

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

The Centers for Advanced Urology, LLP

Establishment of a Medical Care Facility with One PET/CT Scanner

COPN Req. No. VA-8879

June 1, 2026

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

A. Official Name of Facility

The Centers for Advanced Urology, LLP
12600 Fair Lakes Circle
Fairfax, VA 22033

B. Legal Name of Applicant

The Centers for Advanced Urology, LLP
140 W Germantown Pike, Ste 200
Plymouth Meeting, PA 19462

C. Chief Administrative Officer

Steven Krefetz, Chief Executive Officer
140 W Germantown Pike, Ste 200
Plymouth Meeting, PA 19462

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

Erin Whaley
Troutman Pepper Locke LLP
1001 Haxall Point
Richmond, VA 23218
Direct: 804-697-1389 | Mobile: 804-317-8649
erin.whaley@troutman.com

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

Will the facility be operated by the owner? Yes **X** No

Owner of the Facility
(Check one)

Proprietary

Operator of Facility
(Check one)

(1)

(1) Individual

(1)

(2) **X**

(2) Partnership-attach copy of
Partnership Agreement and
receipt showing that
agreement has been recorded

(2) **X**

(3)

(3) Corporate-attach copy of
Articles of Incorporation and
Certificate of Incorporation

(3)

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(4) _____ (4) Other Identify (4) _____

Non-Profit

(5) _____ (5) Corporation-attach copy of (5) _____
 Articles of Incorporation and
 Certificate of Incorporation

(6) _____ (6) Other Identify (6) _____

Governmental

(7) _____ (6) State (7) _____

(8) _____ (8) County (8) _____

(9) _____ (9) City (9) _____

(10) _____ (10) City/County (10) _____

(11) _____ (11) Hospital Authority or (11) _____
 Commission

(12) _____ (12) Other Identify (12) _____

See **Attachment I.E.3** (Articles of Organization and Certificate of Organization for The Centers for Advanced Urology, LLP).

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) X leasehold interest for not less than 11 years
 (4) _____ Renewable lease, renewable every _____ years
 (5) _____ Other _____ Identify

See **Attachment I.F** (Letter of Intent for Lease).

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 corporation also attach:

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

(b) In the case of a non-profit corporation 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
- (3) The name and address of the registered agent for the corporation

(c) In the case of a partnership also attach:

- (1) A list of the names and addresses of all partners.
- (2) The name and address of the general or managing partner.

The three partners are:

Gary Kirsh, MD, 10220 Alliance Rd, Blue Ash, OH 45242

Michael Hagg, MD, 931 E Haverford Rd, Bryn Mawr, PA 19010

Laurence Belkoff, DO, 1 Presidential Boulevard, Suite 100, Bala Cynwyd, PA 19004

Each partner has a 5% or greater interest in TCAU.

The managing partner is Michael Hagg, M.D.

(d) In the case of other types of ownership, also attach such documents as will clearly identify the owner.

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

Midlantic Urology Surgery Center, LLC

Academic Urology of PA, LLC

Bala ASC, LLC

Urology Health Surgery Center, LLC

325 ASC, LLC

The Urologic Surgical Center, LLC

Wayne Lithotripsy, LLC

UMS Hershey URS Lithotripsy, LLC

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

The applicant is not a wholly or partially owned subsidiary of any organization.

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- 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.

Not applicable.

- 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.

Not applicable.

SECTION II

ARCHITECTURE AND DESIGN

A. Location of the Proposed Project

1. Size of site: **0.0361** acres
2. Located in **PD 8** City/County/Planning District
3. Address or directions **12600 Fair Lakes Circle, Fairfax, VA 22033**
4. Has site been zoned for type of use proposed:

 X Yes (attach copy of zoning or use permit)

 No

If no, explain status _____

See **Attachment II.A.4 (Zoning Documentation)**.

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

- (1) New construction
- (2) **X** Remodeling/modernization of an existing facility
- (3) No construction or remodeling/modernization
- (4) Other _____ (Identify)

C. Design of the facility

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

The Centers for Advanced Urology, LLP (“TCAU”) does not have a formal long-range plan, but TCAU’s mission is to provide exceptional, compassionate care that empowers patients to lead healthier lives. With physicians who have decades of experience, we address a wide range of urologic conditions through a comprehensive approach that integrates preventive care, lifestyle modifications, and advanced medical therapies. TCAU’s plan is to provide holistic and comprehensive care for patients and their families including evaluation, testing and treatment.

At TCAU, our vision is to continue strategic growth by addressing the medical needs of the patient populations in our immediate and

neighboring communities. Our patient base continues to grow rapidly, and we continue to expand by adding providers to meet our patients' needs.

This COPN application reflects TCAU's strategic vision to offer state-of-the-art urologic services, including PET/CT. Adding the PET/CT services in this location allows TCAU to fulfill its mission of providing comprehensive care to patients, which brings better outcomes and more efficient cancer diagnoses.

- (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.

TCAU's PET/CT will be located at 12600 Fair Lakes Circle, Fairfax, VA 22033.

This existing space will be renovated to accommodate the installation and use of the PET/CT unit. Major design features include:

- PET scanner room
- Control room
- Hot lab
- Uptake room
- Toilet

Relationship with Long-Range Plan

Although TCAU does not have a formal long-range plan, by integrating urologic PET/CT imaging into its services, TCAU aims to enhance community access to advanced imaging. This expansion aligns with TCAU's long-term strategy to provide superior diagnostic capabilities, leveraging a well-established technique widely recognized in clinical practice for characterizing urologic conditions. This addition supports TCAU's mission to offer comprehensive and cutting-edge care to its patients.

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

Parking and Accessibility Features

TCAU will be conveniently located right off of Fairfax County Parkway, and also has close access to Route 66.

Fairfax Connector Bus Route 615 directly serves the Fair Lakes area and offers extensive coverage within the corridor. This route links the project site to key residential neighborhoods, employment centers, and regional roadways, creating multiple options for riders who prefer or rely on public transportation. The route structure and span of service makes daily commuting practical.¹

In addition to the Connector Bus Route service, TCAU benefits from a dedicated shuttle connection to the Metro station. The Fair Lakes shuttle provides direct service between the Metro station and the Fair Lakes campus, including the FL I and FL II buildings, both of which are under a ten minute walk from where TCAU is located.²

Together, the Metro shuttle and the Fairfax Connector network significantly enhance accessibility, support a broader community pool, and reinforce the project location's suitability for a diverse and transit-oriented population. The project location will also have ample parking in a lot directly adjacent to the building itself.

- (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.

There are no issues related to future expansion, parking, zoning, or the provision of water, sewer, or solid waste services. The building has ample adjacent parking. The demand for water, power, sewer, and waste services can be met with the existing utilities.

- (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.

Not applicable.

- (6) Describe any design features which will make the proposed project more efficient in terms of construction costs, operating costs, or energy conservation.

¹https://www.fairfaxcounty.gov/connector/sites/connector/files/Assets/Documents/PDF/May%202025%20Service%20Changes/Route_605-615_0525-web.pdf

² https://www.fairlakes.com/media/v1/139/2025/09/Schedule_2025.08.20.pdf

TCAU will renovate the existing space to house the PET/CT. Construction will utilize a compact, shielded design to minimize material costs and expedite the buildout process.

Efficient Construction

- **Compact layout and targeted renovations limit construction costs for this project.**
- **Modern shielding and room design ensure regulatory compliance while saving energy and materials.**

Operating and Energy Efficiency

- **Conducting PET/CT imaging for TCAU's patients in PD 8 at one location will streamline staff workflows and patient scheduling, resulting in significantly lower operational expenses.**
- **New PET/CT hardware is state of the art and energy-efficient, with rapid scans and reduced exposure, minimizing utility costs.**

These features make the project cost-effective, operationally streamlined, and environmentally responsible.

- 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:

TCAU will use existing commercial utility connections for water, sewer, and solid waste services through these service providers.

See **Attachment II.D (Utilities Documentation)**.

- (1) Letters from appropriate governmental agencies verifying the availability and adequacy of utilities,
- (2) National Pollution Discharge Elimination System permits,
- (3) Septic tank permits
- (4) Receipts for water and sewer connection and sewer connection fees.

- E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify:

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- 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.)

See **Attachment II.E (Space Tabulation)**.

3. Specify design criteria used or rationale for determining the size of the total facility and each department within the facility.

The remodeled design space meets minimum space requirements for a RS Biograph mCT-S(64) PET/CT scanner and its components (See Attachment II.G). This includes a control room, PET scanner room, hot lab, equipment room, and an uptake room, all equipped with the necessary patient care equipment.

Design and construction will follow equipment manufacturer specifications, safety guidelines, the current requirements of the Facility Guidelines Institute Guidelines for the Design and Construction of Hospital and Health Care Facilities, Americans with Disabilities Act guidelines, International Building Code, National Fire Protection Association 101 Life Safety Code, ASHRAE 90.1 Energy Conservation Code, the Virginia Uniform Statewide Building Code, and relevant local codes.

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

1. The courses and distances of the property line.

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2. Dimensions and location of any buildings, structures, roads, parking areas, walkways, easements, right-of-way or encroachments on the site.

See **Attachment II.F (Site Plan)**.

- 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:

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.

See **Attachment II.G. (Architectural Drawings)**.

- H. Construction Time Estimates

- | | | | |
|----|-------------------------|-------------|---|
| 1. | Date of Drawings: | Preliminary | <u>COPN Approval + 2 months</u> |
| | | Final | <u>COPN Approval + 3 months</u> |
| 2. | Date of Construction: | Begin | <u>COPN Approval + 4 months</u> |
| | | Completion | <u>COPN Approval + 12 months</u> |
| 3. | Target Date of Opening: | | <u>COPN Approval + 14 months</u> |

SECTION III

SERVICE DATA

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

Current Services

The Centers for Advanced Urology (“TCAU”) is a physician-led urology platform serving a broad patient population across Northern Virginia and the greater Washington, D.C. region. In PD 8, TCAU is comprised of two established and complementary practices, Potomac Urology Center (“Potomac Urology”) and The Urology Group of Virginia (“TUG”), each of which has long been recognized as a leading provider of comprehensive urologic care in its respective communities. Together, these practices form a unified regional network of urologists and advanced practice providers delivering high-quality, specialty care to patients with complex urologic conditions, including a substantial number of individuals with actual or suspected genitourinary malignancies.

TCAU, through Potomac Urology and TUG, provides comprehensive urologic care for patients in PD 8, including office-based evaluation, diagnostic testing, and medical and surgical management (such as minimally invasive and robotic surgery, kidney stone management, and cancer care). At present, however, TCAU does not operate an on-site PET/CT scanner. Patients who require PET/CT imaging, including PSMA PET/CT or renal PET/CT for prostate and kidney cancer, must be referred to external imaging providers whose services are largely oriented toward general oncologic indications. This fragmented model can result in delays in scheduling, variability in imaging protocols and interpretation, and less efficient coordination between imaging findings and urologic treatment planning.

Proposed PET/CT Services

Upon completion of the proposed construction, TCAU will add a fixed RS Biograph mCT-S(64) PET/CT scanner in a dedicated, shielded PET/CT suite. The new service will provide on-site, subspecialized PET/CT imaging primarily for urologic oncology, including PSMA PET/CT for prostate cancer and renal-specific PET/CT for kidney cancer, as well as other emerging urologic radiotracers as they become available. By embedding PET/CT within its coordinated urology and oncology programs, TCAU will be able to offer timely, protocol-standardized imaging with urologic subspecialty interpretation, closely linked to clinic visits, multidisciplinary case review, and treatment decision-making. This will allow TCAU to deliver more precise staging, recurrence detection, and treatment monitoring for men with prostate

and other urologic cancers, while existing community PET/CT providers continue to serve broader cardiac and general oncology imaging needs.

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

PET/CT services at TCAU will enhance continuity and coordination of care for urologic patients in PD 8. Patients currently must travel to hospital-based or freestanding imaging centers for PET/CT, which are on different health information technology platforms. This fragmentation adds scheduling complexity, duplicate registration and billing processes, and delays in communication of results.

Under the proposed project, PET/CT imaging will become part of TCAU's comprehensive service offerings. This means that referring urologists will have direct, real-time access to imaging results within the TCAU electronic medical record. Imaging findings will be discussed promptly with patients, within a short follow-up interval, to reduce anxiety and allow timely initiation or modification of treatment.

Care pathways for prostate and kidney cancer will incorporate PET/CT at appropriate points, consistent with national guidelines. Scheduling, pre-authorization, preparation instructions, and post-imaging follow-up will be coordinated by TCAU staff who already manage patients' urologic care. This integrated approach reduces the burden on patients and caregivers, minimizes the risk of missed or delayed studies, and supports more efficient, guideline-concordant care.

- C. What procedures are utilized in quality care assessment?

TCAU maintains an ongoing quality assessment and performance improvement program that applies to all clinical services and will be extended to the proposed PET/CT service. The PET/CT unit will comply with all applicable state and federal laws and regulations, and relevant radiation safety standards.

TCAU will seek and maintain accreditation for PET/CT through the American College of Radiology (ACR), which includes periodic external review of imaging protocols, equipment performance, radiation dose management, and technologist and physician qualifications.

- 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.

TCAU anticipates hiring 1 full-time equivalent (FTE) nuclear medicine technologist with PET/CT training and 1 FTE support staff (a medical

assistant) for the PET/CT unit. These individuals will meet all licensure and certification requirements of the Commonwealth of Virginia and relevant professional bodies.

PET/CT studies will be interpreted by board-certified radiologists and/or nuclear medicine physicians with documented expertise in oncologic and urologic imaging, engaged through a professional services agreement with ProScan Imaging.

Medical oversight of the PET/CT service, including protocol development, radiotracer selection, radiation safety, and coordination with the ProScan physicians will be provided by the designated medical director of PET/CT, Dr. Christine Tran.

E. Facilities and Services to be Provided (Check)

	<u>Existing</u>	<u>This Project To be Added</u>	<u>This Project to be Discontinued</u>
1. Outpatient Surgery	_____	_____	_____
2. Post Operative Recovery Room	_____	_____	_____
3. Pharmacy with full-time pharmacists part-time pharmacists	_____ _____	_____ _____	_____ _____
4. Diagnostic Radio- logical Services x-ray radioisotope (PET) CT scanning	_____ _____ _____	_____ X _____	_____ _____ _____
5. Therapeutic Radio- logical Services Specify Source(s) or Type(s) or Equipment Used	_____ _____ _____	_____ _____ _____	_____ _____ _____

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6.	Clinical Pathology Laboratory	_____	_____	_____
7.	Blood Bank	_____	_____	_____
8.	Electroencephalo- graphy	_____	_____	_____
9.	Electrocardiography	_____	_____	_____
10.	Ultrasonography	_____	_____	_____
11.	Respiratory Therapy	_____	_____	_____
12.	Renal Dialysis chronic outpatient home dialysis training	_____ _____ _____	_____ _____ _____	_____ _____ _____
13.	Alcoholism Service	_____	_____	_____
14.	Drug Addiction Service	_____	_____	_____
15.	Physical Therapy Department	_____	_____	_____
16.	Occupational Therapy Department	_____	_____	_____
17.	Medical Rehabilitation outpatient	_____	_____	_____
18.	Psychiatric Service outpatient emergency service	_____ _____ _____	_____ _____ _____	_____ _____ _____
19.	Clinical Psychology	_____	_____	_____
20.	Outpatient Emergency Service	_____	_____	_____
21.	Social Service	_____	_____	_____
22.	Family Planning Service	_____	_____	_____

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23.	Genetic Counseling Service	_____	_____	_____
24.	Abortion Service	_____	_____	_____
25.	Pediatric Service	_____	_____	_____
26.	Obstetric Service	_____	_____	_____
27.	Gynecological Service	_____	_____	_____
28.	Home Care Service	_____	_____	_____
29.	Speech Pathology Service	_____	_____	_____
30.	Audiology Service	_____	_____	_____
31.	Paramedical Training Program	_____	_____	_____
32.	Dental Service	_____	_____	_____
33.	Podiatric Service	_____	_____	_____
34.	Pre-Admission Testing	_____	_____	_____
35.	Pre-Discharge Planning	_____	_____	_____
36.	Multiphasic Screening	_____	_____	_____
37.	Other (Identify)	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____
	_____	_____	_____	_____

F. Program

1. Is (will) this outpatient facility (be) a department, unit or satellite of a hospital?

_____ Yes (Give name of hospital) _____

 X No

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

_____ Yes (Give name of hospital) _____

 X No

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

_____ Yes (give name of facility)

 X No

TCAU is able to transfer and receive records from any hospital as needed. If a patient is transferred to a hospital directly from TCAU, the records will be provided to the EMS transport.

4. Outpatient services are (will be) available from **8** a.m. to **5** p.m.
 5 days a week.

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

_____ Yes (Attach clinic schedule list)

 X No

Patients will be scheduled for urologic PET/CT during the facility's operating hours.

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

 X Yes _____ No

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

(a) Only by physicians on call: _____ Yes **X** No

(b) By full time physicians: **X** Yes _____ No

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

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

Only TCAU patients for whom PET/CT is medically necessary and clinically appropriate can be imaged on the PET/CT scanner. Based on the specifications for the PET/CT scanner, patients weighing more than 500 lbs cannot be imaged on the machine.

- 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.

Utilization projections for the proposed fixed PET/CT service are based on the existing and projected urologic oncology patient volumes from Potomac Urology and TUG, combined with evolving clinical guidelines and radiotracer availability. As national and specialty-society guidelines increasingly recognize the clinical value of advanced PET imaging for initial staging, **biochemical recurrence**, and treatment response assessment in prostate and other urologic malignancies, demand for PET/CT among TCAU's patients is expected to continue to grow for the foreseeable future. **For planning purposes, TCAU assumes a conservative long-term PET/CT volume growth rate of approximately 3.5% per year.**

Historical PET/CT utilization attributable to Potomac Urology and TUG demonstrates a substantial utilization of PET/CT even prior to the full **implementation of newer PET radiotracers and related guideline changes**. Within this overall utilization, TCAU experienced approximately 20% growth as is further discussed below, **indicating rapid adoption of PSMA PET/CT for prostate cancer patients**. Moreover, national epidemiologic data show that prostate cancer incidence rates have increased since 2014 by about 3% per year overall, ranging from 2.4% per year for localized-stage disease to 4.8% per year for advanced disease from 2017 to 2021.³ At the same time, the male age 65 and older population in PD 8 is projected to increase by roughly 3% per year through 2030.⁴ These clinical and demographic trends support the reasonableness of a projected PET/CT utilization annual growth rate of 3.5%. Table III.G summarizes TCAU's PET/CT referral volumes for 2023–2025.

Table III.G – TCAU Historical PET/CT Utilization

2023 PET/CT	2024 PET/CT	2025 PET/CT	Average Annual Growth
578	854	811	20.2%

Source: Potomac Urology and TUG internal data.

³ [Cancer Facts & Figures 2025](#)

⁴ Weldon Cooper Center for Public Service – Virginia Population Estimates, 2025; Virginia Population Projections, 2030.

These data show an average annual growth of 20.2% in PET/CT referrals from 2023 to 2025.⁵ Taking into account conversion of existing imaging referrals, growth in urologic cancer, and expected adoption of PET/CT in accordance with national guidelines, TCAU conservatively projects performing approximately 818 PET/CT studies in Year 1 of operation and 847 PET/CT studies in Year 2.

In evaluating the capacity of the proposed fixed PET/CT scanner, it is important to recognize that PSMA PET/CT has operational constraints that are not captured by simple unit-count or “percent utilization” statistics. Each PSMA PET/CT examination requires a substantial amount of time per patient: approximately 50 minutes of radiotracer uptake time after injection, followed by roughly 30 minutes of imaging time on the scanner. In addition, commonly used PSMA radiotracers have a physical half-life of about 68 minutes, which limits the time window during which doses can be prepared, delivered, and used while maintaining adequate activity for high-quality imaging. To preserve image quality and safety, injections must be carefully sequenced and clustered within this usable time window, and the number of doses that can be prepared and administered in a day is inherently limited. In practice, these factors cap throughput at no more than eight PSMA PET/CT scans per day, even with an efficiently run schedule. Based on TCAU’s conservative projected volumes and the 3.5% annual growth rate in PET/CT utilization, TCAU will have capacity to meet the growing need for PSMA PET/CT as the PD 8 population ages.

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).

⁵ The 2025 volumes were slightly below the 2024 volumes as the result of one of the highly productive physicians taking parental leave. Based on monthly trend data since that physician’s return and looking at the first few months of 2026, TCAU anticipates that its PET/CT volumes will continue to grow significantly.

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

Other Health

Professionals, Identify 1 (Nuclear Tech) 1

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.

TCAU intends to recruit local talent and, if necessary, use local newspapers, online and other typical methods of recruitment already used by TCAU. If necessary, national forums will also be used to recruit the needed staff.

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

TCAU does not anticipate that the project will have an adverse impact on staffing of other facilities in PD 8, as the staffing needs are very minimal.

- K. Attach the following information or documents:

1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers).

TCAU, as a medical practice, is not licensed.

2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers).

TCAU, as a medical practice, is not accredited.

3. Roster of medical staff (existing facilities). Indicate their specialty, Board Certification, Board eligibility and staff privileges (active, associate, etc.).

See Attachment III.K.3 (Medical Staff Documentation).

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 Attachment III.K.4 (Letter of Commitment from Medical Staff).

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF / COMMUNITY NEED

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

Introduction

TCAU proposes to establish a fixed PET/CT service at its facility to improve access to advanced imaging for patients with urologic cancers and related conditions in PD 8. Patients in the region currently have limited timely access to PET/CT imaging tailored to urologic oncology, including PET/CT utilizing PSMA and other emerging radiotracers. As DCOPN has established, “the use of PET/CT in urological setting is vital to accurate and timely diagnostics and treatment implementation.”⁶ This project will integrate high-quality PET/CT imaging into an established, high-volume urology practice, thereby enhancing diagnostic accuracy and timeliness of care.

Background

The Centers for Advanced Urology (“TCAU”) is a physician-led urology platform serving a broad patient population across Northern Virginia and the greater Washington, D.C. region. In PD 8, TCAU is comprised of two established and complementary practices, Potomac Urology Center (“Potomac Urology”) and The Urology Group of Virginia (“TUG”), each of which has long been recognized as a leading provider of comprehensive urologic care in its respective communities. Together, these practices form a unified regional network of urologists and advanced practice providers delivering high-quality, specialty care to patients with complex urologic conditions, including a substantial number of individuals with actual or suspected genitourinary malignancies.

TCAU, through Potomac Urology and TUG, maintains multiple office locations across Northern Virginia and adjacent communities, offering convenient access to outpatient evaluation and longitudinal management of urologic disease. Their physicians collectively care for a large and growing cohort of patients with prostate, bladder, kidney, testicular, and other urologic cancers, along with patients requiring ongoing surveillance for high-risk or recurrent disease.

The proposed PET/CT unit is intended to meet the demonstrated imaging needs of TCAU’s patient population. Currently, many TCAU patients must obtain PET/CT services at unaffiliated facilities, which can result in fragmented care, longer travel distances, scheduling delays, and challenges in coordinating imaging with specialist visits and procedures. By establishing

⁶ DCOPN Staff Report, COPN Request No. VA-8678, March 21, 2023, p. 19.

PET/CT capacity within its practice, TCAU will be able to provide timely, integrated diagnostic and staging studies directly aligned with the clinical pathways used by TCAU providers. This will enhance continuity of care, improve coordination between treating urologists and interpreting radiologists, and support more efficient, evidence-based decision-making for patients with known or suspected urologic malignancies.

In short, this application rests on the collective needs of the patients served by Potomac Urology and TUG under the TCAU umbrella. The proposed PET/CT service is designed not as a stand-alone imaging venture, but as an essential extension of an existing, high-volume regional urology network to help ensure that patients across Northern Virginia can receive comprehensive, coordinated urologic and oncologic care, including advanced imaging, in a more accessible and clinically integrated setting.

Burden of Urologic Cancers

Prostate and kidney cancers represent a substantial and growing burden of disease in Virginia and, in particular, within PD 8. These malignancies are predominantly diseases of older adults and occur disproportionately in men, meaning that demographic aging and growth of the older male population in PD 8 will translate directly into increased demand for urologic and oncologic care. National cancer registry data indicate that prostate cancer is the second most common cancer in U.S. for men, accounting for roughly 15% of all new male cancer diagnoses, with an incidence of approximately 120 per 100,000 men per year and hundreds of thousands of new cases annually.⁷

The demographic profile of PD 8 is shifting in a way that amplifies this burden. As is demonstrated in Table IV.A.i, the population aged 65 and older in PD 8 is expected to grow from 347,702 in 2023 to 431,728 in 2030 and 462,680 by 2035—an approximate 33% increase over those 12 years. Growth is particularly pronounced in rapidly developing jurisdictions such as Loudoun County and Prince William County. Even in jurisdictions where growth is moderate or slightly declines after 2030, such as Fairfax County, Arlington County, and the City of Alexandria, the absolute number of older adults remains high, sustaining a large pool of residents at elevated risk for urologic malignancies and age-associated urologic disease. These trends mirror national data demonstrating that cancer overall is most frequently diagnosed between ages 65 and 74 and that older adults account for the majority of cancer incidence and mortality in the United States.⁸

⁷ [SEER Cancer Stat Facts: Prostate Cancer.](#)

⁸ [SEER Cancer Stat Facts: Cancer of Any Site; Cancer incidence and mortality trends among older adults.](#)

Table IV.A.i – PD 8 Population Data for 65+

	65+ (2023 most recent year for data)	65+ (2030)	65+ (2035)
Loudoun County	49,711	77,656	92,525
City of Fairfax	3,586	4,740	4,756
Prince William County	57,805	81,201	91,836
City of Falls Church	2,275	2,846	3,033
Fairfax County	177,855	201,526	206,630
Arlington County	29,077	31,175	30,686
City of Alexandria	20,937	23,477	23,285
City of Manassas	4,774	6,801	7,271
City of Manassas Park	1,682	2,306	2,660
Total:	347,702	431,728	462,680

Source: Weldon Cooper Center for Public Service – Virginia Population Estimates, 2023; Virginia Population Projections, 2030.

Male 65+ Population and Implications for Urologic Cancers

The expansion of the older *male* population in PD 8 is particularly consequential for urologic disease. As is demonstrated in Table IV.A.ii, the 65+ male population in PD 8 is projected to increase from 159,250 in 2023 to 193,366 in 2030, before stabilizing at approximately 205,812 by 2035—a net increase of nearly 30%. Loudoun County and Prince William County show especially large proportional increases in older men over this period.

This demographic shift aligns with the age distribution of prostate cancer, which is heavily concentrated in men over 65. SEER data indicate that prostate cancer is most frequently diagnosed in men aged 65–74, who account for roughly 40–45% of new cases, with additional substantial proportions in men 75–84.⁹ The American Cancer Society similarly reports that about 6 in 10 prostate cancers are diagnosed in men aged 65 or older, with a median age at diagnosis of about 67.¹⁰ Prostate cancer thus constitutes a leading driver of cancer burden among older men, and its incidence and mortality rates closely track the growth of the older male population.¹¹

Kidney and renal cancers similarly show a strong association with older age. SEER data indicate that these cancers are most frequently diagnosed in individuals aged 65–74, with additional significant case volumes in patients

⁹ [SEER Cancer Stat Facts: Prostate Cancer](#)

¹⁰ [American Cancer Society. Key Statistics for Prostate Cancer.](#)

¹¹ [SEER Cancer Stat Facts: Prostate Cancer; American Cancer Society. Key Statistics for Prostate Cancer.; Cancer incidence and mortality trends among older adults.; Impact of age at diagnosis on prostate cancer treatment and survival.; and Prostate cancer in elderly men.](#)

aged 75–84 and older.¹² Epidemiologic reviews describe sporadic renal cell carcinoma as a disease of older adults, with an average age at diagnosis in the mid-60s and the largest increases in incidence over recent decades occurring among those aged 75 and older.¹³ Older patients with kidney cancer often present with multiple comorbid conditions, including hypertension, chronic kidney disease, and cardiovascular disease, which complicate operative decision-making and postoperative management.¹⁴ Collectively, these patterns imply that as PD 8's 65+ population grows, the region will experience a rise in the absolute number of kidney and renal cancer cases and will require sustained capacity for advanced imaging, surgical interventions such as partial and radical nephrectomy, ablative therapies, and longitudinal surveillance.

Table IV.A.ii – PD 8 Population Data for 65+ Male

	65+ (2023 most recent yr for data)	65+ (2030)	65+ (2035)
Loudoun County	22,511	34,245	40,498
City of Fairfax	1,547	2,163	2,158
Prince William County	26,445	36,255	40,730
City of Falls Church	954	1,192	1,261
Fairfax County	82,278	91,393	93,177
Arlington County	13,401	14,040	13,753
City of Alexandria	9,115	10,074	9,936
City of Manassas	2,208	3,026	3,187
City of Manassas Park	791	978	1,114
Total:	159,250	193,366	205,812

Source: Weldon Cooper Center for Public Service – Virginia Population Estimates, 2023; Virginia Population Projections, 2030.

Prostate Cancer in PD 8

State-level data reinforces the prevalence of urologic malignancies in Virginia. The Virginia Cancer Plan and Virginia Cancer Registry data identify prostate cancer as one of the most common cancers among men in the Commonwealth, with kidney/renal cancers close behind.¹⁵ Virginia Department of Health cancer dashboards further demonstrate that these urologic sites consistently rank among the most consequential malignancies across health districts.¹⁶ Because PD 8 encompasses some of Virginia's largest and fastest-growing localities, the combination of high baseline cancer incidence at these sites statewide and the projected demographic aging in PD 8 suggests that the

¹² [SEER Cancer Stat Facts: Kidney and Renal Pelvis Cancer](#)

¹³ [Epidemiology of renal cell carcinoma.](#)

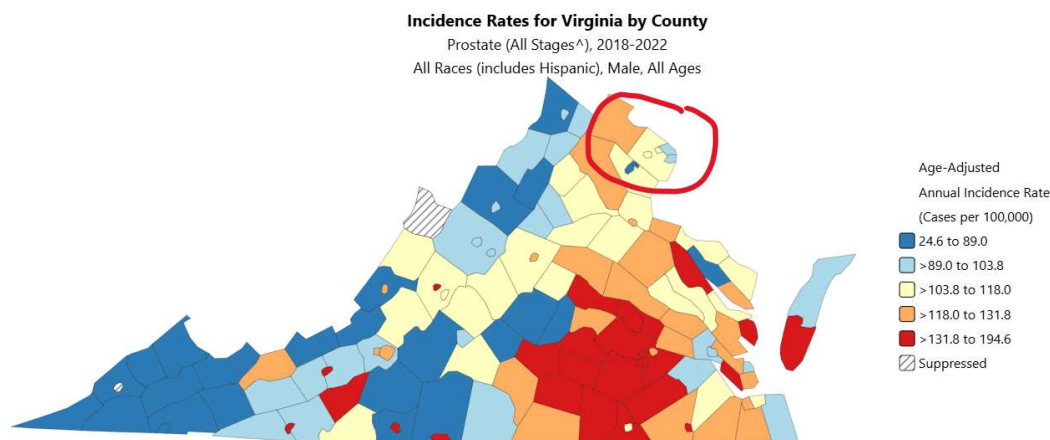
¹⁴ [Epidemiology of renal cell carcinoma.; Prognostic factors of renal cell cancer in elderly patients.](#)

¹⁵ [Virginia Cancer Plan 2018–2022.; Virginia Department of Health – Virginia Cancer Dashboards.](#)

¹⁶ [Virginia Department of Health – Virginia Cancer Dashboards.](#)

region will shoulder an increasing share of the Commonwealth's urologic cancer burden.

As displayed in the map and chart below, many communities within TCAU's service area experience higher incidence rates for prostate cancer than the national and statewide rates. The map and chart below include five years of statistics (2018-2022) for the age-adjusted incidence rates for prostate cancer in PD 8.



PD 8 - Age-Adjusted Incidence Rate cases per 100,000 for Prostate Cancer

	Age-Adjusted Incidence Rate cases per 100,000 for Prostate Cancer ¹⁷
Loudoun County	125.1
City of Fairfax	116.7
Prince William County	106.5
City of Falls Church	106.4
Fairfax County	105.3
Arlington County	99.4
City of Alexandria	98.9
City of Manassas	73.4
City of Manassas Park	62.5

For PD 8, the convergence of all of these demographic and epidemiologic trends has clear implications. The projected increases in the 65+ population and the 65+ male population will, even under optimistic assumptions of stable or slightly improving age-specific cancer rates, produce a meaningful rise in the absolute number of prostate and kidney cancers. Across these disease types, older patients often experience higher rates of treatment-related

¹⁷ <https://statecancerprofiles.cancer.gov/> 2018-2022 is the most current data available.

complications and require individualized, multidisciplinary decision-making that balances oncologic control with functional status, comorbidity, and patient preference. Evidence suggests that under-treatment of high-risk disease in older adults contributes to worse outcomes, underscoring the need for appropriately aggressive but tailored management strategies in this population.¹⁸

To meet this need, PD 8 will require adequate and strategically located urologic and urologic oncology capacity, including diagnostic, surgical, medical, and survivorship services that are specifically designed to serve an older, comorbid population. TCAU can meet this need with the proposed urologic PET/CT. Thoughtful planning now will be critical to mitigate the clinical, operational, and economic impact of the rising urologic disease burden in PD 8.

Prostate-Specific Membrane Antigen (“PSMA”) PET Scan

Prostate cancer remains one of the most common malignancies affecting men, and early, accurate detection is essential for effective treatment and long-term disease control. Traditional diagnostic methods, such as prostate-specific antigen (“PSA”) testing, digital rectal examination, and conventional imaging with CT, MRI, or bone scintigraphy, can miss sites of disease or yield equivocal findings, particularly in early metastatic or recurrent settings. PSMA PET/CT is an advanced form of molecular imaging that directly addresses these limitations.

PSMA is a transmembrane protein that is highly overexpressed on the surface of prostate cancer cells compared to normal prostate tissue, making it an ideal biologic target for imaging. PSMA PET/CT utilizes a radiolabeled ligand (or tracer), such as ⁶⁸Ga-PSMA-11 or ¹⁸F-DCFPyL, that binds specifically to PSMA-expressing cells. After intravenous injection, the tracer circulates and attaches to PSMA on prostate cancer cells, including small, micrometastatic, or otherwise anatomically occult lesions. The PET component detects the positron emissions from the tracer, while the CT component provides high-resolution anatomic detail. Together, PSMA PET/CT generates a detailed three-dimensional map of areas with high PSMA expression, enabling precise localization of prostate cancer within the prostate, lymph nodes, bone, and distant organs.

Because it images tumor biology rather than relying solely on structural changes or size thresholds, PSMA PET/CT is both highly sensitive and highly specific, allowing detection of even small clusters of cancer cells and early metastatic deposits that conventional imaging frequently fails to identify.

¹⁸ [Impact of age at diagnosis on prostate cancer treatment and survival.](#); [Prostate cancer in elderly men.](#); and [Prognostic factors of renal cell cancer in elderly patients.](#)

For this reason, PSMA PET/CT is particularly important for patients experiencing PSA discordance, which is defined as rising or persistently elevated PSA levels that are not explained by findings on conventional imaging. Historically, PSA discordance posed a significant diagnostic and management challenge since CT, MRI, and bone scintigraphy often fail to identify sites of recurrent or metastatic disease because they rely on structural changes (e.g., lesion size, bone remodeling) that lag behind early biologic activity at the cellular level. PSMA PET/CT, by contrast, directly addresses this diagnostic gap by enabling molecular imaging of prostate cancer biology. Because PSMA is highly overexpressed on prostate cancer cells, PSMA-targeted radiotracers can bind to malignant tissue even when lesions are small, micrometastatic, or anatomically occult. As a result, PSMA PET/CT can localize sites of disease at PSA levels that are well below the detection thresholds of conventional imaging.

This level of diagnostic precision directly informs treatment selection—whether to pursue salvage radiation, targeted metastasis-directed therapy, initiation or escalation of systemic therapy, or continued active surveillance. In the absence of PSMA PET/CT, management of PSA discordance is often empirical, increasing the risk of overtreatment with broad systemic therapies or undertreatment due to failure to identify the true sites of disease.

By enabling accurate, early, and biologically targeted localization of prostate cancer, PSMA PET/CT improves the precision of care, reduces unnecessary or ineffective testing and therapies, and supports better alignment of treatment intensity with actual disease burden. For these reasons, integration of PSMA PET/CT into prostate cancer diagnostic and treatment pathways represents a major advancement in the management of patients and is used in multiple key clinical scenarios, including:

- **Initial Staging of Newly Diagnosed Prostate Cancer:** For patients with intermediate- or high-risk disease, PSMA PET/CT can determine whether cancer is confined to the prostate or has spread to regional lymph nodes or distant sites. This information is essential for selecting appropriate primary therapy, including surgery, radiation therapy, and systemic treatment.
- **Detection of Recurrence (Biochemical Recurrence):** Following definitive therapy (e.g., radical prostatectomy, radiation, or systemic therapy), rising PSA levels may indicate recurrent disease. PSMA PET/CT can localize the site of recurrence, whether in the prostate bed, regional lymph nodes, bone, or distant organs, even when PSA levels are relatively low and conventional imaging is negative or inconclusive.

- Evaluation of Metastatic Disease: In patients with known or suspected advanced or metastatic prostate cancer, PSMA PET/CT is used to assess the presence, distribution, and burden of metastases. Accurate identification of nodal, osseous, and visceral metastases is critical for tailoring systemic therapy, considering metastasis-directed interventions, and determining eligibility for certain advanced treatments.
- Monitoring Response to Therapy: For patients undergoing systemic therapy, radiation therapy, or other targeted interventions, PSMA PET/CT can be used to assess treatment response by evaluating changes in PSMA uptake at known sites of disease and detecting new lesions. This allows clinicians to adjust therapy based on real-time assessment of disease biology rather than waiting for delayed anatomic changes.
- Salvage and Metastasis-Directed Therapy Planning: When initial curative treatment is unsuccessful and salvage therapy is being considered, PSMA PET/CT helps identify specific targets for intervention, such as localized recurrence, oligometastatic disease, or regional nodal involvement. This facilitates precise radiotherapy planning, selection of surgical targets, or focused ablative therapies.

While PSMA PET/CT is not required for every patient with prostate cancer, it is particularly beneficial for defined clinical populations, including:

- Patients With Recurrent or Metastatic Prostate Cancer: After primary treatment, patients with rising PSA or symptoms suggestive of recurrence benefit from PSMA PET/CT to identify the location and extent of recurrent or metastatic disease that may not be visible on conventional CT, MRI, or bone scans.
- High-Risk Patients at Initial Diagnosis: Patients with high PSA levels, aggressive histologic features, or other markers of high-risk disease derive substantial benefit from PSMA PET/CT, which can identify occult metastatic sites and thereby refine staging and inform initial treatment intensity.
- Patients Under Active Surveillance: For select patients managed with active surveillance for low-risk disease, PSMA PET/CT can assist in identifying early progression or previously unrecognized higher-risk features, supporting more individualized decisions about whether and when to transition to active treatment.
- Patients With Inconclusive Conventional Imaging: When CT, MRI, or bone scans yield equivocal or discordant findings, PSMA PET/CT serves as a more sensitive and specific modality to clarify the presence and distribution of disease, thereby resolving diagnostic uncertainty.

- **Patients Requiring Detailed Treatment Planning:** PSMA PET/CT guides precise treatment planning for surgery, radiation therapy (including dose painting or stereotactic body radiotherapy to metastatic sites), and other localized or systemic interventions. By mapping actual sites of disease, it reduces the likelihood of “blind” or empiric treatment.

Collectively, these applications demonstrate that PSMA PET/CT benefits a broad spectrum of patients, particularly those with higher-risk disease, biochemical recurrence, suspected metastatic spread, or inconclusive results on standard imaging.

Renal-Specific PET Scan

Kidney cancer, also known as renal cell carcinoma, is a significant health concern that requires accurate detection and staging for effective treatment and management. Traditional methods such as ultrasound, CT scans, and MRI have been widely used for diagnosing renal cancer; however, these imaging modalities can sometimes provide incomplete or ambiguous results. The advent of renal-specific PET scans has revolutionized the approach to diagnosing and managing renal cancer by offering superior sensitivity and precision in identifying cancerous tissues and metastases.

Renal-specific PET scans represent a breakthrough in molecular imaging for kidney cancer. These scans use radiotracers specifically designed to target molecular markers that are overexpressed in renal cancer cells. By utilizing these radiotracers, renal PET scans enable the precise localization of cancerous tissues and offer a more accurate assessment of the disease’s extent, helping physicians improve staging, treatment planning, and patient outcomes.

Renal PET scans are employed in various clinical scenarios to enhance the management of kidney cancer. These scenarios include:

- **Diagnosing and Staging of Renal Cancer:** For patients newly diagnosed with renal cancer, PET scans help determine the tumor’s location, size, and extent of spread to other tissues or organs. Accurate staging is critical for developing an effective treatment plan.
- **Evaluating Recurrence or Metastasis:** In cases where kidney cancer has been treated but there is suspicion of recurrence, PET scans can identify the precise location of recurrent disease. Additionally, they are invaluable in detecting metastases in distant organs, such as the lungs, bones, or liver, which may not be visible on conventional imaging.
- **Monitoring Treatment Response:** Renal PET scans provide a powerful tool for tracking how well the cancer responds to treatments like targeted therapy, immunotherapy, or chemotherapy. By comparing PET scans

taken before and after treatment, physicians can make informed decisions about adjusting or continuing the therapeutic approach.

- **Guiding Biopsies or Surgical Planning:** PET scans allow for targeted biopsies of suspicious lesions, ensuring the accurate sampling of tissues for diagnosis. They also assist in surgical planning by delineating tumor boundaries and identifying potential challenges such as lymph node involvement.
- **Cases with Ambiguous Conventional Imaging:** For patients whose CT or MRI scans yield inconclusive results, renal PET scans provide additional clarity, enhancing diagnostic confidence.

Renal PET scans utilize radiotracers that bind to molecular markers associated with kidney cancer. These markers may include proteins or receptors that are overexpressed on renal cancer cells. Commonly used radiotracers include:

- **18F-FDG (Fluorodeoxyglucose):** Although not specific to kidney cancer, it is often used to assess metabolic activity in tumors.
- **18F-FLT (Fluorothymidine):** A tracer targeting cellular proliferation, providing insights into tumor growth rates.
- **Carbon-11 Acetate or Choline:** These tracers target metabolic pathways altered in renal cancer cells, offering improved detection rates.

Zirconium-89, labeled girentuximab, is an investigational radiotracer designed to enhance the non-invasive detection and characterization of clear-cell renal cell carcinoma (“ccRCC”) through PET/CT imaging.

Girentuximab (“ ^{89}Zr ”) is a chimeric monoclonal antibody that specifically targets carbonic anhydrase IX (“CAIX”), a protein highly expressed on the surface of ccRCC cells. The conjugation of ^{89}Zr to girentuximab enables visualization of CAIX expression in tumors, potentially improving diagnostic accuracy and patient management.

The clinical evaluation of ^{89}Zr -girentuximab has progressed through several phases, with recent studies providing promising results. A pivotal phase 3 trial, known as the ZIRCON study, assessed the efficacy of ^{89}Zr -girentuximab PET/CT imaging in patients with indeterminate renal masses suspicious for ccRCC. The study demonstrated that ^{89}Zr -girentuximab PET/CT achieved a mean sensitivity of 85.5% and a mean specificity of 87.0% in detecting ccRCC, surpassing predefined thresholds for diagnostic accuracy. These findings suggest that ^{89}Zr -girentuximab PET/CT could serve as a highly accurate, non-invasive imaging modality for ccRCC detection and characterization.

In addition to the ZIRCON study, other investigations have evaluated the safety and efficacy of ^{89}Zr -girentuximab. A study conducted in Japan reported that ^{89}Zr -girentuximab administered to patients with suspected ccRCC exhibited a favorable safety profile and was well-tolerated, with no unexpected adverse events observed.

The use of ^{89}Zr -girentuximab radiotracer offers several potential benefits in the management of renal cancer:

1. **Enhanced Diagnostic Accuracy:** ^{89}Zr -girentuximab PET/CT imaging provides high sensitivity and specificity in detecting ccRCC, facilitating accurate differentiation between malignant and benign renal masses. This precision aids in treatment planning and may reduce the need for invasive procedures such as biopsies.
2. **Non-Invasive Assessment:** ^{89}Zr -girentuximab PET/CT offers a non-invasive alternative to traditional imaging modalities, potentially decreasing patient discomfort and associated risks. The ability to visualize CAIX expression in tumors without the need for tissue sampling is a significant advantage.
3. **Improved Patient Management:** Accurate imaging of ccRCC can inform clinical decision-making, including the selection of appropriate surgical interventions and the assessment of tumor aggressiveness. This can lead to more personalized treatment strategies and better patient outcomes.
4. **Potential for Monitoring Therapeutic Response:** ^{89}Zr -girentuximab PET/CT imaging may be utilized to monitor the effectiveness of targeted therapies and immunotherapies in ccRCC patients, providing early insights into treatment efficacy and facilitating timely adjustments to therapeutic regimens.

^{89}Zr -girentuximab radiotracer represents a promising advancement in the non-invasive imaging of ccRCC. Clinical studies have demonstrated its high sensitivity and specificity, favorable safety profile, and potential to enhance patient management. Ongoing research and clinical trials are essential to further validate its clinical utility and to explore its role in monitoring therapeutic responses. If these findings are confirmed, ^{89}Zr -girentuximab PET/CT imaging could become a valuable tool in the diagnostic and therapeutic landscape of renal cancer.

A dedicated urologic PET/CT scanner at TCAU will translate this body of evidence into practical, patient-centered benefits for the populations it serves. By embedding PET/CT within its urology and oncology service lines, TCAU can provide rapid, coordinated access to proper imaging modalities at the key

decision points in each patient’s care journey. This will replace the current fragmented model in which patients are referred to outside imaging centers, causing them to experience delays of days to weeks before scans are performed, and forcing them to begin or continue systemic therapy in the absence of optimal staging information.

Current State of PSMA PET/CT for TCAU’s Patients

TCAU’s patients primarily utilize Metro Region PET Center and PET of Reston for their PSMA PET/CTs. Because of the quality services provided by these facilities, they are highly utilized by a wide variety of oncology patients in need of PET/CTs. Based on the most recent data available, PET of Reston is highly utilized with 2,218 scans in 2024.¹⁹ Metro Region PET Center is even busier having performed 6,081 PET/CT scans on 2 scanners in 2024.²⁰ DCOPN previously found that Metro Region PET Center had demonstrated an institutional need for additional capacity when its single PET/CT was performing 3,802 scans per year in the most recent year for which VHI data was available.²¹ With two scanners, it is quickly approaching operational capacity again.

Timely access to PSMA PET/CT imaging is critical for prostate cancer patients because it provides the most accurate and clinically useful information for staging and restaging diseases. Current wait times are, on average, about 15 days. This interval can leave urologists, radiation oncologists, and medical oncologists making high-consequence treatment decisions without the benefit of PSMA PET/CT results when surgery or radiation has already been scheduled or systemic therapy should be initiated promptly. Clinicians may either proceed with local therapy in a patient who already has occult metastatic disease, or defer necessary systemic treatment while awaiting imaging. In both scenarios, the lack of timely PSMA PET/CT undermines the core purpose of this modality to inform the initial choice and sequencing of appropriate therapy and increases the likelihood that patients will receive care that is misaligned with their true disease status. Any delay also diminishes opportunities for curative or oligometastatic-directed treatment, as disease that might have been limited and amenable to targeted radiation or surgery can progress to more widespread metastatic involvement in a matter of weeks.

Delays in imaging are particularly harmful in patients with aggressive or recurrent cancer. Many of the patients for whom PSMA PET/CT is ordered have a rising PSA after surgery or radiation or have high-risk or very-high-risk localized disease. In such patients, cancer is biologically active and can

¹⁹ VHI ALSD 2024.

²⁰ Did not report volumes to VHI in 2024. Volumes were reported in HSANV Staff Report on COPN Request No. VA-8855 (February 24, 2026) p. 4.

²¹ COPN Request No. VA-8758, DCOPN Staff Report (July 19, 2024) p. 20.

progress measurably over a 1–2 month period. Micrometastatic or limited disease can proliferate and spread, particularly in biologically aggressive tumors, increasing nodal and distant involvement and, in some cases, converting a potentially curable or controllable presentation into one that is more advanced and less responsive to therapy. This progression not only reduces the range of available treatments, but can also adversely affect long-term survival and quality of life.

Wait times for imaging also lead to prolonged exposure to ineffective or suboptimal therapy. In the absence of timely PSMA PET/CT results, clinicians often must “bridge” patients with empiric treatments or simply continue existing regimens without knowing whether those treatments are appropriate for the patient’s actual disease burden. Patients may remain on local therapy alone despite unrecognized metastatic disease, or clinicians may escalate systemic therapy based solely on biochemical markers such as PSA without imaging confirmation. This pattern exposes patients to additional toxicity and cost, and may delay initiation of the most effective, evidence-based regimen. It also drives the use of additional conventional imaging such as CT, bone scans, or MRI as interim measures, leading to more appointments, more radiation exposure, and further fragmentation of care that could have been avoided if PSMA PET/CT were promptly accessible.

The impact of imaging delays is not limited to clinical outcomes. It also significantly affects patients’ psychological well-being and overall experience of care. The period between the suspicion of progression and definitive staging is one of the most distressing times for patients and their families. Even a modest wait for PSMA PET/CT prolongs uncertainty about whether the cancer is localized, oligometastatic, or widely metastatic. Patients frequently experience heightened anxiety, fear, sleep disturbance, and difficulty focusing on work and family responsibilities because they do not know what treatment they will need or when it will begin. Ongoing scheduling challenges can erode trust in the healthcare system and increase the likelihood that patients will seek imaging or treatment outside the local area, fragmenting care and complicating coordination among providers.

Importantly, the current access constraints do not affect all patients equally. Patients with financial limitations, transportation challenges, mobility issues, or caregiving responsibilities often have little practical ability to “shop around” for shorter wait times at distant facilities. Older adults and lower-income patients, who are overrepresented in the prostate cancer population, are particularly vulnerable. For these individuals, waiting for the only realistically accessible providers can effectively function as a denial of timely access to guideline-concordant imaging. The result is a de facto disparity in care, where more advantaged patients may find ways to circumvent delays, while vulnerable patients endure prolonged waits, increased risk of disease progression, and higher levels of distress. Expanding

PSMA-capable PET/CT capacity within TCAU, as a dedicated urology practice, directly addresses these inequities by bringing advanced imaging closer to where patients receive their routine urologic care and by reducing structural barriers to access.

Finally, the systemic consequences of ongoing PSMA PET/CT wait times are substantial. Delays in definitive imaging contribute to more clinic visits, more interim imaging studies, and more frequent rescheduling or modifications of treatment plans when belated imaging results alter the intended course of care. As disease progresses during the waiting period, patients are more likely to present with more advanced cancer that requires more intensive, complex, and expensive treatments, including combination systemic therapies, hospitalizations, and palliative interventions. These downstream effects increase overall costs for payors and the healthcare system and decrease the efficiency of cancer care delivery in the region.

By integrating PSMA PET/CT services within TCAU's practice, TCAU can mitigate the harms associated with imaging wait times, improve clinical outcomes and patient experience, reduce inequities in access, and promote more efficient, cost-effective use of healthcare resources.

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 TCAU includes Fairfax County, Ashburn, Woodbridge, Leesburg, Manassas, Herndon, Sterling, Reston, Alexandria, Springfield, Haymarket and extends south to Stafford and Fredericksburg. See [Attachment IV.B.1](#) (Map of Primary Service Area).

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

The proposed PET/CT service will primarily serve TCAU's existing prostate patients in PD 8. See [Attachment IV.B.2](#) for TCAU's existing patient origin data for its prostate cancer patients.

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

There are currently 19 approved PET/CT scanners in PD 8. Nine of these scanners are restricted to cardiac imaging, two are mobile, and none of these providers are integrated into a urology practice.

COPN Req. No. VA-8879 – The Centers for Advanced Urology, LLP
Addition of PET/CT Scanner

2. If Yes,
- a. Identify the facility(ies)

Authorized PD 8 PET Inventory	
Facility	Total Scanners
PET and PET/CT Restricted to Cardiac Imaging	
Carient Heart & Vascular (Manassas)	1
Nova Cardiovascular Care, Inc.	1
Virginia Heart (Falls Church)	1
Open Restricted to Cardiac Imaging	3
Amelia Heart & Vascular Center ²²	1
Carient Heart & Vascular (Vienna) ²³	1
Virginia Heart (Alexandria) ²⁴	1
Virginia Heart (Leesburg) ²⁵	1
Cardiac Care Associates ²⁶	1
Inova Health Care Services ²⁷	1
Unopened Restricted to Cardiac Imaging	6
Total Restricted to Cardiac Imaging	9
Unrestricted PET and PET/CT Scanners	
Fairfax PET/CT Imaging Center	1
Sentara Northern Virginia Medical Center	1
Kaiser Permanente Woodbridge Imaging Center	1
Metro Region PET Center ²⁸	2
UVA Cancer Care Gainesville	1
PET of Reston	1
Virginia Hospital Center	1
Open Un-Restricted	8
Inova Reston MRI Center, LLC	1
Virginia Hospital Center Arlington Health System ²⁹	1
Unopened Un-Restricted	1
Total Authorized PD 8 PET Inventory	19

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

²² Expected open 9/9/24, reported project delays

²³ Open 7/30/23

²⁴ Expected to be completed by 3/31/26

²⁵ Expected to be completed by 9/30/25, though unclear if completed as of 3/31/26

²⁶ Open 6/19/22. Did not report utilization to VHI

²⁷ Expected to be completed by March 31, 2026

²⁸ Second PET/CT scanner expected open 1/1/24, no report of being open. Did not report volume on first PET/CT scanner to VHI

²⁹ PET/CT scanner technically not restricted, but 90% of the time shall be used for cardiac-related purposes.

The current facilities cannot satisfy the needs of TCAU's patients for accessible, convenient PSMA PET/CT services in PD 8. Of the eighteen approved PET/CT services, only two of them regularly provide PSMA PET/CT services. These two facilities, Metro Region PET Center and PET of Reston, are highly utilized for other oncology PET/CT studies. Because TCAU will be focused solely on meeting its patients' needs for PET/CT imaging, it will be able to image patients within days of a TCAU physician ordering the imaging.

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

The existing PET/CT providers in PD 8 cannot meet the needs of TCAU's patients now and will certainly not be able to do so five years from now.

Population Growth and Aging

PD 8 is expected to experience population growth of approximately 4.2% from 2025 to 2030,³⁰ with the 65+ age group increasing by over 24% from 2023 to 2030.³¹ This aging trend significantly elevates the number of residents at risk for urologic disease. The advanced diagnostic capability for urologic PET/CT is particularly well-suited for the aging population and complex cases.

Facility Capacity and Community Impact

TCAU will operate the urologic PET/CT service using established infrastructure and will only need to hire minimal staff. This will ensure timely access and efficient patient flow without disruptions to the workforce at other facilities.

The integration of PET/CT within a comprehensive urology practice eliminates referral delays, supports best practices for managing high-risk and chronic diseases, and maintains high standards and continuity of care. By providing cutting-edge urologic imaging in-house, TCAU will be able to satisfy the expanding diagnostic needs of its patient population, reducing barriers to care and supporting better health outcomes for the

³⁰ Weldon Cooper Center for Public Service – Virginia Population Estimates, 2025; Virginia Population Projections, 2030.

³¹ See Section IV.A.

community. Given forecasted demographic and disease trends, TCAU's PET/CT service will be well-equipped to meet local demand for at least the next five years.

- 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 fixed PET/CT service at TCAU will complement, rather than duplicate, existing PET/CT capacity in PD 8. The primary purpose of the project is to provide specialized, integrated imaging for patients with urologic cancers and related conditions who are already under the care of TCAU or referred to it for subspecialty management. The project will not create a new general imaging provider competing for broad oncology or non-oncologic PET/CT volume.

By situating a PET/CT within TCAU's existing urology practice, the project will:

- **Improve geographic and functional access to urologic PET/CT for patients in PD 8;**
- **Reduce patient burden associated with multiple registrations, separate appointments, and fragmented billing;**
- **Facilitate faster treatment decisions through more rapid turnaround of imaging results; and**
- **Offer urologic PET/CT services in an outpatient setting with lower site-of-service costs than many hospital-based alternatives.**

Given the focus on the urologic patient population, the projected PET/CT volume is not expected to materially reduce utilization or jeopardize the financial viability of existing PET/CT providers. Rather, the project will fill a specialized niche by providing advanced imaging tightly integrated with urologic oncology disease management.

- 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 project involves the addition of a dedicated fixed PET/CT scanner for urologic imaging. The project is consistent with the SMFP standards as described below.

Article 4. Positron Emission Tomography

12VAC5-230-200. Travel Time.

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

While PET/CT services are available within 60 minutes driving time for 95% of the population within PD 8, there are no solely dedicated urologic PET/CT services available in PD 8. The proposed service would be the first of its kind in PD 8. As DCOPN has previously stated when recommending approval of a urological practice's request for a PET/CT:

While the PSMA tracer is available in the PD, the timeframe for accessibility is limited. . . . Having the PET/CT for urological needs specifically will allow for access to new radiotracers to be used as the medical field continues to progress in that area. . . . Having a dedicated PET/CT scanner for urological needs in the planning district will improve access for all urological patients in the area.³²

12VAC5-230-210. Need for New Fixed Site Service.

- A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

Not applicable.

- B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images are made concurrently.

³² DCOPN Staff Report, COPN Request No. VA-8678, March 21, 2023, p. 36.

“DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written, and should be treated as such:

Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization. . .”³³

As HSANV has also concurred, “PET service planning guidance in the State Medical Facilities Plan is dated. It is not useful in assessing proposals to develop additional services . . .”³⁴

Existing PET/CT services in PD 8 are well utilized, particularly the two that provide the majority of PSMA PET/CT – Metro Region PET Center and PET of Reston.

Table IV.E.3 – 2024 PET Utilization

Facility	Total Scanners	Scans (2024)	% of 6,000 Scan Threshold
PET and PET/CT Restricted to Cardiac Imaging			
Carient Heart & Vascular (Manassas)	1	3,478	58%
Nova Cardiovascular Care, Inc.	1	1,210	20%
Virginia Heart (Falls Church)	1	5,448	91%
Carient Heart & Vascular (Vienna) ³⁵	1	1,082	18%
Open Restricted to Cardiac Imaging			
4			
Amelia Heart & Vascular Center ³⁶	1		
Virginia Heart (Alexandria) ³⁷	1		
Virginia Heart (Leesburg) ³⁸	1		
Cardiac Care Associates ³⁹	1		
Inova Health Care Services ⁴⁰	1		

³³ Id. (page 15).

³⁴ HSANV Staff Report, COPN Request No. VA-8855, p. 9.

³⁵ Did not report volumes to VHI in 2024. Volumes were reported in HSANV Staff Report on COPN Request No. VA-8855 (February 24, 2026) p. 4.

³⁶ Expected open 9/9/24, reported project delays

³⁷ Expected to be completed by 3/31/26

³⁸ Expected to be completed by 9/30/25, though unclear if completed as of 3/31/26

³⁹ Open 6/19/22. Did not report utilization to VHI

⁴⁰ Expected to be completed by March 31, 2026

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Unopened Restricted to Cardiac Imaging	5		
Total Restricted to Cardiac Imaging	9		
Unrestricted PET and PET/CT Scanners			
Fairfax PET/CT Imaging Center	1	4,139	69%
Sentara Northern Virginia Medical Center	1 (mobile)	360	6%
Kaiser Permanente Woodbridge Imaging Center ⁴¹	1		
Metro Region PET Center ⁴²	2	6,081	51%
UVA Cancer Care Gainesville	1 (mobile)	839	14%
PET of Reston	1	2,218	37%
Virginia Hospital Center	1	1,422	24%
Open Un-Restricted	8		
Inova Reston MRI Center, LLC	1		
Virginia Hospital Center Arlington Health System ⁴³	1		
Unopened Un-Restricted	1		
Total Authorized PD 8 PET Inventory	19	26,277	27.3%

TCAU anticipates performing 818 PET/CT studies in Year 1 and 847 PET/CT studies in Year 2. To determine these projections, TCAU considered its existing PSMA PET/CT referral volume, the population growth in the area, the applicable cancer indicate rates, and the proportion of current referrals likely to transfer to TCAU. Given that other PET/CT providers are well utilized, TCAU does not anticipate that its project will have an adverse impact on those providers.

12VAC5-230-220. Expansion of Fixed Site Services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

Not applicable. TCAU is not expanding an existing site.

12VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were

⁴¹ Did not report volume on PET/CT scanner to VHI in 2024

⁴² Second PET/CT scanner expected open 1/1/24. Did not report volumes to VHI in 2024. Volumes were reported in HSNV Staff Report on COPN Request No. VA-8855 (February 24, 2026) p. 4.

⁴³ PET/CT scanner technically not restricted, but 90% of the time shall be used for cardiac-related purposes.

performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

Not applicable. This application does not involve adding or expanding mobile PET or mobile PET/CT services.

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The PET/CT services will be under the direction and supervision of the medical director, Christine Tran, MD, who is appropriately authorized and licensed to interpret urologic PET/CT (see [Attachment III.K.3](#) for her CV).

- 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.

To determine the need for adding a new PET/CT service in the proposed project's service area, TCAU utilized evidence-based clinical standards, population health data, and TCAU's historic PET/CT referral trends. See Sections III.G and IV.A for additional information.

- 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.)

TCAU does not have formal agreements or affiliations to share personnel, facilities, services or equipment.

- H. Attach copies of the following documents:

1. A map of the service area indicating:
 - a. Location of proposed project.
 - b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).

See [Attachment IV.H.1](#) (Map of Area Providers).

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.

See **Attachment IV.H.2 (Letters of Endorsement)**.

3. Letters to other area facilities advising of the scope of the proposed project.

See **Attachment IV.H.3 (Letters of Notification)**.

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.

TCAU does not use per diem rates in its reimbursement methodology for patient care or in negotiated contracts for urologic PET/CT imaging services.

TCAU participates in a broad spectrum of managed care and governmental payer relationships, including Medicare, Medicaid, Anthem, Aetna, Blue Cross/Blue Shield, and additional insurers that serve its patient base. The group anticipates no significant barriers to amending contracts or negotiating successful payment arrangements for PET/CT services, given the recognized diagnostic benefits and alignment with evolving payer coverage policies. All reimbursement agreements are structured according to service-specific fee schedules or established billing methodologies, rather than per diem rates.

This approach ensures that TCAU remains flexible and responsive to payer requirements, supporting patient access while maintaining compliance with federal, state, and private insurance standards for advanced urologic imaging reimbursement.

- 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.

Upon the approval of the COPN, TCAU will participate in VHI reporting for its urologic PET/CT.

- 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)

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Part I – Direct Construction Costs

1.	Cost of materials	<u>\$337,968.40</u>
2.	Cost of labor	<u>\$655,031.60</u>
3.	Equipment included in construction contract	<u>\$7,500</u>
4.	Builder's overhead	<u>\$92,000</u>
5.	Builder's profit	<u>\$57,500</u>
6.	Allocation for contingencies	<u>\$40,000</u>
7.	Sub-total (add lines 1 thru 6)	<u>\$1,190,000</u>

Part II – Equipment Not Included in Construction Contract
If leasehold, lease expense over entire term of lease
(List each separately)

8.	a. RS Biograph mCT-S(64)	<u>\$1,587,200</u>
	b. Hot Lab	<u>\$125,000</u>
	c. _____	\$ _____
	d. _____	\$ _____
	e. _____	\$ _____
9.	Sub-total (add lines 8a thru 8e)	<u>\$1,712,200</u>

Part III – Site Acquisition Costs

10.	Full purchase price	\$ _____
11.	For sites with standing structures	\$ _____
	a. purchase price allocable to structures	\$ _____
	b. purchase price allocable to land	\$ _____
12.	Closing costs	\$ _____
13.	If leasehold, lease expense over entire term of lease	<u>\$687,972.29</u>
14.	Additional expenses paid or accrued:	
	a. _____	\$ _____

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b. _____ \$ _____

c. _____ \$ _____

15. Sub-total (add lines 10 thru 14c) **\$687,972.29**
Part IV – Site Preparation Costs

16. Earth work \$ _____

17. Site utilities \$ _____

18. Roads and walks \$ _____

19. Lawns and planting \$ _____

20. Unusual site conditions:

a. _____ \$ _____

b. _____ \$ _____

21. Accessory structures \$ _____

22. Demolition costs \$ _____

23. Sub-total (add lines 16 thru 22) \$ _____

Part V – Off-site Costs (List each separately)

24. _____ \$ _____

25. _____ \$ _____

26. _____ \$ _____

27. _____ \$ _____

28. Sub-total (add lines 24 thru 27) \$ _____

Part VI – Architectural and Engineering Fees

29. Architect's design fee **\$62,500**

30. Architect's supervision fee **\$11,000**

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31.	Engineering fees		<u>\$30,000</u>
32.	Consultant's fees		<u>\$6,500</u>
33.	Sub-total (add lines 29 thru 32)	VI	<u>\$110,000</u>

Part VII – Other Consultant Fees (List each separately)

34.	a. Legal Fees	_____	<u>\$50,000</u>
	b.	_____	\$ _____
	c.	_____	\$ _____
35.	Sub-total (add lines 34a thru 34c)		<u>\$50,000</u>

Part VIII – Taxes During Construction

36.	Property taxes during construction		\$ _____
37.	List other taxes:		
	a.	_____	\$ _____
	b.	_____	\$ _____
38.	Sub-total (add lines 36 thru 37b)		\$ _____

Part IX-A – HUD Section 232 Financing

39.	Estimated construction time(in months)	_____	
40.	Dollar amount of construction loan		\$ _____
41.	Construction loan interest rate	_____	%
42.	Estimated construction loan interest costs		\$ _____
43.	Term of financing (in years)	_____	
44.	Interest rate on permanent loan	_____	%
45.	FHA mortgage insurance premium		\$ _____
46.	FHA mortgage fees		\$ _____

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

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) _____
 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) _____
56. Dollar amount of construction loan \$ _____
57. Construction loan interest rate _____%
58. Estimated construction loan interest cost \$ _____
59. Nature of bond placement (direct, underwriter, if other, specify) _____
60. Will bonds be issued prior to the beginning of construction? _____ Yes _____ No
61. If the answer to question 60 is yes, how long before (in months)? _____
62. Dollar amount of bonds expected to be sold prior to the beginning of construction \$ _____

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63. Will principal and interest be paid during construction or only interest? _____
64. Bond interest expense prior to the beginning of construction(in dollars) \$ _____
65. How many months after construction begins will last bond be sold?_ _____
66. Bond interest expense during construction \$ _____
67. What percent of total construction will be financed from bond issue? \$ _____
68. Expected bond interest rate _____%
69. Anticipated term of bond issued (in years) _____
70. Anticipated bond discount (in dollars) _____
71. Legal costs \$ _____
72. Printing costs \$ _____
73. Placement fee \$ _____
74. Feasibility study \$ _____
75. Insurance \$ _____
76. Title and recording fees \$ _____
77. Other fees (list each separately)
- a. _____ \$ _____
- b. _____ \$ _____
- c. _____ \$ _____
78. Sinking fund reserve account (Debt Service Reserve) \$ _____
79. Total bond interest expenses (in dollars) \$ _____
80. Sub-total Part IX_B (add lines 58, 64, 66, 71, 72, 73, 74, 75, 76, 77a, b, c and 78) \$ _____

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Part IX_C – Conventional Mortgage Loan Financing

- | | | |
|-----|--|----------|
| 81. | Estimated construction time (in months) | _____ |
| 82. | Dollar amount of construction loan | \$ _____ |
| 83. | Construction loan interest rate | _____ % |
| 84. | Estimated construction loan interest cost
(in dollars) | \$ _____ |
| 85. | Term of long term financing (in years) | _____ |
| 86. | Interest rate on long term loan | _____ % |
| 87. | Anticipated mortgage discount (in dollars) | \$ _____ |
| 88. | Feasibility study | \$ _____ |
| 89. | Finder's fee | \$ _____ |
| 90. | Legal fees | \$ _____ |
| 91. | Insurance | \$ _____ |
| 92. | Other fees (list each separately) | |
| | _____ | \$ _____ |
| 93. | _____ | \$ _____ |
| 94. | Total permanent mortgage loan
interest expense (in dollars) | \$ _____ |
| 95. | Sub-total Part IX_C (add lines 84 & 88 thru 93) | \$ _____ |

Financial Data Summary Sheet

- | | | | |
|-----|--------------------|---|----------------------------|
| 96. | Sub-total Part I | Direct Construction Cost (line 7) | <u>\$1,190,000</u> |
| 97. | Sub-total Part II | Equipment not included in
construction contract (line 9) | <u>\$1,712,200</u> |
| 98. | Sub-total Part III | Site Acquisition Costs (line 15) | <u>\$687,972.29</u> |

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99.	Sub-total Part IV	Site Preparation Cost (line 23)	\$ _____
100.	Sub-total Part V	Off-Site Costs (line 28)	\$ _____
101.	Sub-total Part VI	Architectural and Engineering fees (line 33)	<u>\$110,000</u>
102.	Sub-total Part VII	Other Consultant fees (line 35)	<u>\$50,000</u>
103.	Sub-total Part VIII	Taxes During Construction (line 38)	\$ _____
104.	Sub-total Part IX-A	HUD-232 Financing (line 53)	\$ _____
105.	Sub-total Part IX-B	Industrial Development Authority Revenue & General Revenue Bond Financing (line 80)	\$ _____
106.	Sub-total Part IX-C	Conventional Loan Financing (line 95)	\$ _____
107.	TOTAL CAPITAL COST (lines 96 thru 106)		<u>\$3,750,172.29</u>
108.	Percent of total capital costs to be financed _____%		
109.	Dollar amount of long term mortgage (line 107 x 108)		\$ _____
110.	Total Interest Cost on Long Term Financing		\$ _____
	a.	HUD-232 Financing (line 53)	\$ _____
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 79)	\$ _____
	c.	Conventional Loan Financing (line 94)	\$ _____
111.	Anticipated Bond discount		
	a.	HUD-232 Financing (line 53)	\$ _____
	b.	Industrial Development Authority Revenue & General Revenue Bond Financing (line 70)	\$ _____
	c.	Conventional Loan Financing (line 87)	\$ _____
112.	TOTAL CAPITAL AND FINANCING COST		

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	(ADD LINES 107, 110a, b or c AND 111a, b or c)	<u>\$3,750,172.29</u>
D.	1. Estimated costs for new construction (excluding site acquisition costs)	\$ _____
	2. Estimated costs of modernization and renovation (excluding site acquisition costs)	\$ _____
E.	Anticipated Sources of Funds for Proposed Project	<u>Amount</u>
	1. Public Campaign	\$ _____
	2. Bond Issue (Specify Type) _____	\$ _____
	3. Commercial Loans _____	\$ _____
	4. Government Loans (Specify Type) _____	\$ _____
	5. Grants (Specify Type) _____	\$ _____
	6. Bequests	\$ _____
	7. Private Foundations	\$ _____
	8. Endowment Income	\$ _____
	9. Accumulated Reserves	\$ _____
	10. Other (Identify) _____	\$ _____
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.	
	TCAU will not be obtaining any third-party financing to fund the proposed project. The construction project will be funded through accumulated reserves. The space and equipment leases will be funded through TCAU's cash flow.	
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 will not affect the cost of providing care at TCAU. The project will be funded through accumulated reserves and revenue generated from the provision of urologic PET/CT services. This revenue is based on agreed rates with third-party payers and is not related to TCAU's cost of providing care.

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

1. The existing and/or proposed room rate schedule, by type of accommodation.

Not applicable.

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.

While TCAU is not a subsidiary of Solaris Health Holdings, LLC, it is included in the consolidated financials of Solaris. See [Attachment V.H.2](#) (2023 and 2024 Audited Financial Statements).

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.

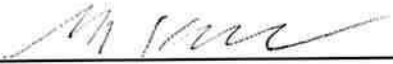
See [Attachment V.H.3](#) (Pro Forma).

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.

 _____ Signature of Authorizing Officer	<u>140 W. Germantown Pike</u> Address – Line 1
<u>Steven Krefetz</u> Type/Print Name of Authorizing Officer	<u>Suite 200</u> Address – Line 2
<u>Chief Executive Officer</u> Title of Authorizing Officer	<u>Plymouth Meeting, PA 19462</u> City/State/Zip
<u>207-307-4492</u> Telephone	<u>5/28/26</u> 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.**

Pro Forma

	Year 1		Year 2	
Revenue				
Projected Volume		818		847
Charge per Case	\$	6,860	\$	6,860
Gross Patient Revenue	\$	5,611,505	\$	5,807,907
Bad Debt	\$	215,883	\$	223,439
Charity Care	\$	123,453	\$	127,774
Net Revenue	\$	5,272,169	\$	5,456,695
Expenses				
Salaries, Benefits and Taxes	\$	260,000	\$	267,800
Professional Fees	\$	168,345	\$	174,237
Utilities	\$	-	\$	-
Insurance	\$	-	\$	-
Supplies	\$	3,105,782	\$	3,214,485
Purchased Services	\$	605,900	\$	605,900
Depreciation & Amortization	\$	76,667	\$	76,667
Interest	\$	-	\$	-
Lease Expense	\$	-	\$	52,594
Other Expense	\$	50,000	\$	-
Total Expenses	\$	4,266,694	\$	4,391,683
Net Income	\$	1,005,474	\$	1,065,012