

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

January 19, 2023

COPN Request No. VA-8672

Inova Reston MRI Center, LLC

Herndon, Virginia

Expansion of MRI Services by Adding One Additional MRI

Applicant

Inova Reston MRI Center, LLC (IRMC) is a Virginia limited liability company jointly owned by Inova Health Care Services and Fairfax Radiological Consultants, PLLC. The applicant has no subsidiaries. The applicant proposes to expand MRI services by adding one MRI at IRMC at the new Springpark Place location to be in Herndon, Virginia, Inova Reston-Herndon MRI Center (IR-HMC). Herndon is in Planning District (PD) 8, located within Health Planning Region (HPR) II.

Background

IRMC was approved and authorized to relocate and replace an existing fixed site MRI unit from 100 Elden Street, Suite 16, Herndon, Virginia, Inova MRI Center-Reston (IMC-R), to 450 Springpark Place, Suite 100, Herndon, Virginia in COPN No. VA-04800, issued August 22, 2022. IRMC's Springpark Place location, IR-HMC, is scheduled to open in August 2023, whereby the Elden Street location will cease operation. The Elden Street location is currently being leased; the building is aging beyond reasonable repair to retain ability to accommodate IRMC needs. During planning and construction, it became evident to the applicant that the patient volume at a single MRI would be significantly over capacity. IRMC is requesting to add one MRI scanner to have a complement of two MRI scanners in total at the new Springpark Place location, R-HMC.

IRMC is a multi-modality imaging site which operates the following diagnostic systems (some of which are not COPN regulated): relocated MRI services (COPN No. VA-04800), a relocated CT service (COPN No. VA-04798), mammography, DEXA, ultrasound, and X-ray. An MRI produces high-resolution images of the inside of the body that can help diagnose a variety of conditions and injuries, including but not limited to brain aneurysms, stroke, tumors, joint abnormalities caused by trauma or repetitive injuries, disk abnormalities in the spine, or bone infections. MRI is frequently used in addition to mammography to detect breast cancer, particularly in women who have dense breast tissue or who may be at high risk for breast cancer. Currently, with only one MRI, IRMC is not able to schedule MRI following mammography on the same patient visit; however, with an additional MRI, patients would be able to have an MRI conducted in the same visit, increasing timeliness of diagnosis and ultimately, treatment.

DCOPN emailed applicant for clarification regarding the MRI and mammography link discussed in the application, and DCOPN received the following information, reportedly gathered from Dr. Elise Berman, MD, Head of Breast Imaging at Inova/FRC, via email:

Approximately 20% of patients who have an ultrasound or stereotactic (mammogram) guided breast biopsy will have a result of breast cancer or a “high risk lesion” that requires surgery or surgical consultation. Breast MRI is often performed prior to breast cancer surgery and prior to high-risk breast lesion surgery, depending on the patient’s presentation, and is almost always performed if the patient is to have neoadjuvant chemotherapy treatment (chemotherapy prior to surgery) so that response to treatment can be monitored.

Same-day MRI is generally not performed immediately after a mammogram unless it has previously been scheduled, as these studies require insurance pre-authorization which can take up to several days. Rather, the MRI unit is required in the breast center in order to provide continuous breast care immediately after the breast MRI and/or MRI biopsy.

The following are examples of the need for mammogram or ultrasound that would be performed immediately after the breast MRI:

- *Mammogram performed on every patient 30 years and older immediately after an MRI biopsy.*
- *Breast ultrasound and ultrasound guided marker placement performed immediately after an MRI biopsy if the MRI biopsy marker was inadvertently extruded after the MRI biopsy.*
- *“Second look” ultrasound performed on patients who have a recommendation for biopsy after an abnormal breast MRI and have a discrete mass on MRI to determine if the MRI abnormality is amenable to ultrasound biopsy.*

Some additional statistics:

- *Approximately 30% of patients who have a screening/diagnostic breast MRI will have a recommendation for a biopsy.*
- *Of screening mammogram patients (those without any breast symptoms), 1-2% will eventually have a recommendation for biopsy.*
- *Of diagnostic mammogram patients (those who have a breast symptom or breast problem), approximately 20-30% will have a recommendation for biopsy.*
- *Of those women who have a breast biopsy, approximately 80% will be benign (not cancer) and the remainder will be cancer or high-risk lesions that require surgical consultation.*

Division of Certificate of Public Need (DCOPN) records show that there are currently 57 COPN authorized fixed-site magnetic resonance imaging (MRI) scanners in PD 8 (Table 1).

Table 1. HPR II* COPN Authorized Fixed MRI Units

Facility	Total Authorized Scanners
Fairfax MRI and Imaging Center at Tysons	1
Fairfax MRI Center at Reston	0
Inova Alexandria Hospital	2
Inova Fair Oaks Hospital	2
Inova Fairfax Medical Campus	4
Inova Center for Personalized Health	5
Inova Imaging Center - Ballston	1
Inova Imaging Center - Mark Center	1
Inova Loudoun Diagnostic Imaging Center -- Leesburg	1
Inova Lorton Healthplex	1
Inova Loudoun Hospital	1
Inova Mount Vernon Hospital	1
Inova Reston-Herndon MRI Center	1
Inova Reston MRI Center	1
Inova Springfield HealthPlex	1
Insight Imaging - Arlington / Medical Imaging Center of Arlington	2
Insight Imaging - Fairfax / Medical Imaging Center of Fairfax	1
Insight Imaging Woodbridge / Medical Imaging Center of Woodbridge	2
Kaiser Permanente - Reston Medical Center	1
Kaiser Permanente - Tysons Corner Imaging Center	2
Kaiser Permanente - Woodbridge Imaging Center	2
Lakeside at Loudoun Tech Center	1
MRI of Reston	4
Novant Imaging Centerville dba Vienna Diagnostic Imaging	2
UVA Prince William Medical Center d/b/a UVA Health Haymarket Medical Center	1
UVA Prince William Medical Center d/b/a UVA Health Prince William Medical Center	2
Radiology Imaging Associates at Lansdowne	2
Radiology Imaging Associates at Sterling	1
Reston Hospital Center	1
Sentara Advanced Imaging Center - Lake Ridge	1
Sentara Northern Virginia Medical Center	1
Stone Springs Hospital Center	1
Tysons Corner Diagnostic Imaging	2
Virginia Hospital Center	4
Washington Radiology Associates, PC	1
HPR II Total	57

Source: DCOPN records
*HPR II only includes PD8.

Table 2. PD 8 COPN Authorized Fixed MRI Units and Utilization: 2021

Facility	Number of Units	Total Procedures (OP+IP)	Utilization Rate (%)
Fairfax MRI and Imaging Center at Tysons	2* ¹	9,937	99.4
Fairfax MRI Center at Reston²	1	6,161	123.2
Fairfax Radiology Center of Sterling ³	1	4,040	80.8
Inova Alexandria Hospital	2	8,563	85.6
Inova Arlington MRI Center ⁴	1	3,372	67.4
Inova Fair Oaks Hospital	2	7,259	72.6
Inova Fairfax Hospital	3	15,869	105.8
Inova Fairfax MRI Center ⁵	6	33,994	113.3
Inova Imaging Center - Leesburg	1	2,209	44.2
Inova Imaging Center-Mark Center	1	3,265	65.3
Inova Lorton HealthPlex	1	2,360	47.2
Inova Loudoun Hospital	1	5,917	118.3
Inova Mount Vernon Hospital	1	5,116	102.3
Inova Springfield HealthPlex	1	3,745	74.9
Insight Imaging - Arlington / Medical Imaging Center of Arlington	2	7,451	74.5
Insight Imaging - Fairfax / Medical Imaging Center of Fairfax	1	4,236	84.7
Insight Imaging Woodbridge / Medical Imaging Center of Woodbridge	2	8,349	83.5
Kaiser Permanente - Reston Medical Center	1	5,844	116.9
Kaiser Permanente - Woodbridge Medical Center ⁶	1	5,587	111.7
Kaiser Permanente Tyson's Corner	2	13,726	137.3
Kaiser Permanente Tysons Corner Surgery Center ⁷	2	5,844	58.4
Lakeside at Loudoun Tech Center ⁸	1	---	---
MRI of Reston	4	20,128	100.6
Novant Imaging Centerville dba Vienna Diagnostic Imaging	1	5,866	117.3
Prince William Hospital ⁹	2	6,092	60.9
Radiology Imaging Associates at Lansdowne	2	7,727	77.3
Reston Hospital Center	1	3,959	79.2
Sentara Advanced Imaging Center - Lake Ridge	1	2,351	47.0
Sentara Northern Virginia Medical Center	1	3,867	77.3
Stone Springs Hospital Center	1	1,831	36.6
Tysons Corner Diagnostic Imaging	2	6,381	63.8
UVA Haymarket Medical Center	1	4,683	93.7
Virginia Hospital Center ¹⁰	3	15,746	104.9
Washington Radiology Associates ¹¹	1	---	---
Totals¹²	54*	241,475	
Average Per Scanner		4,472	89.4

Source: VHI Data (2021)

*Figure based upon 2021 operational units, DCOPN accounts for 57 authorized units in 2022.

¹ In 2022, DCOPN inventory accounts for one approved MRI unit.

² The VHI data refers to IMC-R at Fairfax MRI Center at Reston. The website for 100 Elden St. Suite 16M states the name as "The Fairfax MRI Center at Reston." For the purpose of this report- the bolded name and data refers to the 100 Elden Street MRI that is relocating to Springpark Place.

³ DCOPN records refer to this as Radiology Imaging Associates at Sterling.

⁴ Inova Arlington MRI Center is not existent in DCOPN 2022 inventory.

⁵ DCOPN 2022 inventory reflects 5 authorized MRI units under the name "Inova Center for Personalized Health".

⁶ DCOPN 2022 inventory reflects 2 authorized MRI units.

⁷ In 2022, DCOPN lists this under the new location name "Tyson's Corner Imaging Center".

⁸ Not available in VHI 2021 data.

⁹ Prince William Hospital dba UVA Prince William Medical Center

¹⁰ 2022 DCOPN inventory shows 4 authorized MRI scanners.

¹¹ 2022 DCOPN inventory shows 1 authorized MRI scanner.

¹² There are currently 57 MRI units within PD 8.

In 2021, the average utilization rate for each scanner in PD 8 was 89.4%, or 4,472 scans per MRI machine. Assuming the same 2021 data for procedures (which is not including the expected growth of the area), the average utilization rate for the current authorization of 57 units would be 84.73%, or 4,237 procedures per authorized unit. Bolded in Table 2, IMC-R is above the State Medical Facilities Plan (SMFP) threshold as well as above the average calculated utilization per scanner.

Proposed Project

IRMC proposes to add one new MRI scanner to their outpatient office at 450 Springpark Place, Suite 100, Herndon, Virginia, currently undergoing construction with the Commissioner’s approval via COPN Nos. VA-04800 and VA-04798, for a total complement of two MRI scanners. Upon the addition of one MRI scanner, the new site will include the relocated MRI services and the proposed MRI for a complement of 2 in total, a relocated CT service (COPN No. VA-04798), mammography, DEXA, ultrasound, and X-ray. The additional proposed MRI will be leased from the manufacturer with IRMC owning the equipment at the end of the 6-year lease term.

The applicant expects the construction of the outpatient clinic to be completed by August 2023 and the proposed new MRI to be operational between December 2023 and early 2024. During the intermediate time-period, to adequately facilitate patient care and community needs, the applicant requests to use the mobile MRI approved in COPN No. VA-04800 as a second MRI while awaiting the delivery of the proposed fixed MRI, in conjunction with the relocated MRI for a complement of two machines upon opening IR-HMC. Once the proposed, new, fixed MRI is operational, the applicant assures use of the mobile MRI will cease immediately.

The projected capital costs of the proposed project total \$2,618,538 (**Table 2**). The applicant will fund the construction portion of the project (\$700,000) via commercial financing from a United Bank loan at an interest rate of 5.2%. The MRI equipment will be leased from the vendor. At the end of the lease term, IRMC will own the MRI equipment. The addition of MRI capacity is not expected to impact the cost of providing care per the applicant.

Table 2. IRMC Projected Capital Costs

Direct Construction	\$663,027
Direct Construction Loan Interest Cost	\$23,987
Equipment Not Included in Construction Contract	\$1,890,085*
Site Acquisition Costs	\$383,113
Architectural and Engineering Fees	\$41,439
Total Capital Costs	\$2,618,538

Source: COPN Request No. VA-8672

*This figure includes the cost of the lease.

Construction for the proposed project is expected be concurrent with projects authorized under COPN Nos. VA-04800 and VA-04798. The project will utilize energy-saving utilities and provided evidence of operational utilities at the proposed site. The applicant anticipates an opening date of August 2023 for the initial MRI and the second MRI in temporary mobile form. The applicant expects the second fixed MRI to be operational, with the mobile MRI no longer in use, by December

2023; however, there is a possibility of the proposed MRI not being operational until 2024 depending on supply chain aspects of manufacturing and delivery.

The applicant provided assurances that all MRIs are inspected annually by a physicist and receive regularly scheduled preventative maintenance several times a year. Inova Health System employs three certified MRI Safety Officers who work with site managers and staff to develop and implement safety protocols.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part as the “Addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of...magnetic resonance imaging (MRI)...” A medical care facility includes “Any specialized center or clinic or that portion of a physician's office developed for the provision of ... magnetic resonance imaging (MRI)...”

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be considered when applicable.

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served, and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, the Springpark location in Herndon where the Reston-Herndon MRI Center will be relocated to is approximately 0.6 miles northwest of Fairfax County Parkway, with the closest cross street at Spring Street, and is approximately the same distance from the Dulles Toll Road. Fairfax County Parkway and the Dulles Toll Road are both major thoroughfares in the area. The site is easily accessible from both directions of Spring Street (Route 675). Additionally, the location is approximately one mile from the future Herndon Silver Line Metro station. Effective summer 2022, a new bus route on the Herndon Connector was initiated, which connects downtown Herndon to the Herndon Metro station and serves Spring Street with stops within easy walking distance of the building. The office park also immediately abuts the W&O Regional Trail.

According to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2020, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 3.4% of all reported total gross patient revenues (**Table 3**). Pursuant to § 32.1-102.4 of the Code of Virginia, should the Commissioner approve the proposed project, IRMC should be subject to a charity care condition no less than the 3.4% HPR II average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 3. HPR II Charity Care Contributions: 2020

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

Source: VHI (2020)

Table 4 shows projected population growth in PD 8 through 2030. Overall, the planning district was projected to add an estimated 356,377 people in the 10-year period ending in 2020. For the 10-year period ending in 2030, the planning district is projected to add an estimated 350,128 people. The population of PD 8 was expected to increase approximately 16% for the 10-year period ending in 2020 and approximately 14% for the 10-year period ending in 2030, rates nearly double that of the statewide average.

Regarding the 65 and older age cohort, Weldon-Cooper projects a much more rapid increase (**Table 4**). Specifically, Weldon-Cooper projects an increase of approximately 56% for the period ending in 2020 and approximately 38% for the period ending in 2030. This is significant, as this age group uses medical care resources, including diagnostic services, at a rate much higher than the rest of the population.

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

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

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

The 65+ cohort is at greater risk for breast cancer, which as mentioned above, utilizes MRI in the diagnosis and confirmation of the disease. Currently, patients must wait approximately two weeks to be scheduled for an MRI for any condition. With a second MRI scanner, patients in need of an MRI for breast cancer diagnostic purposes will be able to have same day scanning if needed following a mammography. Not only does this reduce the anxiety for patients awaiting confirmation status of the diagnosis, but this process would allow for timelier start of treatment, both of which increase quality of care. Consider breast cancer, the most diagnosed form of cancer globally¹³; “The Covid-19 pandemic [healthcare constraints, staffing, and supply availability] affects mortality and morbidity, with disruptions expected to continue for some time, with access to timely cancer-related services a concern. For breast cancer, early detection and treatment is key to improved survival and longer-term quality of life.”¹⁴

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

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

DCOPN received four letters of support for the proposed project from the local medical community. Collectively, these letters articulate several benefits of the project, including:

¹³ Wilkinson L, Gathani T. Understanding breast cancer as a global health concern. Br J Radiol. 2022 Feb 1;95(1130):20211033. doi: 10.1259/bjr.20211033. Epub 2021 Dec 14. PMID: 34905391; PMCID: PMC8822551.

¹⁴ Breast Screening Working Group (WG2) of the Covid-19 and Cancer Global Modelling Consortium; Figueroa JD, Gray E, Pashayan N, Deandrea S, Karch A, Vale DB, Elder K, Procopio P, van Ravesteyn NT, Mutabi M, Canfell K, Nickson C. The impact of the Covid-19 pandemic on breast cancer early detection and screening. Prev Med. 2021 Oct;151:106585. doi: 10.1016/j.ypmed.2021.106585. Epub 2021 Jun 30. PMID: 34217412; PMCID: PMC8241687.

- It is imperative to shorten the time from diagnosis to treatment in breast cancer patients; the addition of one MRI machine at IRMC will significantly decrease the time for treatment, such as surgery or neoadjuvant chemotherapy, to begin.
- Patients with dense breast tissue, have a higher lifetime risk of breast cancer, or who are newly diagnosed are often referred to IRMC due to their fellowship-trained breast imaging physicians specialized in interpreting the studies via using technologically advanced MRI equipment that specifically meets the needs of this population.
- The expansion of MRI capacity is urgently needed to meet the needs of patients who seek to utilize services at one of the busiest MRI sites within FRC. The additional capacity will help alleviate the extended wait times and other difficulties associated with the increasing referrals for MRI as a preferred imaging modality.
- The increased capacity will allow neurology patients to be referred and have access to timely care and quality imaging via the proposed, updated MRI scanner.

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

Public Hearing

The proposed project is not competing with another project in this batch cycle and no request to conduct a public hearing for the proposed project was received by the HSANV or the DCOPN, so no public hearing was required for the proposed project.

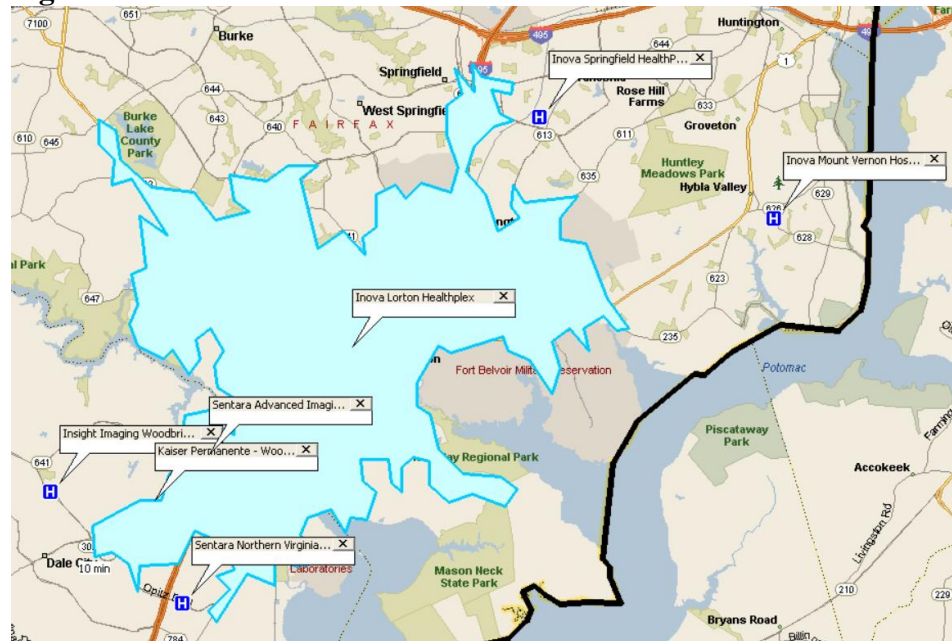
(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

Neither DCOPN nor the applicant identified a reasonable alternative to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner. While there is not a regional need for an additional MRI scanner, facilitating public choice in healthcare providers and allowing IRMC to operate at a capacity comparable to other MRI operators in the region, an additional MRI is necessary when considering the projected volumes. IRMC's new location, IR-HMC, is not yet open and operational; however, it is reasonable to apply IRMC's data from the IMC-R location as the old and new locations are only one mile apart. The current MRI at Elden Street is having to be staffed from Monday-Friday 6am to 11pm, and Saturday and Sunday from 7am to 7pm. With the extended hours of operation, their current patient demand is yielding a waiting period of approximately 14 days for a procedure from the first date of communication.

Furthermore, the applicant does not report aiming to increase their capacity to draw from other providers but aims to reduce wait times for current and normal patient growth projections. IRMC also aims to allow for same-day follow-up MRI scanning for high-risk patients (such as those with dense breast tissue) and to alleviate anxiety resulting from a two-week wait period. As such, the proposed project is highly unlikely to affect the utilization and efficiency of existing providers. Additionally, there are no other MRI scanners to reallocate to this facility within the Inova system. As seen in **Figure 1** below, Inova Lorton Healthplex is relatively close to Inova Springfield and Inova Mount Vernon, however, within a 10-minute drive time, there are other

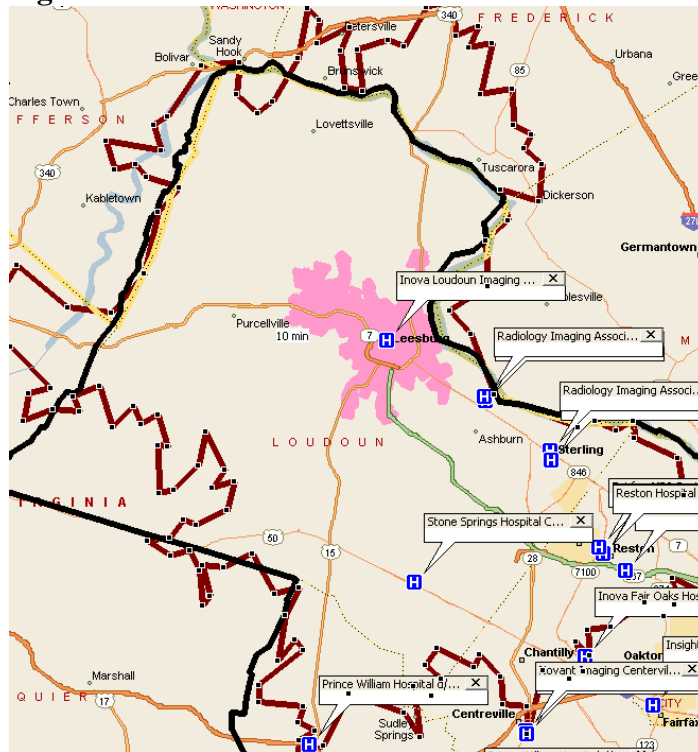
providers closer. Additionally, Inova Lorton Healthplex, as seen in **Table 2**, is at 47.2% utilization, however, Inova Springfield and Inova Mt. Vernon are at 74.9% and 102.3% utilization for 2021. Assuming all Inova patients wanted to continue using their services for continuity of care, they would have to travel farther, and likely experience longer wait times as Inova Mt. Vernon is above the threshold and Springfield is getting closer. Furthermore, while the Sentara Advanced Imaging was at 47% for the 2021 VHI report, Kaiser-Woodbridge, Insight-Woodbridge, and Sentara-Northern Virginia in 2021 were at 111.7%, 83.5%, and 77.3% MRI utilization respectively. While not all of these are above the SMFP threshold, they are coming ever closer to meeting it.

Figure 1



Considering the other Inova location with less than 50% utilization showcased below in **Figure 2**, Inova Leesburg at 44.2% in 2021, Figure 2 shows this location as being the only one for this portion of the district. The solid pink area is a 10-minute drive-time, while the dark red shows a 30-minute drive time. Relocating the Inova Leesburg MRI would be at a detriment to this rural portion of the district. Furthermore, the two closest MRI locations, Radiology Imaging Associates at Lansdowne and Inova Loudon Hospital, were at 77.3% and 118.3% utilization respectively.

Figure 2



For these reasons, DCOPN finds that the proposed project to add one fixed MRI unit within PD 8 at IRMC specifically, is more advantageous than maintaining the status quo.

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

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed the COPN application filed by Inova Reston MRI Center (COPN Request VA-8632) at its meeting on December 5, 2022, where IRMC seeks authorization to add one MRI scanning service in Herndon, Virginia. The Board was provided the following information within a memorandum prepared by Mr. Dean Montgomery:

A. Summary Conclusions and Findings

- a. Though use varies considerably among services, there is substantial unused MRI capacity in Northern Virginia. Average regional service volumes have ranged between 80-85% of Virginia State Medical Facilities Plan planning standard, 5,000 scans per scanner annually, for much of the last decade.
- b. There is no indication of a current or near-term regional need for additional MRI services or additional MRI scanners.
- c. Inova Reston MRI Center has high and increasing use, with service volumes substantially higher than the regional average.

- d. There is no unused, or inefficiently used, MRI capacity within Inova Health System that can be reallocated or otherwise used to respond to increasing demand at IRMC.
 - e. Current and projected service volumes qualify Inova Reston for consideration to add capacity under the institutional need provision of the VSMP as that consideration has been applied to similar proposals in recent years.
 - f. The proposal is consistent with the circumstances and considerations that led to the approval of similar diagnostic imaging expansion projects, locally and statewide.
 - g. The capital cost of the proposal is within the range commonly seen locally and elsewhere.
 - h. There is no indication that any party or population would be disadvantaged or poorly served by the expansion of Inova Reston MRI Center.
 - i. The project is not likely to have significant negative health system effects.
- B. Alternatives for Agency Action
- a. The HSANV 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:
 - i. Though there is no near-term regional need for additional MRI capacity, benefits of the project outweigh concerns about over supply and unnecessary duplication of capacity.
 - ii. The proposal is consistent with the substance and principles inherent in similar projects that have been authorized locally and statewide.
 - iii. The service has high use and need to be expanded to serve its primary service area population effectively.
 - iv. The project is not likely to have discernible negative health systems effects.
 - b. The HSANV may recommend to the Commissioner of Health that a COPN need not be granted based upon the following:
 - i. There is substantial unused MRI capacity in the region. The project is not necessary assure reasonable access to MRI services.
 - ii. Given unused capacity in the region the proposed capital outlay is not necessary to improve access to care or to address and identified system deficiency.

The HSANV, has not yet voted on the project at this time.

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

As demonstrated by **Table 2**, the projected capital costs of the proposed project are \$2,618,538. The applicant will fund the construction portion of the project with financing from a United Bank loan at a 5.2% interest rate. The MRI equipment will be leased from the vendor and at the end of the lease term, IRMC will own the MRI equipment. DCOPN concludes that the project's estimated Capital costs are reasonable when compared to similar projects, such as:

- COPN No. VA-04665, issued September 3, 2019, where Tidewater Physicians Multispecialty Group, PC were approved to convert one mobile MRI unit to a fixed unit

at Tidewater Medical Center at New Town with a total associated capital cost of \$1,384,062.

- COPN No. VA-04731, issued December 7, 2020, where Riverside Hospital, Inc. was approved to replace one mobile MRI scanner with a fixed site MRI scanner at Riverside Diagnostic Center-Hampton with a total associated capital cost of \$3,213,510.

Both similar projects are comparable in that they were to add an MRI unit, following utilizing a mobile MRI unit (as the applicant proposes to do), in a medical center, as opposed to a larger hospital setting.

The applicant and letters of support identified numerous benefits of the proposed project, including:

- Reducing volume utilization to under the SMFP threshold, decreasing patient wait times, currently at approximately 14 days.
- Reduce anxiety in patients awaiting diagnostic imaging for diagnosis confirmation through having same-day availability for scans in high-risk patients.
- Increasing the timeliness of beginning certain life-saving treatments, such as with breast cancer diagnosis.
- Allowing for additional and timely access for cardiac patients as MRI is becoming more prevalent in that field for diagnostic imaging and clinical decision making.

DCOPN detected the following additional benefit:

- There is a clear patient and provider preference for IRMC's diagnostic imaging services in comparison to other service providers in the region (as exemplified through utilization rates). Whether this preference is due to service provision quality, customer satisfaction, or (an)other factor(s) is unknown; however, authorizing IRMC another MRI scanner will place IRMC with utilization rates in comparable to others in the region and allow for patients and providers to continue utilizing their service provider of choice.

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

According to regional and statewide data regularly collected by VHI for 2020, the most recent year for which such data is available, the average amount of charity care provided by HPR II facilities was 3.4% of all reported total gross patient revenues (**Table 3**). As previously discussed, recent changes to § 32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. If approved, the proposed project should be subject to the system-wide charity care condition applicable to Inova Health Care Services d/b/a Inova Health System pursuant to COPN No. VA-04381 (issued April 2, 2013), as amended by the State Health Commissioner by letter dated January 4, 2016 (the Inova System-Wide Condition). Pursuant to the 2016 reconsideration, the Inova System-Wide Condition reset to 3.9% as of January 1, 2022.

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

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed project.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, these regulations provide the best available criteria and DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for the establishment or expansion of MRI services. They are as follows:

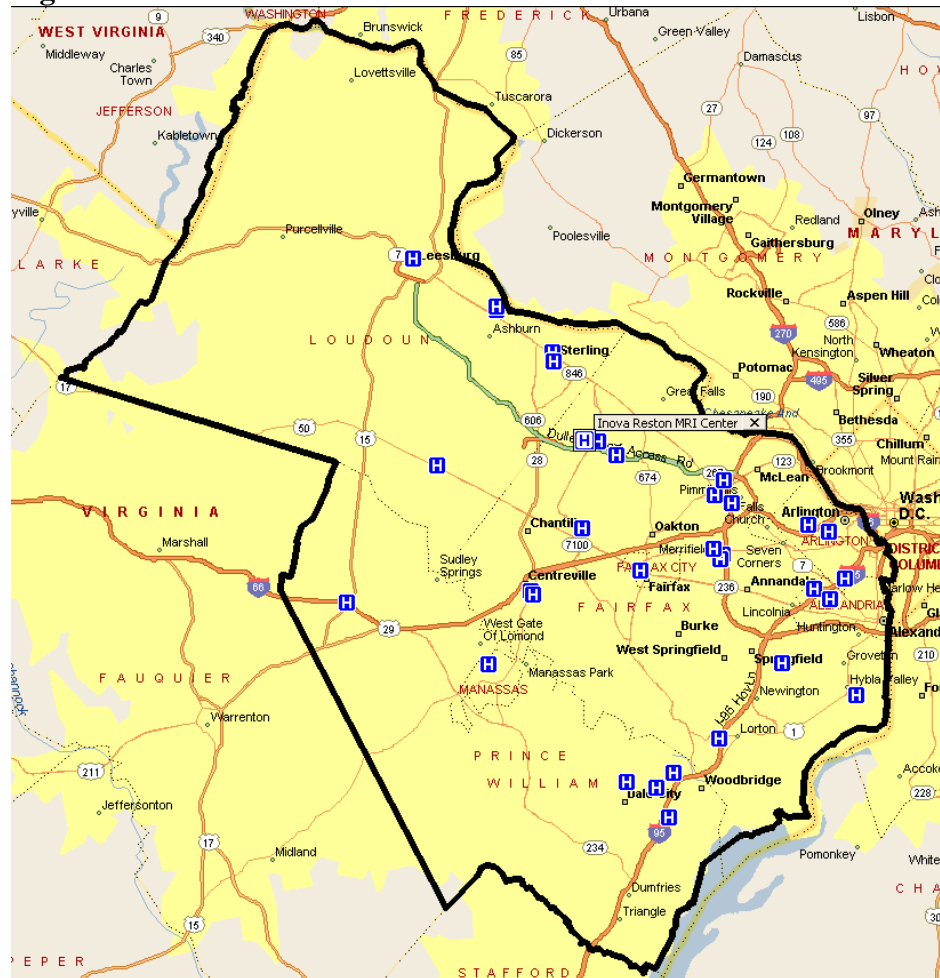
Article 2
Criteria and Standards for Magnetic Resonance Imaging

12VAC5-230-140. Travel time.

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

The heavy black line in **Figure 1** is the boundary of PD 8. The blue “H” symbols mark the locations of existing MRI providers in PD 8. The white “H” symbol marks the location of the proposed project. The yellow shaded area includes the area that is within 30 minutes driving time one-way under normal conditions of existing MRI services in PD 8. **Figure 1** clearly illustrates that MRI services are already well within a 30-minute drive under normal conditions of 95% of the residents of PD 8.

Figure 1



12VAC5-230-150. Need for new fixed site service.

No new fixed site MRI service should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI 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 may be disregarded in computing average utilization of MRI scanners in such planning district.

As shown in **Table 2** above, the then-existing PD 8 fixed MRI inventory performed a collective MRI volume of 199,616 MRI procedures in 2021 with an overall utilization of 76.8%. Based on this data, DCOPN has calculated a current surplus of 8 fixed MRI scanners in PD 8 as follows:

- 2022 COPN authorized fixed MRI units = 57
- Needed MRI units = $241,475$ (2021 MRI procedures) \div $5,000$ = 49 units needed
- 2022 MRI unit inventory = 57
- Fixed MRI unit surplus = 8**

In PD 8, there is an average of 4,472 procedures per unit for the 54 operational units during the 2021 reporting period, yielding an average utilization rate of 89.4%. Assuming the same data for procedures (which is not including the expected growth of the area), the average utilization rate for the current authorization of 57 units would be 84.73%, or 4,237 procedures per authorized unit.

The applicant asserts that this section is not applicable because “IRMC proposes the expansion of MRI services due to institutional need.” While the applicant argues expansion due to institutional need, DCOPN finds this misleading; IRMC is proposing to expand MRI services at an institution that is not yet operational. The current section is not applicable as COPN VA-04800 authorizes the new facility where the first MRI will be relocated, and the second proposed MRI is to be fixed. While this section may not be directly applicable, the calculations provide valuable insight, as outlined below.

As noted in **Table 5** above, in 2021, the utilization of existing MRI services in the planning district was only 89.4% of the 5,000 procedures per scanner necessary to introduce MRI scanning services to a new location under this section of the SMFP. For that same year, the applicant’s one MRI unit (that is being relocated to the new site) was well utilized at 123.2% of the SMFP standard (displayed as “Fairfax MRI Center at Reston”) in **Table 5** and 2021 VHI data.) Therefore, DCOPN concludes that IRMC has shown an institutional need for an additional fixed site MRI in order to adequately meet patient care needs.

12VAC5-230-160. Expansion of fixed site service.

Proposals to expand an existing medical care facility’s MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant’s existing medical care facility, or at a separate location within the applicant’s primary service area for MRI services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health-planning district.

The applicant requests an additional MRI scanner based on institutional need as the MRI service at its current location on Elden Street exceeds the SMFP expansion standard and is expected to continue to exceed the SMFP expansion standard when relocated from Elden Street to Springpark Place. The applicant is proposing to expand MRI services at a location that is not yet open and operational. 12VAC5-230-160 states “*The commissioner may authorize placement of the new unit... or at a separate location within the applicant’s primary service area for MRI services...*” The proposal is better addressed through this section of the regulation as the approved new site at Springpark Place (authorized in COPN VA-04800) is 1-mile from the current site, as is not likely to reduce utilization of existing providers in the district.

According to data provided by the applicant, in 2022, based on 8 months year-to-date annualized data (January – August 2022), the existing unit is projected to perform 6,246 procedures, placing utilization at 125% of SMFP. Without the additional capacity and with the continued growth in the population and in the use of MRI services for expanded clinical criteria as described in

previous sections, the applicant warns IRMC will be constrained from providing optimal responsiveness in scheduling appointment times for its own current institutional patient base which currently already average 14 days from date of first communication to date of appointment. Utilizing the same 2022 data, without accounting for natural growth, a second unit would yield a utilization rate of 62.5% per unit. Assuming the applicant's reported projected growth of 7,000 procedures in 2024, the utilization rate would be 70%, and with the projections for 2025, 7,500 procedures yielding a utilization rate of 75%. Keeping the rate below 100% would allow the facility the opportunity to work in same-day scans for those with potential breast cancer diagnostic needs as the applicant is intending. Additionally, the extended hours of operation could be reduced, too.

12VAC5-230-170. Adding or expanding mobile MRI services.

- A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health-planning district.**
- B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health-planning district.**

Not applicable. The applicant is not proposing to add or expand mobile MRI services.

12VAC5-230-180. Staffing.

MRI services should be under the direct supervision of one or more qualified physicians.

The applicant has provided assurances that all MRI services will be under the direction and supervision of qualified physicians.

Required Considerations Continued

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

The proposed project is not anticipated to foster institutional competition, but rather is intended to improve patient experience and accessibility for IRMC's current patients. IRMC does not expect that its primary service area or patient base will materially change. Regarding the effect on other providers of diagnostic services, the applicant states, "because the proposed project involves IRMC's own patient base and IRMC's institution-specific need for additional MRI services, IRMC does not expect the expansion to negatively impact other existing MRI providers in PD8." The proposed project will reduce wait times and increase same-day access for IRMC's current patient-base. Additionally, the applicant calculated projected growth based upon "expected population growth and pent-up demand due to existing backlog. IRMC MRI volume is already artificially constrained as evidenced by increasing wait times."

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

As discussed above, the proposed project is intended to improve patient experience and accessibility for IRMC patients. Additionally, the proposed project’s expected utilization rate will be comparable to other utilization rates within the region. As such, the proposed project is highly unlikely to affect the utilization and efficiency of existing providers.

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

As already discussed, DCOPN contends that the projected costs of \$2,618,538 are reasonable when compared to previously authorized projects similar in scope. For example, COPN No. VA-04665, issued September 3, 2019, where Tidewater Physicians Multispecialty Group, PC were approved to Convert one mobile MRI unit to a fixed unit at Tidewater Medical Center at New Town where the total associated Capital costs were \$1,384,062. An additional example is COPN No. VA-04731, issued December 7, 2020, where Riverside Hospital, Inc. was approved to replace one mobile MRI scanner with a fixed site MRI scanner at Riverside Diagnostic Center-Hampton where the total associated Capital costs were \$3,213,510.

The applicant will fund the construction portion of the project using financing from United Bank at a 5.2% interest rate. The MRI equipment will be leased from the vendor. At the end of the lease term, IRMC will own the MRI equipment. The Pro Forma Income Statement provided by the applicant projects, for the project only, a net profit of (\$173,356) in Year 1 and \$334,943 in Year 2.

Table 6. IRMC Pro Forma Income Statement (Project Only)

	Year 1	Year 2
Total Gross Revenue	\$1,553,004	\$2,904,118
Contractual/Other Discounts	(\$881,429)	(\$1,652,310)
Charity Care	(\$46,590)	(\$87,124)
Net Revenue	\$616,770	\$1,149,321
Total Expenses	\$790,126	\$814,378
Excess of Revenue over Expenses	(\$173,356)	\$334,943

Source: COPN Request No. VA-8672

With regard to staffing, the applicant states that three additional staff comprised of one Administration-Business Office Registered Nurses and two Radiologic Technologists are needed. The applicant further states, “Fairfax Radiology Centers (FRC), [minority owner and operator of IRMC], recruits for all positions internally and has two recruiters dedicated to clinical recruitment. Additionally, FRC has a formal in-house MRI Tech training program, partners with outside educational facilities, and maintains a float pool of technologists to cover vacancies and employee absences. IRMC do[es] not anticipate any impact on other facilities in the service area as MRI Technologist continues to be a desirable career advancement opportunity internally from X-ray, Mammo[graphy], and CT technologist positions.”

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

The proposed project would neither introduce new technology that would promote quality or cost effectiveness in the delivery of inpatient acute care, nor will the proposed project increase the potential for provision of services on an outpatient basis, as the applicant already provides MRI services on an outpatient basis.

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

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

DCOPN Findings and Conclusions

DCOPN finds that Inova Reston MRI Center, LLC's COPN request to expand MRI services with the addition of one MRI scanner is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia due to institutional need. The proposed project is intended to improve patient experience and accessibility for IRMC patients rather than draw from patients of other providers. Additionally, the projected utilization rates following the proposed project's implementation will yield rates comparable to competitors in the area. Support for the additional MRI machine from non-Inova providers request access to MRI scans more quickly than the current 14-day waiting period. For these reasons, DCOPN concludes that the proposed project is more favorable than maintaining the status quo.

DCOPN finds that the total capital costs of the proposed project are reasonable and consistent with previously approved projects similar in scope. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Finally, there is no known opposition to the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Inova Reston MRI Center, LLC's COPN request to establish a specialized center for MRI services with one relocated and replaced MRI scanner for the following reasons:

1. The proposed project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The project is not anticipated to negatively affect competitors and is more favorable than maintaining the status quo.
3. The capital costs are reasonable.
4. The proposed project appears economically viable in the immediate and the long-term.
5. There is no known opposition to the proposed project.

Recommended Condition

This project shall be subject to the system-wide charity care condition applicable to Inova Health Care Services d/b/a Inova Health System pursuant to COPN No. VA-04381 (issued April 2, 2013), as amended by the State Health Commissioner by letter dated January 4, 2016 (the Inova System-Wide Condition). Pursuant to the 2016 reconsideration, the Inova System-Wide Condition reset to 3.9% as of January 1, 2022. Provided, however, that charity care provided under the Inova System-Wide condition shall be valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Inova Health System will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. In addition to any right to petition the Commissioner contained in the Inova System-Wide condition, to the extent Inova Health System expects its Inova System-Wide condition as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. or any revised percentage to materially alter the value of its charity care commitment thereunder, it may petition the Commissioner for a modification to the Inova System-Wide condition to resolve the expected discrepancy.