Health Systems Agency of Northern Virginia

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#### June 11, 2024

### TO: Board of Directors, HSANV

**Interested Parties**

**FROM: Dean Montgomery**

### SUBJECT: Certificate of Public Need Applications

**Inova Reston MRI Center, Expand MRI Service (COPN Request VA-8755)**

**IFRC, Establish MRI Service (COPN Request VA-8756)**

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**I. Summaries of the Proposals**

Two established providers of medical imaging services in northern Virginia seek certificate of public need (COPN) authorization to add magnetic resonance imaging (MRI) capacity. Inova Reston MRI Center (IRMC) proposes to expand Tysons MRI and Imaging Center (COPN Request VA-8755). IFRC proposes to establish a new MRI Service in Woodbridge, Virginia (COPN Request VA-8756). Both IRMC and IRFC are joint ventures of Inova Health Care Services and Fairfax Radiological Consultants. Inova Health Care Services is the operating arm of Inova Health System. Fairfax Radiological Consultants, the region’s largest radiology practice, provides professional radiology services at most Inova Health System facilities. Inova Health System holds a majority interest in both joint ventures.

COPN applications filed in the same review cycle for the same or similar services are deemed competing proposals, requiring comparative review and evaluation. The discussion below places the applications in the context of northern Virginia MRI service development and use, and examines them relative to required regional planning considerations.[[1]](#footnote-1)

1. I**nova Reston MRI Center, Expand MRI Service (COPN Request VA-8755)**

Inova Reston MRI Center[[2]](#footnote-2) has three MRI services, each with one MRI scanner: Centreville MRI Center, Reston-Herndon MRI Center, and Tysons MRI and Imaging Center. This project would add a second scanner to the Tysons service. Table 1 shows current MRI capacity and recent service volumes at Tysons MRI and Imaging Center and other local MRI services.

Projected capital cost totals $2,420,196, slightly more than half of which ($1,250,049) would be for the scanner and associated equipment. Most of the remainder ($1,170,147) would be for construction. Capital costs would be paid from internal operations (48%) and a capital lease for the MRI system (52%).

IRMC justifies the proposal on the grounds that:

* Tysons MRI and Imaging Center’s service volume is high and increasing.
* IRMC’s three MRI services have an average annual caseload higher than the Virginia State Medical Facilities Plan (SMFP) service volume planning standard.
* There is no unused capacity within IRMC that can be reallocated to respond to increased demand at Tysons MRI and Imaging Center.
* IRMC has an internal, “institution specific” need for additional MRI capacity to meet current and projected demand.
* Given current and projected caseloads, expanding MRI capacity at IRMC should not affect demand or service volumes at other imaging services.
* Capital costs are reasonable, within the expected range, for the service and equipment proposed.
* The project is consistent with the applicable provisions of the Virginia State Medical Facility Plan (SMFP), including the institutional need provision of the plan as it has been interpreted and applied in recent years.

If authorized on schedule, the additional scanner would be in service in about a year, in the summer of 2025.

1. **IFRC, establish MRI Service in Woodbridge, Virginia (COPN Request VA-8756**)

IFRC, which plans to do business as *FRC at Inova Health Center-Woodbridge (FRC-Woodbridge),* is a newly formed joint venture with two members, Inova Health Care Services and Fairfax Radiological Consultants. Inova Health Care Services, an operating arm of Inova Health System, holds a majority interest in the venture. IFRC proposes to establish the Woodbridge service by replacing and relocating the MRI scanner now at Fairfax Radiology Center-Sterling. Table 1 shows current MRI capacity and recent MRI service volumes at authorized Northern Virginia services, including Fairfax Radiology Center-Sterling.

Estimated capital costs are $4,383,690, about half of which ($2,149,604, 49%) would be for the scanner and associated equipment. The remainder $2,234,086) would be for construction ($1,099,108) space lease ($ 652,834), lease interest expense ($415,434) and related development expenses. The project would be financed with a mix of IFRC reserves (49%) and internal operations (51%). The scanner and associated technology would be acquired by means of a capital lease with a vendor. FRC-W would own the MRI system at the end of the lease.

FRC Woodbridge justifies the proposal on the grounds that:

* The MRI scanner at IFRC’s Sterling, Virginia service is dated, essentially at the end of its useful life, and must be replaced.
* The lease for space housing the Sterling service ends soon, so the service must be closed or relocated.
* IFRC has outpatient diagnostic imaging services in much of northern Virginia but not in Prince William County where it has a notable patient population.
* Relocating the Sterling service to Woodbridge would improve the distribution of IFRC diagnostic imaging services and, consequently, access to MRI imaging among IFRC and Inova Health System patients.
* Projected capital costs are reasonable, within the range seen for similar projects locally and statewide.
* The project is generally consistent with the applicable provisions of the Virginia State Medical Facility Plan (SMFP), as it has been applied in similar circumstances.

If authorized on schedule, the new scanner should be in service early next year, the first half of 2025.

**II. Discussion**

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

There are 58 MRI scanners in Northern Virginia authorized for use in diagnostic imaging. They are widely distributed in various settings. More than half (31 of 58) are in hospitals. About one-third (17 of 58) are freestanding services with no hospital affiliation. The remainder are in joint ventures of local hospital systems and local radiology groups. Most freestanding (not hospital based or affiliated) services are classified and reimbursed by insurers as independent diagnostic testing facilities (IDTFs), rather than as hospital outpatient departments.

MRI service volumes and the number of authorized scanners increased substantially in recent years, between 2017 and 2022 (Table 1).[[3]](#footnote-3) Demand increased by 23.5% between 2010 and 2019. With the advent of the COVID-19 epidemic, demand fell sharply, 12.4% in 2020 (Table 1). Service volumes rebounded region wide in 2022, returning to the local growth trend. With these gyrations, the compound annual growth rate (CAGR) was about 3.0% over the last decade, between 2012 and 2022.

Average recent use of northern Virginia MRI scanning services in 2022 was below the *minimum* service volume planning standard (5,000 scans per scanner per year) specified in the Virginia SMFP. In 2019, the year before the dislocations induced by the COVID-19 epidemic, average use was 4,320 scans per scanner, about 87% of the nominal service volume standard. This metric dropped 12.4% to 3,708 scans per scanner in 2020, about 74% of the target value. With the rebound and return to trend in 2021-2022, the regional average was about 4,762 scans per scanner, about 95% of the *minimum* planning standard.

With the authorization of three additional MRI scanners this year, an increase in capacity of about 6.0%, there is no indication of a current or near-term *regional* need for additional MRI services or scanners.

Though reported service volumes vary from year to year, there is no indication that near term (next five years) use rates and average annual increases in demand are likely to vary significantly from the experience of the last decade. MRI demand is likely to continue to increase at a rate marginally higher than the regional population growth rate.

Unlike most other diagnostic imaging services, average use of freestanding MRI scanners (4,990 scans per scanner in 2022) is comparable to that of hospital-based services (4,572 scans per scanner in 2022). There is unused capacity in both settings. But it is worth noting that much of the unused capacity is in facilities where a second (or third) scanner has been added recently, under the institutional need provision of the Virginia SMFP, to respond to institution specific demand at a specific high use service.

It also is worth noting that unlike the comparatively low use rates for most other acute care services in the region, typically about 30% lower than rates elsewhere in Virginia, northern Virginia MRI scanning use rates and service volumes are comparable to those reported in other Virginia planning regions. The local facility MRI service volumes and scan rates are higher than the statewide averages and greater than comparable rates in three of the other four planning regions (Table 2).[[4]](#footnote-4) There is no indication of suppressed demand or significant migration for MRI scanning outside the planning region.



Given no evident regional need for additional MRI capacity, the question of authorizing additional scanners, whether in the form of new services or expansions of existing services, is a matter of weighing the inherent merit of such proposals against their potential negative effects.



***SMFP Planning Guidance***

The Virginia State Medical Facilities Plan (SMFP) provides planning guidance for establishing and expanding MRI services. The sections covering establishing new services and expanding existing services read:

**“12VAC5-230-250 - Need for new fixed site service.**

No new fixed site MRI services 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 site may be disregarded in computing the average utilization of MRI scanners in such health planning district.

**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.” (**Virginia State Medical Facilities Plan, p. 10)**

Inova Reston MRI Center proposes to expand its Tysons Corner service. Section 12VAC5-230-160 applies to the proposal. IFRC proposes to replace and relocate its Sterling service in Woodbridge. Under Virginia COPN regulations this constitutes establishing a new service. Section 12VAC5-230-150 applies.

Neither of the applicant justifies its proposal on the grounds of a documented general regional need, as formulated in the Virginia State Medical Facilities Plan. IRMC argues that it has a service specific need for additional capacity as permitted by Section 12VAC5-230-80 which states:

**“12VAC5-230-80. When institutional expansion needed.**

A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.

B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.

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

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

The high and increasing service volumes at Tysons MRI and Imaging Center support IRMC’s claim of consistency with Section 12VAC5-230-80. A. The 2023 service volume was 6,601 cases, about 30% above the guidance of 5,000 cases per scanner per year.

IFRC notes that replacement and relocation of its Sterling Imaging Center, though technically defined as the establishment of a new service, would not increase the regional MRI complement. It argues, in effect, that neither Section 12VAC5-230-150 nor Section 12VAC5-230-160 apply.

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

**Inova Reston MRI Center**

Inova Reston MRI Center proposes to expand its MRI service by adding a second scanner. The request is based largely on high use and the need to accommodate increasing demand. Tysons MRI and Imaging Center (TMIC) reported providing 6,601 MRI scans in 2023, more that 30% higher than the recommended service volume caseload of 5,000 sans for scanner annually.

The scanner that would be acquired would be placed in space vacated when one of TMIC’s scanners was relocated and replaced as Centreville MRI Center in 2023. Other than the Sterling Imaging Center scanner, which IFRC plans to replace and relocate in Woodbridge, VA, there is no unused MRI capacity within IRMC, Reston-Herndon MRI Center, Fairfax Radiological Consultants, or Inova Health System that could be used to meet the need for additional capacity at TMIC.

The Inova Reston MRI Center proposal satisfies the requirements of the institutional need provisions of the Virginia State Medical Facilities Plan as it is commonly interpreted and applied. There is no indication that adding the capacity requested for the center would negatively affect other MRI services.

**IFRC Woodbridge**

IFRC proposes to replace and relocate its Sterling Imaging Center MRI service. The replacement scanner would be placed in an outpatient center Inova Health System is developing in Woodbridge, VA. The applicant notes that the project would be inventory neutral, i.e., would not result in a net increase in the licensed regional MRI scanner complement.

IFRC served 34,575 MRI patients at its six services in Fairfax, Arlington and Loudoun counties in 2023. About 7.2% (2,484 patients) were Prince William County residents. Most of these were western Prince William County residents (about 75%) and obtained scans at IFRC’s Centreville MRI Center (55%). IFRC served 601 MRI patients from eastern Prince William County in 2023, about one-fourth of the Prince William County total and less than 2.0% of the IFRC total. Eastern Prince William County is not a substantial part of the IFRC patient population.

There are four MRI services and six MRI scanners in eastern Prince William County: Sentara Northern Virginia Medical Center (1), Sentara Advanced Imaging-Lake Ridge (1), Rayus Radiology-Woodbridge (2), and Kaiser Foundation Health (2)[[5]](#footnote-5). The Sentara MRI services have modest service volumes. Average use in 2022, the most recent year for which vetted service volumes are available, was 3,127 patients per scanner, about 65% of the nominal planning standard of 5,000 patient scans per scanner. It is also noteworthy that, as noted above, the regional compound annual growth rate (CAGR) was about 3.0% over the last decade, between 2012 and 2022. During this period of substantial regional growth, the MRI service volume at the Sentara services fell from 6,997 cases in 2012 to 6,434 in 2022, an 8.0% decrease. Most of the loss appears to have gone to Rayus Radiology Woodbridge.

Given the relatively small number of MRI patients IFRC now serves from eastern Prince William County and the greater Woodbridge area, it is possible that adding the capacity requested by IFRC would affect nearby MRI services negatively.

**B. Cost Considerations**

Projected capital costs of the projects, summarized in Table 3, are within the range commonly seen for similar projects. The principal difference is the notably higher cost of the IFRC Woodbridge project which entails acquiring a state of the art 3.0 Tesla scanner and establishing the service in a new multiservice imaging center. Both imaging systems would be acquired via capital leases from a vendor. The scanners leased would be conveyed to IRMC and IFRC at the end of the leases. In both cases the scanner leased is likely to have about one-third of its useful life remaining at the end of the lease.



Scanner costs vary by nearly 100%, from about $1.25 million to about $2.15 million. Though substantial, there is nothing inherently problematic about the capital cost of either proposal. Both are within the capital expenditure range seen for similar projects locally (PD 8) and statewide. Both scanners would be in independent diagnostic testing facilities (IDTFs) and would be paid accordingly by Medicare and other insurers.

There is no reason to doubt that the projects can be undertaken and completed as described. The *pro forma* budgets for the initial two years of operations indicate that the applicants expect the projects to be profitable. Profit margins can be expected to increase significantly over the useful lives of the scanners, as depreciation and amortization costs decrease, and fixed costs are spread over larger caseloads. Like other diagnostic imaging services, the marginal cost of providing a scan will decrease as demand and service volumes increase.

Inova Health Care Services (Inova) and Fairfax Radiological Consultants (FRC) are the members of both joint ventures. Inova and FRC commit to providing a reasonable amount of charity care and have done so for decades.

##### Access Considerations

With 29 MRI services and 58 widely distributed scanners, Northern Virginians have ready geographic access to MRI scanning. Nearly all northern Virginia residents are within less than 30 minutes travel time of several MRI services. Neither additional services nor additional scanners are necessary to ensure reasonable geographical access.

Expansion of IRMC’s service is not likely to have notable health system effects. No change in the primary service area is expected or likely. It 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 services. All the MRI services in central Fairfax County have substantial service volumes. Some are adding capacity.

Though characterized as a straightforward replacement and relocation project, the IFRC proposal entails establishing a new MRI service in Woodbridge, VA. The proposed location is about forty miles from Fairfax Radiology Center-Sterling, the service that would be closed, less than two miles from Sentara Northern Virginia Medical Center, and about four miles from Sentara Advance Imaging-Lake Ridge and the Rayus Radiology-Woodbridge (Rayus). Rayus, the largest provider of MRI imaging in eastern Prince William County, has two MRI scanners with average use above the nominal service volume standard of 5,000 scans per scanner per year. Average use of the Sentara and Rayus scanners was 4,218 cases in 2022, about 85% of the service volume planning standard.

Both IRMC and IFRC are experienced, successful MRI service providers with acceptable charity care policies and practices. There is no indication that economic access to MRI scanning services would be affected significantly by either project.

##### Health System Considerations

The Inova Reston MRI Center proposal to acquire a scanner to meet current and near-term demand qualifies for consideration to add capacity under the institutional need provision of the Virgina State Medical Facilities Plan as that provision has been interpreted and applied historically. It is unlikely that adding a second scanner at Tysons MRI and Imaging Center would affect operations of neighboring service negatively. The scanner that would be acquired is likely to be used efficiently during its useful life. The project appears to be advisable, a necessary capital investment to maintain an efficient high-volume service.

The IFRC proposal to replace and relocate its Sterling service in eastern Prince William County may affect demand at Sentara Healthcare and Rayus Radiology MRI services. Eastern Prince William County residents are now served principally by Rayus Radiology and two Sentara Healthcare services: Sentara Northern Virginia Medical Center and Sentara Advance Imaging Center-Lake Ridge. Both have one MRI scanner. Both have modest use. Rayus Radiology has two MRI scanners with high and growing caseloads. All of these are a short distance, and within ten minutes’ travel time, of the proposed IFRC service.

The IFRC proposal is not needed to respond to a regional need or to address a health system deficiency. It would improve the regional distribution of IFRC diagnostic imaging services and inure to IFRC’s benefit.

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

**A. Summary Conclusions and Findings**

Neither applicant asserts a regional need for additional MRI capacity. IRMC claims a service specific need to add capacity as permitted by the institutional need provision (Section 12VAC5-230-80) of the Virgina State Medical Facilities Plan. IFRC argues its proposal is a straightforward replacement and relocation of the aged Sterling Imaging Center MRI service.

The applications, and related market information, support the following findings and conclusions:

1. Use of northern Virginia MRI services varies considerably. Some have sustained high service volumes, others more modest caseloads. Average regional service volumes range between 85% and 95% of Virginia State Medical Facilities Plan planning guidance, 5,000 scans per scanner annually.
2. There is no indication of a current or near-term regional need for additional MRI services or capacity.
3. Regional demand for MRI services, which grew at a compound annual rate of about 3.0% over the last decade, is expected to continue to grow at a rate marginally higher than the population growth rate.
4. Most of the additional capacity authorized over the last decade has been in expansion projects at heavily used services in accordance with the institutional need provision of the Virginia SMFP. IRMC proposes a similar project.
5. Current and projected near term service volumes qualify IRMC for consideration to add capacity at Tysons MRI and Imaging Center under sections 12VAC5-230-60 and 12VAC5-230-80 of the Virginia State Medical Facilities Plan as those provisions have been applied to similar proposals in recent years.
6. IFRC’s proposal to establish a new MRI service in Woodbridge, Virginia is characterized as a straightforward necessary replacement and relocation of its dated Sterling MRI Center service. Most similar proposals are authorized routinely. The principal question to be resolved in this case is whether potential negative effects at Sentara and Rayus MRI services are acceptable.
7. The capital cost of both proposals is within the range commonly seen locally and elsewhere.
8. Both applicants have acceptable charity care policies and practices.

**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 both projects be granted.

Support for the proposals could be based on concluding that:

* + IRMC’s Tysons MRI and Imaging Center has sustained high use, qualifying for consideration to expand under Section 12VAC5-230-80 of the Virginia SMFP.
  + Though there is no near-term regional need for additional MRI capacity, the benefits of each project outweigh concerns about over supply, unnecessary duplication of capacity, and potential negative effects on other MRI service providers.
  + Both proposals are generally consistent with the substance and principles inherent in similar projects that have been authorized routinely locally and statewide.
  + Neither project is likely to have significant long-term negative health system effects.

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 one or both projects.

Negative recommendations could be based on concluding that:

* There is unused MRI scanning capacity in the region. Neither project is necessary to assure reasonable access to MRI services.
* The IFRC project poses unacceptable negative risks for the Sentara and Rayus Radiology MRI services in eastern Prince William County.
* Given unused capacity in the region, and the distribution of capacity within the region, the proposed capital outlays are not necessary to improve access to care or to address an identified system deficiency.

**IV. Checklist of Mandatory Review Criteria**

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

Northern Virginia residents have ready access to diagnostic imaging services, including magnetic resonance imaging. There is no documented regional need for additional MRI services or capacity.

Nevertheless, it is evident that, over their useful lives. the projects are likely to contribute to maintaining ready access to care. No enduring negative health system effects are likely.

1. **Meet Needs of Residents**

The diagnostic imaging needs of the populations and communities the applicants serve, and proposed to serve, are being met by existing service providers, including all IRMC and IFRC services. Neither project would alter this market condition appreciably.

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

The IRMC project which entails the expansion of Tysons MRI and Imaging Center, is consistent with the service expansion provisions of the Virginia State Medical Facilities Plan, including the institutional need provisions of the plan, and with the treatment accorded historically to similar proposals to add capacity at high volume diagnostic imaging services.

Consistency with the Virginia SMFP is less clear for the IFRC project. It is presented as a timely scanner replacement and relocation project that merits routine approval. That interpretation and associated assumptions typically apply to projects relocated well within the primary service area of the service relocating. It is not evident that this interpretation of the rules and regulation applies, or should apply, to market development ventures that entail distant relocations into the primary service areas of other service providers.

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

The projects are from existing local MRI services who compete regularly with other service providers. It is unclear how beneficial any competition for patients generated by the IFRC project would be. No price competition is suggested or anticipated. Net physical and economic access to MRI services would not be changed appreciably. Arguably, both projects would help maintain reasonably convenient access to MRI scanning.

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

No significant health system effects are likely. The IRMC proposal, the expansion of Tysons MRI and Imaging Center, should permit more efficient operations. It is not likely to affect demand or operations at other MRI services.

The near-term effects of relocating Sterling MRI Center to Woodbridge, about 40 miles southeast of Sterling, are less clear and potentially negative. Establishing a new service in the primary service area of the Sentara and Rayus Radiology MRI services is likely to reduce demand at those services over the next three to five years. IFRC now serves about 600 MRI patients from the greater Woodbridge area. Success of the IFRC project depends on developing a caseload of eastern Prince William County patients who otherwise would use nearby services.

**6. Economic, Financial Feasibility**

The capital outlays proposed are within the range commonly seen for MRI projects. Both are financially feasible and would be expected to generate substantial operating profits and returns on investment. The *pro forma* budgets submitted reflect these expectations.

**7. Financial, Technological Innovations**

Neither project involves innovative technologies, practices or economic aspects that warrant special consideration.

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

Neither project includes research or training elements that warrant special consideration.

1. The Virginia State Medical Facilities Plan (SMFP) defines competing proposals as “applications for the same or similar services and facilities that are proposed for the same health planning district, or same health planning region for projects reviewed on a regional basis and are in the same batch review cycle.” Virginia SMFP, p. 1. [↑](#footnote-ref-1)
2. Inova Reston MRI Center, like the competing IFRC proposal, is a joint venture with two members, Inova Health Care Services and Fairfax Radiological Consultants. Inova Health Care Services, an operating arm of Inova Health System, holds a majority interest in both entities. [↑](#footnote-ref-2)
3. Three MRI scanners, one hospital based and two freestanding services. have been added to the regional licensed complement since the 2023 inventory shown in Table 1 was published. The current authorized complement is 58 MRI scanners. [↑](#footnote-ref-3)
4. The information discussed here is reported facility use data, not population-based data. Northern Virginia is a net importer of MRI services, so indigenous northern Virginia use rates are lower than rates derived from facility data. The information presented in Table 2 is Virginia Health Information statewide 2022 MRI capacity and use data for Virginia’s five planning regions. Absent statewide population-based MRI use, these data are the most reliable available to make interregional comparisons. [↑](#footnote-ref-4)
5. The Kaiser serves only Kaiser Foundation Health Plan members. Kaiser’s market share in eastern Prince William County is the highest in the planning region. [↑](#footnote-ref-5)