complexity, lower-margin colorectal surgery.

4. Reimbursement Barriers for Independent Practices

Government payers reimburse colorectal procedures performed in an office at:

- Significantly reduced rates
- Without a facility fee

This creates disincentives for existing facilities and limits the availability of complex services for Medicare, Medicaid, and Tricare patients.

Resulting Impact on Patients

Due to these structural constraints, government-insured patients experience:

- Longer wait times
- Fewer scheduling options
- Delays for time-sensitive colorectal procedures
- Reduced access to appropriate outpatient surgical settings

How FCRSC Will Address These Gaps

FCRSC's proposed ASC will:

- Provide dedicated GPORs accessible to all payers
- Offer equitable and predictable scheduling for Medicare, Medicaid, Tricare, and uninsured patients
- Remove the block-time and ownership barriers that currently limit access
- Improve availability of timely, high-quality outpatient colorectal care in PD 8

Section IV (Allison's Email)

1. Need SMFP calculations per 12VAC5-230-500 (if applicable)

Metric	Number of GPORs / Hours	Notes
Licensed GPORs in PD 8	203	Total general-purpose operating rooms
Specialty-restricted GPORs	4	2 ophthalmic, 2 vascular access
GPORs available for general/ambulatory surgery	199	203 – 4 specialty-restricted
Surplus GPORs in PD 8	0–6	Statewide surplus is 6, but not evenly distributed; effective outpatient hours remain constrained

2. ***Please provide recent service volumes (2023 and 2024) by major payer (e.g., commercial insurance, Blue Cross, Medicare, Medicaid, uninsured).***
3. **Please provide the numbers of Medicaid and Medicare patients served in 2023 and 2024.**
4. **Please provide the number of charity care patients served in 2023 and 2024.**

Details of unique patient service volumes for questions 2-4 are listed in the table below:

Payer	2023	%	2024	%
Aetna	363	9.9%	404	10.9%
Anthem	420	11.5%	395	10.7%
CareFirst	910	24.8%	886	24.0%
Cigna	576	15.7%	539	14.6%
Other /Self	75	2.0%	71	1.9%
Inova	15	0.4%	30	0.8%
Medicaid	86	2.3%	110	3.0%
Medicare	567	15.5%	553	15.0%
Tricare	65	1.8%	124	3.4%
UHC	521	14.2%	525	14.2%
Charity	64	1.7%	53	1.4%
Total	3662	100%	3690	100%

At present, only colonoscopy and flexible sigmoidoscopy may be performed within our office-based surgery practice for government payers, including Medicare, Medicaid, commercial Medicare/Medicaid products, and Tricare. Although these procedures are permissible in the office setting, reimbursement is limited to the reduced “in-office” professional rate, with no facility fee, despite incurring the facility costs. FCRSC continues to offer these procedures in-office at the reduced rate both to preserve patient convenience and to support efficient clinical operations.

However, *all other anorectal procedures—which constitute approximately 60% of FCRSC’s annual surgical volume, are not reimbursable by government payers when performed in an office setting.* As a result, these cases must be performed in hospital operating rooms, even though they are safe and wholly appropriate for an ambulatory surgical center (ASC). This requirement:

- Increases costs to both patients and payers
- Consumes hospital OR capacity needed for higher-acuity cases
- Reduces access and scheduling flexibility for government-insured patients
- Limits the efficiency and continuity of care that an ASC could provide

By establishing the proposed ambulatory surgical center, FCRSC will be able to shift this significant portion of procedures from the hospital setting to a high-quality, lower-cost ASC environment, ensuring that Medicare, Medicaid, Tricare, and commercially insured government-product patients have equitable access to timely, cost-effective, and specialized outpatient colorectal surgery.

5. The application does not address the question of a public need for additional surgical capacity in the planning region as specified in the Virginia State Medical Facilities Plan. Please do so.

According to the Virginia State Medical Facilities Plan (SMFP), demonstrating a public need for additional surgical capacity requires evidence of unmet demand, patient access limitations, and inefficiencies or constraints within existing operating room resources. FCRSC's proposed conversion to an ASC directly addresses a clearly documented need for expanded dedicated outpatient colorectal surgical capacity in Planning District (PD) 8.

Existing Capacity and Documented Limitations

As highlighted in the answer in Section III, Item 2 above, current outpatient surgical facilities in the region, including hospital-based ambulatory surgery centers (ASCs) have limited capacity for colorectal procedures due to:

1. Shared block-time/operating room across multiple specialties : Hospitals prioritize high-volume service lines and inpatient cases, leaving limited and inconsistent access for outpatient colorectal procedures. Surgeons compete with multiple specialties for block time, resulting in delayed procedures.
2. Restricted access for government payers: Office-based surgery centers cannot treat Medicare, Medicaid, and Tricare patients for anorectal procedures (60% of our case volume), forcing these patients into hospital Ors where reimbursement and access barriers reduce throughput.
3. Operational inefficiencies in existing facilities: High turnover times and inability to batch multiple lower-acuity procedures reduce case throughput and contribute to prolonged scheduling delays.
4. Ownership and alignment constraints: Many existing ASC facilities are owned by unrelated physician groups or hospital joint ventures, limiting or preventing equitable access for independent referring physicians.

Despite a nominal surplus of GPORs in PD 8, these rooms are heavily utilized for complex inpatient and multispecialty surgical cases. The available hours realistically accessible for outpatient, lower-acuity colorectal care remain insufficient.

Need for a Dedicated Specialty ASC

The conversion of FCRSC's long-standing office-based surgery center into a Medicare-certified ASC demonstrates substantial need based on the following:

1. Specialized Case Mix Not Available Elsewhere in PD 8:

FCRSC will focus exclusively on outpatient colorectal and anorectal procedures, including hemorrhoidectomy, fissurectomy, fistulotomy/seton placement, pilonidal cyst surgery, high-resolution anoscopy and endoscopy.

No other freestanding ASC in PD 8 provides this dedicated colorectal/anorectal specialty service.

2. Efficiency and Cost Savings:

- Transitioning appropriate cases from hospital ORs to a specialty ASC will:
- Reduce per-case costs for payers and patients
- Increase surgical throughput,
- Free hospital ORs for higher-acuity surgical demand

3. Improved Access for All Payers:

Existing GPOR capacity in PD 8 is concentrated in hospitals with high utilization rates. As a result, Medicare, Medicaid, Commercial Medicare/Medicaid, Tricare, and uninsured patients experience longer delays and fewer outpatient options.

FCRSC's central location, private setting, and multilingual staff directly address geographic and cultural barriers.

FCRSC's ample parking and proximity to public transit will reduce geographic and transportation barriers.

4. Documented Physician and Patient Support:

Letters of support from primary care physicians, gastroenterologists, OB/GYNs, and other referring providers highlight the need for timely access to lower-acuity colorectal procedures outside hospital settings.

5. Alignment with SMFP Objectives:

The project advances the SMFP's goals by:

- Improving surgical capacity distribution,
- Expanding access for government-sponsored and underserved patients
- Providing care in the most appropriate, cost-effective outpatient setting.

These factors satisfy the institutional, qualitative, discretionary, and access-related criteria under 12VAC5-230-500.

Projected Volume and Patient Impact:

FCRSC currently performs over 4,200 procedures annually for approximately 3,700 patients in its office-based surgical practice. Conversion to a Medicare-certified ASC is expected to increase total procedure volume by 5–10%, driven primarily by newly eligible Medicare, Tricare, Medicaid, Commercial Medicare/Medicaid beneficiaries.

This represents approximately 210–420 additional procedures each year-cases that would otherwise require hospital OR time.

The proposed ASC will continue to accept Medicaid, uninsured patients, and all government payers, with an increased commitment of at least 2.5% of gross revenue dedicated to indigent care.

Evidence of Unmet Need

1. Growing demand for colorectal procedures:

The prevalence of hemorrhoids, fissures, fistulas, abscesses, pilonidal disease, anal neoplasia, and colorectal cancer screening is increasing, particularly in an aging PD 8 population.

2. Delays in care:

Patients face significant wait-times for outpatient colorectal procedures in hospital-based settings, delaying diagnosis and treatment.

3. Access disparities:

Minority and non-English-speaking patients encounter additional barriers; limited bilingual capacity in existing facilities further restricts access.

Public Benefit & Capacity Expansion

The proposed ASC will provide:

- *Dedicated operating and procedure rooms* exclusive to colorectal and anorectal surgery
- *Expanded access* for procedures not offered in other office-based practices settings
- *Equitable access* for all payers, including government-sponsored and uninsured patients.
- *Culturally competent care*, with Spanish- and Korean language support, and translation technology services

Public benefits include:

- Reduced wait times for outpatient colorectal procedures
- Improve patient outcomes through timely interventions
- Greater efficiency in regional outpatient surgical care delivery
- Enhanced access for underserved and government-sponsored populations

The proposed FCRSC meets clear public need for additional outpatient colorectal surgical capacity in Planning District 8. The combination of specialty focus, demonstrated community demand, improved access for all payers, operational efficiencies, multilingual capabilities, and strong physician support fully satisfies the need criteria in the SMFP.

Although 12VAC5-230-500 reflects a nominal surplus of GPORs in PD 8, the regulation explicitly permits the Commissioner to consider institutional, qualitative, and access-related factors. Based on these discretionary criteria, the proposed ASC provides a compelling demonstration of public need and warrants approval.

6. Do any of the owner/directors of Fairfax Colon & Rectal Surgery Center, PC, own shares in any other surgery service(s)? If so, please identify those parties and their ownership interests.

No: The owners/directors of *Fairfax Colon & Rectal Surgery, PC* do not own shares in any surgery service/location other than *Fairfax Colon & Rectal Surgical Center, LLC*.

Section V (Allison's Email)

1. **Section V of the application is opaque, essentially incomplete. Please explain the necessity of the \$3.0 million "tenant allowance" to finance the buildout of the facility and specifically how it would be spent.**

Since the tenant and landlord are closely aligned, a collaborative buildout structure was pursued. Based on guidance from our legal and accounting team, the tenant allowance repayment model offers a predictable, non-debt-based financing approach that supports project stability without the need for external loans or additional equity contributions. Under this structure, the landlord alone carries the interest-bearing debt, thereby reducing financial exposure for both tenants, FCRSC (*Fairfax Colon & Rectal Surgical Center, LLC*) and *Fairfax Colon & Rectal Surgery, PC*.

The estimated \$3.0 million tenant allowance reflects the full demolition and comprehensive renovation of the 1st-floor interior to convert previously unlicensed medical office space into a fully compliant, Medicare-certified ambulatory surgery center. The allowance will directly fund all construction, infrastructure, and life-safety work required to meet federal, state, and accrediting-body standards. Specifically, the tenant allowance is allocated for:

- **Interior demolition and structural modification:** Removal of existing office partitions, flooring, ceilings, and mechanical components; reinforcement and reconfiguration required for OR buildout.
- **Construction of three Class-B Operating Rooms:** Including hard-wall construction, lead-lined partitions (if required), medical gases, emergency power integration, and infection-control compliant finishes.
- **Mechanical, Electrical, and Plumbing (MEP) Upgrades:** Installation of dedicated HVAC systems meeting ASHRAE standards for surgical environments (air exchanges, humidity control, pressure differentials), new electrical panels, medical-grade lighting, and plumbing necessary for sterilization, scrub sinks, and recovery areas.
- **Life-safety and code compliance systems:** Upgrade and installation of fire sprinklers, fire alarm upgrades, smoke evacuation systems, emergency lighting, and nurse-call integration to meet NFPA and CMS requirements.
- **Sterilization and support areas:** Buildout of a Central Sterile Processing area, clean/soiled utility rooms, environmental services spaces, medication prep areas, and equipment storage.
- **Pre-operative and Post-Anesthesia Care Unit (PACU):** Construction of pre-op bays, Phase I and Phase II recovery, patient privacy systems, and required clinical support spaces.
- **ADA and patient-flow improvements:** Lobby/registration redesign, restrooms, patient egress routes, and accessibility upgrades.
- **Finishes, casework, and millwork:** OR-appropriate surfaces, cabinetry, countertops, flooring, and clinical-grade finishes compliant with infection control standards.

2. The 2.75 to 2.99 million cost estimate is mentioned in body text but not built into the direct construction costs—can this be rectified so we can get a more accurate total capital cost

At the time the application was submitted, detailed buildout costs had not yet been finalized. As a result, the “tenant improvement allowance” was calculated using industry-standard construction estimates and the projected square footage of the first-floor renovation at the facility.

Although still not finalized, since the time of submission, the landlord has obtained more accurate cost estimates. Specific to the applicant FCRSC’s (*Fairfax Colon & Rectal Surgical Center, LLC*) allocation only Section V-C has been updated accordingly, the details of which are as follows:

C. Estimated Capital Costs

Part I – Direct Construction Costs

1.	Cost of materials	<u>\$ 1,440,000</u>
2.	Cost of labor	<u>\$ 1,260,000</u>
3.	Equipment included in construction contract	<u>\$ 90,000</u>
4.	Builder’s overhead	<u>\$ 0</u>
5.	Builder’s profit	<u>\$ 150,000</u>
6.	Allocation for contingencies	<u>\$ 60,000</u>
7.	Sub-total (add lines 1 thru 6)	<u>\$ 3,000,000</u>

Updating Section V-C in this manner would also require updating to Section V, C-Part III, Items 14-15, by removing the “Additional expenses paid/or accrued”, but the end result of the nu

14.	Additional expenses paid or accrued:	
	a. _____	<u>\$ 0</u>
	b. _____	<u>\$ 0</u>
	c. _____	<u>\$ 0</u>
15.	Sub-total (add lines 10 thru 14c)	<u>\$ 1,296,143</u>

Despite these changes, the end result on the Financial Data Summary Sheet would be the same for FCRSC, just reallocated:

Financial Data Summary Sheet

96.	Sub-total Part I	Direct Construction Cost (line 7)	<u>\$ 3,000,000</u>
97.	Sub-total Part II	Equipment not included in construction contract (line 9)	<u>\$ 288,470</u>
98.	Sub-total Part III	Site Acquisition Costs (line 15)	<u>\$ 1,296,143</u>
99.	Sub-total Part IV	Site Preparation Cost (line 23)	<u>\$ 0</u>
100.	Sub-total Part V	Off-Site Costs (line 28)	<u>\$ 0</u>
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	<u>\$ 0</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	<u>\$ 1,850</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	<u>\$ 0</u>
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	<u>\$ 0</u>
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	<u>\$ 0</u>
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	<u>\$ 0</u>
107.	TOTAL CAPITAL COST (lines 96 thru 106)		<u>\$ 4,586,463</u>
108.	Percent of total capital costs to be financed		<u>N/A%</u>
109.	Dollar amount of long-term mortgage (line 107 x 108)		<u>\$ 0</u>
110.	Total Interest Cost on Long Term Financing		<u>\$ 0</u>
	a.	HUD-232 Financing (line 53)	<u>\$ 0</u>
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	<u>\$ 0</u>
	c.	Conventional Loan Financing (line 94)	<u>\$ 0</u>
111.	Anticipated Bond discount		
	a.	HUD-232 Financing (line 53)	<u>\$ 0</u>

- b. Industrial Development Authority Revenue &
General Revenue Bond Financing (line 70) \$ 0
- c. Conventional Loan Financing (line 87) \$ 0

112. TOTAL CAPITAL AND FINANCING COST
(ADD LINES 107, 110a, b or c AND 111a, b or c) \$ 4,586,463

3. Are the membership and economic interests of the members, of the applicant and the landlord identical? Is the "allowance" the result of an "arm's length" negotiation?"

As described on page 1, Section 1, of this response letter, the membership and economic interests of the members of Fairfax Colon & Rectal Surgical Center, LLC (the applicant), Fairfax Colon & Rectal Surgery, PC, (owner of the applicant), and FCRS Real Estate, LLC (the landlord) are partially overlapping, as certain members hold interests in both entities.

Despite the partial overlap in membership, the tenant improvement allowance and lease terms were negotiated based on independent assessments of market conditions, comparable lease transactions in the area, and the cost of tenant improvements, ensuring that the terms are consistent with fair market value. The negotiation process was conducted with the objective of establishing terms that are commercially reasonable and reflective of an arm's-length transaction, with no preferential treatment or undue influence.

As such, the allowance and lease terms reflect an agreement that would be expected between unrelated parties in a similar market setting, supporting both the financial feasibility of the project and compliance with regulatory standards.

Thank you for allowing us to respond to your questions. Should you require any additional information or have questions during the review process, please feel free to contact me directly at mdelac@fxcrs.com, my office phone at (703) 650-2333, or my cell phone (703) 600-9226.

We look forward to continuing working with your office throughout the application process.

Sincerely,



Michael Delac, CMPE
Chief Operating Officer

Fairfax Colon & Rectal Surgery, PC & Fairfax Colon & Rectal Surgical Center, LLC

CC: Erik Bodin III, Division of Certificate of Public Need
erik.bodin@vdh.virginia.gov



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April 30, 2026

VIA Email: copn@vdh.virginia.gov / hsanvstaff@hsanv.org

Health Systems Agency of Northern Virginia
Attn: Dean Montgomery
3040 Williams Dr. Suite 200
Fairfax, VA 22031

Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233

RE: COPN Request No VA-8833

Mr. Montgomery:

Please accept this letter as our formal response to your request for current and anticipated reimbursement by primary condition.

During a detailed review of our procedural datasets for this request, we identified a variance in reported volumes attributable to CPT capture methodology. Specifically, certain qualifying procedures were not fully captured in the original dataset. The dataset on Table 1: *Corrected Procedural Volume 2024*, on the following page, now fully reflects all applicable procedures performed during the reporting period.

As a result of this correction, the reported colonoscopy volume is higher than originally presented in the application, the reported hemorrhoid volume is lower than originally presented; and we isolated the “Other Not-Listed” procedures. The *Other Not-Listed* procedures are all anorectal procedures that do not fall into one specific condition/procedural category.

Importantly, this adjustment does not reflect a change in underlying clinical activity or growth assumptions, but rather a refinement in data accuracy and completeness.

Table 1. Corrected Procedural Volume 2024

Condition/Procedure	Originally Report % of Total Volume (2024)	Corrected % of Total Volume (2024)
Hemorrhoids	28%	11%
Anal Fissures	4%	4%
Fistulas	9%	9%
Perirectal Abscess	1%	1%
Pilonidal Cysts	1%	1%
Colon & Rectal Cancer (Colonoscopy/Flex Sigmoidoscopy)	41%	66%
Anal Cancer (High-Resolution Anoscopy)	6%	6%
Excision of Rectal Lesions	10%	1%
Other Procedures Not Listed	Not reported	1%

Current and Anticipated Reimbursement by Primary Condition

Typically, hospital-based reimbursement is reported using Diagnosis-Related Groups (DRGs). In contrast, within our outpatient and ambulatory surgery center (ASC) setting, reimbursement is more appropriately analyzed at the procedure level using CPT coding. Accordingly, our analysis categorizes reimbursement by primary condition through the associated procedural services performed.

In our original application, we utilized a conservative financial modeling approach by applying an adjusted blended reimbursement rate. This methodology incorporated our existing commercial payer mix alongside anticipated inclusion of government payers (Medicare/Medicare Advantage, Medicaid, and Tricare), combined with historically consistent growth trends. The intent of this conservative approach was to provide a prudent and system-level estimate of financial performance without overstating reimbursement assumptions across individual CPT codes.

The tables and supporting information included on the following pages provide a condition-specific view of current facility reimbursement within our existing outpatient model, as well as anticipated facility reimbursement under a Medicare-certified ASC structure, contingent upon COPN approval.

All figures presented reflect facility reimbursement only and explicitly exclude professional fees, which are separately billed and collected by the physician practice and do not materially impact system-level cost comparisons.

Table 2 below, list the current Novitas DC/Medicare ASC January 2026 Fee Schedule (our Medicare Administrative Contractor) and our current average reimbursement.

Table 2: Projected FCRS-ASC Medicare Facility Reimbursement vs. Current Facility Reimbursement

Service Category	Projected FCRS ASC Reimbursement (Medicare)	Current FCRS ASC Avg Reimbursement
Hemorrhoids	\$ 1,465	\$ 911
Anal Fissures	\$ 1,465	\$ 1255
Fistulas	\$ 1,465	\$ 1141
Perirectal Abscess	\$ 1,485	\$ 747
Pilonidal Cysts	\$ 1,276	\$ 1191
Colon & Rectal Cancer (Colonoscopy/Flex Sigmoidoscopy)	\$ 522	\$ 518
Anal Cancer (High-Resolution Anoscopy)	\$ 671	\$ 252

Projected FCRS-ASC Medicare Facility Reimbursement per Category

Applying regional payer-specific reimbursement multipliers to the Medicare ASC facility rates allows for the estimation of reimbursement across each payer category, as outlined below:

Payer	ASC Facility Multiplier
Medicare	100%
Medicaid	70%
Tricare	100%
Commercial	125%

Table 3: Projected Reimbursement by Payer Category

Service Category	Projected FCRS ASC Reimbursement (Medicare/Tricare)	Projected FCRS ASC Reimbursement (Medicaid)	Projected FCRS ASC Reimbursement (Commercial)
Hemorrhoids	\$ 1,465	\$ 1,026	\$ 1,831
Anal Fissures	\$ 1,465	\$ 1,026	\$ 1,831
Fistulas	\$ 1,465	\$ 1,026	\$ 1,831
Perirectal Abscess	\$ 1,485	\$ 1,040	\$ 1,856
Pilonidal Cysts	\$ 1,276	\$ 893	\$ 1,595
Colon & Rectal Cancer (Colonoscopy/Flex Sigmoidoscopy)	\$ 522	\$ 365	\$ 653
Anal Cancer (High-Resolution Anoscopy)	\$ 671	\$ 470	\$ 839

It is also important to note that our original projections did not incorporate any potential adjustments in commercial payer reimbursement associated with a transition to a Medicare-certified ASC. Currently, certain private payers reimburse services performed in our existing outpatient setting under office-based or non-ASC classifications which may not fully reflect the facility component typically recognized in a certified ASC environment. While market experience suggests that payer alignment often occurs following Medicare ASC certification, any such adjustments are subject to individual payer contracting and have not been assumed in our original financial projections.

Thank you for allowing us to respond to your request. Should you require any additional information or have questions please feel free to contact me directly at mdelac@fxcrs.com, my office phone at (703) 650-2333, or my cell phone (703) 600-9226.

We look forward to continuing working with your office throughout these last phases of the application process.

Sincerely,

A handwritten signature in black ink, appearing to read 'MDL', is positioned above the typed name.

Michael Delac, CMPE
Chief Operating Officer

Fairfax Colon & Rectal Surgery, PC & Fairfax Colon & Rectal Surgical Center, LLC

CC: Erik Bodin III, Division of Certificate of Public Need
erik.bodin@vdh.virginia.gov

