Health Systems Agency of Northern Virginia

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#### September 4, 2024

### TO: Board of Directors, HSANV

**Interested Parties**

**FROM: Dean Montgomery**

### SUBJECT: Certificate of Public Need Applications

**UVA Health Outpatient Imaging Gainesville, Establish CT Scanning Service (COPN Request VA-8769)**

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**I. Background and Summaries of the Proposal**

UVA Health Outpatient Imaging Gainesville (UVA OIG), a newly formed subsidiary of University of Virginia Health (UVA Health), proposes to establish a CT scanning service in Gainesville, Virginia. The service would be one of the diagnostic imaging modalities in a freestanding outpatient imaging center UVA Community Health Services (UVACH), the umbrella operating arm of UVA Health in northern Virginia, is developing in Gainesville. In addition to the array of imaging capabilities found in most imaging centers, the Gainesville center is to include two services subject to certificate of public need (COPN) regulation, CT and MRI scanning.[[1]](#footnote-1)

UVACH now has three CT scanning services in the region (PD 8). These are UVA Prince William Medical Center (PWMC), UVA Haymarket Medical Center (HAMC), and UVA Health Outpatient Imaging Centreville (UVA OIC). UVA Prince William Medical Center (PWMC) has two CT scanners. UVA Haymarket Medical Center (HAMC) has one scanner, and UVA Health Outpatient Imaging Centreville (UVA OIC) has one. PWMC and HAMC report high use and increasing demand in recent years. Reported service volumes at UVA OIC are unusually low. Recent service volumes are shown in Table 1.

Projected capital costs total $ 1,709,102, about 38% of which ($640,347) would be for the scanner and associated equipment. Most of the remainder ($1,068,755) would be for space acquisition, furnishings, and construction. Capital costs would be paid from internal UVA Health funds.

UVA OIG justifies the proposal on the grounds that:

* There is a regional need for additional CT capacity.
* Western Prince William County is an appropriate location to add capacity in northern Virginia.
* Given current and projected service volumes regionwide, establishing a CT service in Gainesville should not affect demand or service volumes at imaging services other than those owned and operated by UVACH, e.g., PWMC and HAMC.
* Capital costs are reasonable for the service and equipment proposed. They are within the range seen for similar projects locally and statewide.
* The project is consistent with public need provisions of the Virginia State Medical Facility Plan (SMFP), which indicates there is a public need for additional CT scanners.

If authorized on schedule, the new CT service should open in in the spring of 2026.

#### II. Discussion

1. **Northern Virginia CT Scanning Capacity, Use, Trends**

There are 75 CT scanners in Northern Virginia authorized for use in diagnostic imaging.[[2]](#footnote-2) They are distributed widely in hospitals, in satellite hospital emergency departments, and in nonhospital freestanding imaging centers. Distribution by setting is as follows:

* Thirty-six are in hospitals or in buildings on a hospital campus,
* Ten are in freestanding hospital emergency departments,
* Five are hospital services in off-campus sites with other imaging services, and
* Twenty-four are in freestanding settings not linked to a hospital.

Given the number, distribution and service volumes of local CT scanning services, most approvals of additional CT scanning capacity over the last two decades have been at hospital-based services with high service volumes and increasing demand.



CT capacity has increased by more than two-thirds during the last decade. In addition to the increase in the number of scanners, replacement of older, slower, and less capable equipment with newer, faster, and more capable scanners that accommodate larger numbers of patients has significantly increased the functional capacity at most CT scanning services.[[3]](#footnote-3)

Region wide, average CT service caseloads, an estimated 10,784 scans per scanner in 2022, are above the *minimum* Virginia State Medical Facilities Plan (SMFP) target levels (7,400 scans per scanner per year), but there is wide variation among CT programs and substantial unused capacity, principally in nonhospital freestanding services. The average service volume in hospital and hospital-affiliated settings was 14,251 procedures per scanner in 2022, about 93% above the nominal planning standard. Average volumes in freestanding imaging centers are relatively low, 6,699 procedures per scanner in 2022, about 9% below the recommended minimum service volume caseload.

Thus, the average 2022 service volume of hospital CT services was about 2.1 times the average volume of nonhospital freestanding services, and nearly twice the Virginia SMFP minimum volume standard. Most hospital-based services routinely operate at annual service volumes much higher than the SMFP standard.

As these data suggest, the Virginia SMFP CT service volume standard of 7,400 scans per scanner per year is a recommended *minimum* operating threshold, not a measure of capacity or an operating level that in and of itself justifies adding capacity. Most of the unused CT scanning capacity in the region is in chronic low volume freestanding services. There is little unused capacity in hospitals or hospital-affiliated services.

CT scanning service volumes are likely to continue to increase locally and statewide with population growth and greater reliance on diagnostic imaging in medical practice.

***Consistency with Planning Guidelines and Principles***

The Virginia State Medical Facilities Plan (SMFP) provides guidance in assessing COPN proposals seeking authorization to establish new CT services or to expand existing services: The applicable provisions, sections 12VAC-230-100 and 12VAC5-230-110, read:

**“12VAC5-230-100. Need for new fixed site or mobile service.**

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing 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 CT scanners in such health planning district.

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

**12VAC5-230-110. Expansion of fixed site service.**

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.” **Virginia State Medical Facilities Plan, P. 9.**

The UVA OIG proposal calls for the establishment of a new CT scanning service, section 12VAC-230-100.A applies.

With the reported sharp increase in CT scanning caseloads in 2021 and 2022, application of the SMFP public need determination guidance, as interpreted and routinely applied, suggests a regional public need for between 71 and 83 CT scanners.[[4]](#footnote-4) Including the CT scanners authorized between 2022 and 2024, the authorized regional complement is now 75 diagnostic scanners. Application of the public need determination formula specified in the Virginia SMFP suggests that up to eight additional CT scanners may be authorized.

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1. **Cost Considerations**

The projected capital cost of the CT component of the Gainesville diagnostic imaging center is $1,709,102. The scanner and associated medical equipment and technology ($640,347) account for a little more than one-third of the total. The remainder ($1,068,755) is largely space lease expense, construction, and furnishings. Capital expenses would be paid from internal UVA Health funds. There would be no direct, project specific financing expense.

There is nothing inherently problematic about the capital cost of the project. It is within the capital expenditure range seen for similar projects locally and statewide. The scanner would be in an independent diagnostic testing facility (IDTF) and would be paid accordingly by Medicare, Medicaid and other insurers.

The project is economically viable. The *pro forma* budget for the initial two years of operations envision a modest caseload and essentially breakeven operations initially. It assumes an average caseload of 2,268 patient scans per year during the first two operational years and average payment of $271 per case. These assumptions yield a projected modest profit of $2.36 per case during the first two years. Both revenue and profit percase estimates are notably lower than most CT service development projects.

As with most diagnostic imaging centers, operating returns and profit margins can be expected to increase quickly and significantly over the useful life of the scanner, as depreciation and amortization costs decrease, and fixed costs are allocated over larger service volumes. The marginal cost of providing a scan will decrease as demand and service volumes increase.

UVA OIG commits to providing a reasonable amount of charity care (2.63% of revenue) and to serving the medically indigent equitably. UVA Health and UVACH have local histories of doing so.

##### Access Considerations

With 39 CT service delivery sites and 75 widely distributed scanners, Northern Virginians have ready geographic access to CT scanning. All residents in Northern Virginia have access within less than 30

minutes driving time. Neither additional services nor additional scanning capacity are necessary to ensure reasonable physical access.

It is evident however that the UVA OIG CT service in Gainesville would enhance access to CT scanning within the UVACH diagnostic imaging services network and within western Prince William County generally. UVA Community Health has three medical care facilities in northern Virgina with CT scanning. These services are authorized to operate four CT scanners: UVA Health Prince William Medical Center (two scanners); UVA Haymarket Medical Center (one scanner); UVA Health Centreville Imaging (one scanner). Prince William Health System and Haymarket Health Center have high and increasing service volumes. The UVA OIC CT service has unusually low use, far below the regional average service volume.

The proposal is to establish a fourth UVACH service in Gainesville with one CT scanner. The Gainesville site is near the center of the population served by UVACH facilities in western Prince William County and southwestern Fairfax County (Map 1). The Gainesville location would permit many of those now using UVACH services to obtain outpatient CT scans at a closer, more convenient, and less costly location. UVACH patient origin and destination data suggest that many of those now using PMWC and HAMC would shift to the Gainesville CT service, reducing demand at the two UVACH hospitals.



Establishing a UVACH CT service in Gainesville is not likely to have notable health system effects outside the UVA Health Community Service northern Virginia network. No change in the overall UVACH service area is expected or likely. The project would permit more flexible, and arguably more convenient, scheduling of patients, particularly as service volumes increase. There is no indication of likely negative effects on nearby competing services. CT services in neighboring areas of Fairfax County and Loudoun County have substantial service volumes and all are more than ten miles from the proposed Gainesville site. Many have recently added capacity.

UVA Health and UVACH provides reasonable amounts of charity care and serve the medically indigent equitably. Economic access to care is not likely to change appreciably.

**D. Health System Considerations**

The Virginia SMFP public need determination formulation suggests that there is a regional need for additional CT scanning capacity, more than the additional CT scanner proposed by UVA OIG. The project is consistent with the public need determination provisions of the plan (Section 12VAC5-230-100) as that guidance has been interpreted and applied in recent years.

Redirection of outpatient CT service demand from PWMC and HAMC is intended by UVACH and, arguably, would benefit the region.

Though it is not necessary to respond to a local health care system deficiency, there is no indication of likely negative health system effects. Any reduction in demand at nearby imaging services would be at UVACH CT services.

. **III. Conclusions and Alternatives for Agency Action**

**A. Summary Conclusions and Findings**

The UVA OIG application, and the related data and information gathered, supports the following findings and conclusions.

1. Though northern Virginia CT scanning use rates are comparatively low, recent increases in demand, and higher recent service use rates, suggest additional CT capacity is needed.
2. The Virginia SMFP public need determination formulae suggests that there is a regional need for up to eight additional CT scanners.
3. UVA Health and UVACH provides reasonable amounts of charity care and serve the medically indigent equitably. Economic access to care is not likely to change appreciably.
4. There is no indication of likely negative health system effects. Any reduction in demand at nearby imaging services would be at UVACH CT services and would be beneficial.
5. The cost of the proposal is within the capital cost range commonly seen for similar projects locally and elsewhere in Virginia.

**B. Alternatives for Agency Action**

* 1. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need authorizing the project be granted. Support for the proposal could be based on concluding that:

* + There is a regional need for additional CT scanners within the planning horizon (PD 8), .
  + The projected capital outlay is within the range commonly seen for similar projects.
  + A UVA OIG CT service would be likely to improve access to outpatient CT scanning within the UVACH diagnostic imaging services network and within western Prince William County generally.
  + There are no known negative health systems effects from the project.

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

An unfavorable recommendation could be based on concluding that:

* Average regional use of freestanding CT services is low. Additional freestanding capacity is not essential to maintain or improve access to care.
* The current freestanding UVACH CT service has low use. An additional UVACH outpatient CT service should not be authorized until the UVA OIC service volume reaches the nominal planning standards of 7,400 scans per year.

**IV. Checklist of Mandatory Review Criteria**

* + 1. **Maintain or Improve Access to Care**

Northern Virginia residents have ready access to diagnostic imaging services, including CT scanning. Virtually everyone is within 30 minutes travel time of a CT service. With three dozen service delivery sites most residents have access to multiple CT services within a 15 to 20 minutes commute.

1. **Meet Needs of Residents**

There is no indication that UVACH, and UVA Health generally, do not try to meet the needs of the patients and communities they serve. A freestanding UVACH CT service in Gainesville should permit UVA Health to continue to respond to the clinical needs of the UVACH service area population.

1. **Consistency with Virginia State Medical Facilities Plan (SMFP)**

The project is consistent with the Virginia State Medical Facilities Plan public need criteria and standards and the planning principles in which the plan is grounded.

1. **Beneficial Institutional Competition while Improving Access to Essential Care**

Though the service proposed is not essential, patient origin data and local medical trade patterns suggest that a UVACH CT service in Gainesville would contribute to maintaining and improving access to care with the UVACH diagnostic imaging services network, and in western Prince Wiliam County generally.

The new service would operate as an independent diagnostic testing facility, but there is no indication or expectation that the project would generate measurable price or quality competition.

1. **Relationship to Existing Health Care System**

UVACH and UVA Health are successful operators of multiple CT scanning services locally and elsewhere. The proposed Gainesville site is near the center of the geographic area and populations served by UVACH facilities. No significant negative health system effects are likely. A UVACH CT service in Gainesville is not likely to affect noticeably demand or operations at competing services.

UVACH now serves most of those residing in the Gainesville area. Success of the project depends on attracting (redirecting) western Prince William County patients who otherwise would be likely to use neighboring UVACH services.

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1. **Economic, Financial Feasibility**

The capital outlay proposed is reasonable for the project described, within the range commonly seen for similar projects locally and statewide. It is financially feasible and is likely to be increasingly profitable over the useful of the scanner acquired.

**7. Financial, Technological Innovations**

The project does not entail innovative technologies, practices or economic aspects that warrant special consideration.

**8. Research, Training Contributions and Innovations**

The project does not have significant research or training element that warrants special consideration.

1. UVA Health Outpatient Imaging Gainesville filed two certificate of public (COPN) applications to establish new services in the current diagnostic imaging review cycle: COPN Request VA-8768, for MRI Scanning, and COPN Request VA-8769, for CT scanning. The MRI scanning application is examined in a separate report.

   The corporate structure of Prince Wiliam Health System (PWHS), formerly a subsidiary of Novant Health, changed recently. PWHS is now a subsidiary of UVA Community Health (UVACH), which is a wholly owned subsidiary of University of Virgina (UVA) Health. The facilities within PWHS, UVA Prince William Medical Center (PWMC), UVA Haymarket Medical Center (HAMC), and UVA Health Outpatient Imaging Centreville (UVA OIC), are now owned and operated by UVACH. The applicant, UVA Outpatient Imaging Gainesville (UVA OIG), will be (is) a subsidiary of UVACH. [↑](#footnote-ref-1)
2. This count includes eleven scanners authorized recently that were not in service in 2022, the most recent year for which vetted service volumes have been reported, and not included in the Virginia Health Information (VHI) inventory data presented in Table 1. This count excludes CT scanners dedicated to radiation therapy treatment planning and operating room use. It includes one known “extra-legal” scanner, Fair Oaks Imaging Center (FOIC), which does not have, and has not sought, COPN authorization. FOIC, established by Reston Radiology Associates, the professional radiology group now known as Reston Radiology Consultants (RRC), provides professional radiology services at Reston Hospital Center and several other affiliated services. FOIC reported 2,864 scans in 2022, higher than several authorized services. Though never authorized, the service is in the Virginia Department of Health inventory and reports its service volumes as part of the annual licensing survey. [↑](#footnote-ref-2)
3. Onsite replacement of existing diagnostic imaging equipment is not subject to COPN review. Replacement equipment is registered with the Virginia Department of Health. Services usually replace dated scanners with higher speed equipment that serves a wider array and larger number of patients. High speed CT services are commonplace in Northern Virginia. They are added to the regional inventory as older equipment is retired. Replacement scanners usually are state-of-the-art equipment that minimize exposure to ionizing radiation. Most CT scans in Northern Virginia are from such services.

   [↑](#footnote-ref-3)
4. Recent reported service volume increases are unusually large. The regional compound annual growth rate (CAGR) between 2018 and 2022 was 9.9%. The reported 2022 service volume (657,815 scans) was about 36% higher than the 2019 service volume (482,783 scans), the year before the COVID-19 induced service disruptions. These are unusually large increases, not sustainable over the long run. They may prove anomalous.

   The lower need estimate (71 scanners) is based on the reported service volumes of the last five years (2018-2022). The high estimate (83 scanners) is based on the average volume over the last two years (2021-2022). [↑](#footnote-ref-4)