

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

March 20, 2020

COPN Request No. VA-8479

Franconia-Springfield Surgery Center, LLC

Alexandria, Virginia

Establish lithotripsy services at the Inova Franconia-Springfield Ambulatory Surgery Center

Applicant

Franconia-Springfield Surgery Center, LLC (FSSC) is a Virginia Limited Liability Corporation. Inova Health Care Services (Inova Health System) maintains a majority membership interest in FSSC, and the remaining membership interests are held by physician investors. Each physician investor holds less than a 5% membership interest in the LLC, and collectively, the physician investors hold less than 50% of the membership interests. FSSC is located in Alexandria, Virginia, Planning District (“PD”) 8, Health Planning Region (“HPR”) II.

Background

FSSC is one of three outpatient surgical hospitals (OSHs), and eight total medical facilities, operated by the Inova Health System in HPR II. FSSC was originally authorized under COPN No. VA-03280, issued on May 24, 1996, and became operational in 2001. FSSC currently operates four ambulatory surgical operating rooms.

Renal lithotripsy is a clinical procedure in which shock waves are generated outside of the body to disintegrate one or more kidney stones within the body. Once the kidney stones are disintegrated, they can be passed out of the body through urination. Most kidney stones are treated through pain management and allowing the stones to pass naturally. In cases where this treatment is not viable, surgery is sometimes required. When it can be employed, renal lithotripsy offers a less invasive alternative to surgery for patients. As demonstrated below, there were two COPN authorized fixed renal lithotripsy units and nine mobile renal lithotripsy sites in HPR II in 2018, the last year for which DCOPN has data. DCOPN records show that there are two additional mobile lithotripsy sites that were approved by DCOPN that have not yet commenced operations.

Table 1. HPR II COPN Authorized Renal Lithotripsy Sites: 2017-2018

| Facility | Stationary Units | Mobile Units | Inpatient Renal Visits | Outpatient Renal Visits | Total Renal Visits |
|---|------------------|--------------|------------------------|-------------------------|--------------------|
| Inova Alexandria Hospital | 1 | 0 | 0 | 174 | 174 |
| Inova Ambulatory Surgery Center at Lorton | 0 | 1 | 0 | 91 | 91 |
| Inova Fair Oaks Hospital | 0 | 1 | 59 | 77 | 136 |
| Inova Fairfax Hospital | 0 | 1 | 0 | 23 | 23 |
| Northern Virginia Surgery Center | 0 | 1 | 0 | 123 | 123 |
| Prince William Ambulatory Surgery Center | 0 | 1 | 0 | 259 | 259 |
| Reston Hospital Center | 1 | 0 | 0 | 68 | 68 |
| Reston Surgery Center | 0 | 1 | 0 | 154 | 154 |
| Sentara Northern Virginia Medical Center | 0 | 1 | 0 | 14 | 14 |
| Stone Springs Hospital Center | 0 | 1 | 0 | 89 | 89 |
| Virginia Hospital Center | 0 | 1 | 0 | 18 | 18 |
| 2017 TOTAL and Average | 2 | 9 | 59 | 1,090 | 1,149 |
| Current Total¹² | 2 | 11 | n/a | n/a | n/a |

Source: VHI and DCOPN Records

Proposed Project

The applicant proposes to introduce mobile renal lithotripsy services at FSSC. The applicant expects to contract with United Medical Systems, the mobile renal lithotripsy vendor utilized by Inova Health Systems facilities, and will initially offer the service for two one-half days per week with the potential to expand as needed. The applicant has proffered that, should the proposed project receive approval, Inova Ambulatory Surgery Center at Lorton (“Inova Lorton”), which is located 8.3 miles from the FSSC, would cease to offer mobile lithotripsy service when the proposed project becomes operational. Many of the physicians who were members of Inova Lorton recently ended their membership at Inova Lorton, and became members of FSSC. The applicant states that lithotripsy cases that historically were performed at Inova Lorton would be performed at FSSC.

The proposed project has no capital costs and would not require any special construction, remodeling, or purchase of equipment. The mobile lithotripsy equipment will be operated by qualified technicians supplied by the mobile vendor and will be supervised by a board-certified urologist who is already on the staff at FSSC

Project Definition

Section 32.1 of the Code of Virginia defines a project, in part as, “Introduction into an existing medical care facility of any new...lithotripsy..., which the facility has never provided or has not

¹ The Commissioner issued COPN No. VA-04530 to Loudoun Hospital Center d/b/a Inova Loudoun Hospital on October 15, 2016, which authorized the introduction of mobile renal lithotripsy at Inova Loudoun Hospital. The applicant asserted that the project would become operational on January 31, 2017, but DCOPN has not received an indefinite extension from the applicant.

² The Commissioner issued COPN No. VA- 04601 to McLean Ambulatory Surgery, LLC on May 10, 2018, which authorized the introduction of mobile renal lithotripsy services at McLean Ambulatory Surgery Center. The project became operational on August 21, 2018.

provided in the previous 12 months;” A medical care facility includes “Specialized centers or clinics or that portion of a physician's office developed for the provision of ... lithotripsy...”

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 taken into account when applicable:

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

The applicant proposes to introduce mobile renal lithotripsy services at FSSC. HSANV asserts, and DCOPN agrees, that, while most residents of HPR II have ready access to multiple renal lithotripsy services, approval of the project would improve access for residents of Fairfax County. Geographically, FFSC is accessible from the north and south via I-95, which is located 3 miles from the facility and from the east and west via the Franconia/Springfield Parkway. Additionally, public transport is available at the Metro Park Office Park next to the facility and via metro within two at the Franconia-Springfield metro station. DCOPN is not aware of any geographic, socioeconomic, cultural, or transportation barriers to access to care.

- 2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:**

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

DCOPN received two letters of support from physicians from Potomac Urology, both of whom are also urologists at FSSC. Collectively, these letters articulated the benefits of lithotripsy. Moreover, the letters stated that the introduction of mobile renal lithotripsy would help improve access and provide “state-of-the-art care to the local community.”

Public Hearing

The Health Services Agency of Northern Virginia (“HSANV”) conducted the required public hearing on February 10, 2020. Three attendees spoke on behalf of the applicant. There was no public comment on the proposed project beyond the statements submitted in support of the application. No attendees voice opposition to the proposed project.

(ii) the availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner;

While the status quo is a viable alternative to the proposed project, approval of the project would offer some additional benefit to the planning district. As mentioned above, HSANV

concluded, and DCOPN concurs, that approval of the project would improve access to lithotripsy for residents of Fairfax County. Moreover, HSANV determined, and DCOPN agrees, that "... the use of existing space, equipment, and personnel could result in marginally more efficient and cost-effective operations at FSSC. Finally, the proposed project is site neutral, highly unlikely to affect materially the utilization at existing facilities, and has no associated capital costs. As such, DCOPN concludes that the proposed project is preferable to the alternative of the status quo.

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

The HSANV Board of Directors reviewed the COPN application filed by Franconia-Springfield Surgery Center, LLC (COPN Request No. VA-8479) seeking authorization to offer mobile renal lithotripsy at its February 10, 2020 meeting. The Board voted nine in favor and none opposed to recommend approval of the application.

The Board based the recommendation on its review of the application, on the HSANV staff report on the proposal, on the information and testimony presented at the February 10, 2020 public hearing and Board of Directors meeting on the proposal, and on several basic findings and conclusions, including:

1. Franconia-Springfield Surgery Center is an established provider of outpatient surgery in southeastern Fairfax County, VA.
2. Franconia-Springfield proposes to offer mobile renal lithotripsy comparable to, and in the manner of, renal lithotripsy services available at a dozen community hospitals and surgery centers in the region (PD 8).
3. Lithotripsy (ESWL) is the preferred treatment for kidney stone disease where clinically appropriate.
4. Arguably, offering part-time renal lithotripsy at Franconia-Springfield would help maintain access to the service for some Fairfax County residents.
5. Potential negative health system effects, e.g., decreases in lithotripsy service volumes at other renal lithotripsy services, are likely to be minimal, if discernible.
6. The project does not entail a capital expenditure or other investment.
7. Projected operating costs and charges are likely to be similar to those of existing services.
8. Franconia-Springfield, and Inova Health System its parent corporation, are committed to serving the uninsured, the medically indigent, and Medicaid patients equitably.

DCOPN agrees with the HSANV recommendation for approval, concurs with, and adopts, the attached HSANV staff report and analysis.

(iv) any costs and benefits of the project;

As discussed above, there are no capital costs associated with the proposed project. The proposed project would not require any special construction, remodeling, or purchase of equipment. The mobile lithotripsy equipment would be operated by qualified technicians supplied by the mobile vendor and would be supervised by a board-certified urologist who is already on the staff at FSSC. As discussed above, the proposed project would improve access to mobile renal lithotripsy for residents of Fairfax County without materially effecting the utilization of existing providers or increasing the number of mobile renal lithotripsy sites within the HPR.

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

According to regional and statewide data regularly collected by VHI, for 2018, the average amount of charity care provided by the facilities in HPR II that reported such charity care for that year was 4.1% of all reported total gross patient revenues. In that same year, no charity care was reported by FSSC on the spreadsheet provided by VHI. As such, should the proposed project receive approval, FSSC is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR II.

Table 3. HPR II 2018 Charity Care Contributions

| Health Planning Region II | | | |
|--|-------------------------------|---|--|
| 2018 Charity Care Contributions at or below 200% of Federal Poverty Level | | | |
| Hospital | Gross Patient Revenues | Adjusted Charity Care Contribution | Percent of Gross Patient Revenue: |
| Novant Health UVA Health System Prince William Medical Center | \$495,433,432 | \$44,647,076 | 9.01% |
| Sentara Northern Virginia Medical Center | \$789,301,159 | \$56,962,621 | 7.22% |
| Inova Mount Vernon Hospital | \$479,308,693 | \$25,072,214 | 5.23% |
| Inova Alexandria Hospital | \$924,056,506 | \$46,277,537 | 5.01% |
| Inova Fairfax Hospital | \$3,422,077,165 | \$157,062,195 | 4.70% |
| Inova Loudoun Hospital | \$730,947,536 | \$26,227,153 | 3.59% |
| Novant Health UVA Health System Haymarket Medical Center | \$255,870,637 | \$8,844,583 | 3.46% |
| Inova Fair Oaks Hospital | \$672,995,830 | \$22,827,171 | 3.39% |
| Virginia Hospital Center | \$1,361,001,590 | \$32,175,893 | 2.36% |
| StoneSprings Hospital Center | \$204,255,017 | \$2,703,533 | 1.32% |
| Reston Hospital Center | \$1,323,668,487 | \$14,710,834 | 1.20% |
| Total \$ & Mean % | \$10,658,916,052 | \$437,510,810 | 4.1% |

Source: 2018 VHI Data

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

The State Medical Facilities Plan (SMFP) contains criteria and standards for mobile equipment including mobile renal lithotripsy equipment. DCOPN notes that the Commissioner determined that mobile services should be reviewed and authorized on a site-specific basis.³ Accordingly, DCOPN no longer evaluates the need to add mobile equipment to the inventory in a PD or HPR. DCOPN further notes that once approved by the Commissioner to introduce or establish a mobile lithotripsy service, a facility may unilaterally increase the number of days of service without DCOPN review or authorization by the Commissioner. As such, while the average annual utilization of existing and approved mobile services (12VAC5-230-70.B) standard has not been formally set aside, it has not been applied in recent years. DCOPN observes that rarely do mobile renal lithotripsy providers meet this volume standard. DCOPN currently focuses its review of mobile renal lithotripsy projects on the public need for establishing a new site rather than anticipated service volume. Additionally, DCOPN notes that there is no definition within the SMFP of minimum service volume for fixed renal lithotripsy units. In recent staff reports, DCOPN has concluded, based on the factors above, that it is unable to perform the calculations within this section of the SMFP. DCOPN concurs with this determination and, solely for the purposes of this staff report, adopts this stance.

The SMFP contains standards and criteria for the establishment of lithotripsy services. They are as follows:

Part I. Definitions and General Information

12VAC5-230-70. Calculation of Utilization of Services Provided with Mobile Equipment.

A. The minimum service volume of a mobile unit shall be prorated on a site-by-site basis reflecting the amount of time that proposed mobile units will be used, and existing mobile units have been used, during the relevant reporting period, at each site using the following formula:

| | | | | |
|---|---|--|---------|---|
| Required full-time minimum service volume | X | Number of days the service will be on site each week | X 0.2 = | Prorated minimum services volume (not to exceed the required full-time minimum service volume) |
|---|---|--|---------|---|

Pursuant to 12VAC5-230-660(B), the required full-time minimum service volume is 750 renal lithotripsy procedures annually. According to the applicant, the proposed service will operate two half days a week, which DCOPN concludes equals one day per week. Therefore, the prorated minimum service volume calculation is as follows:

750 procedures X 1 days per week X 0.2 = 150 renal lithotripsy procedures minimum

³ COPN Request No. VA-7849 Commissioner's Decision p.2

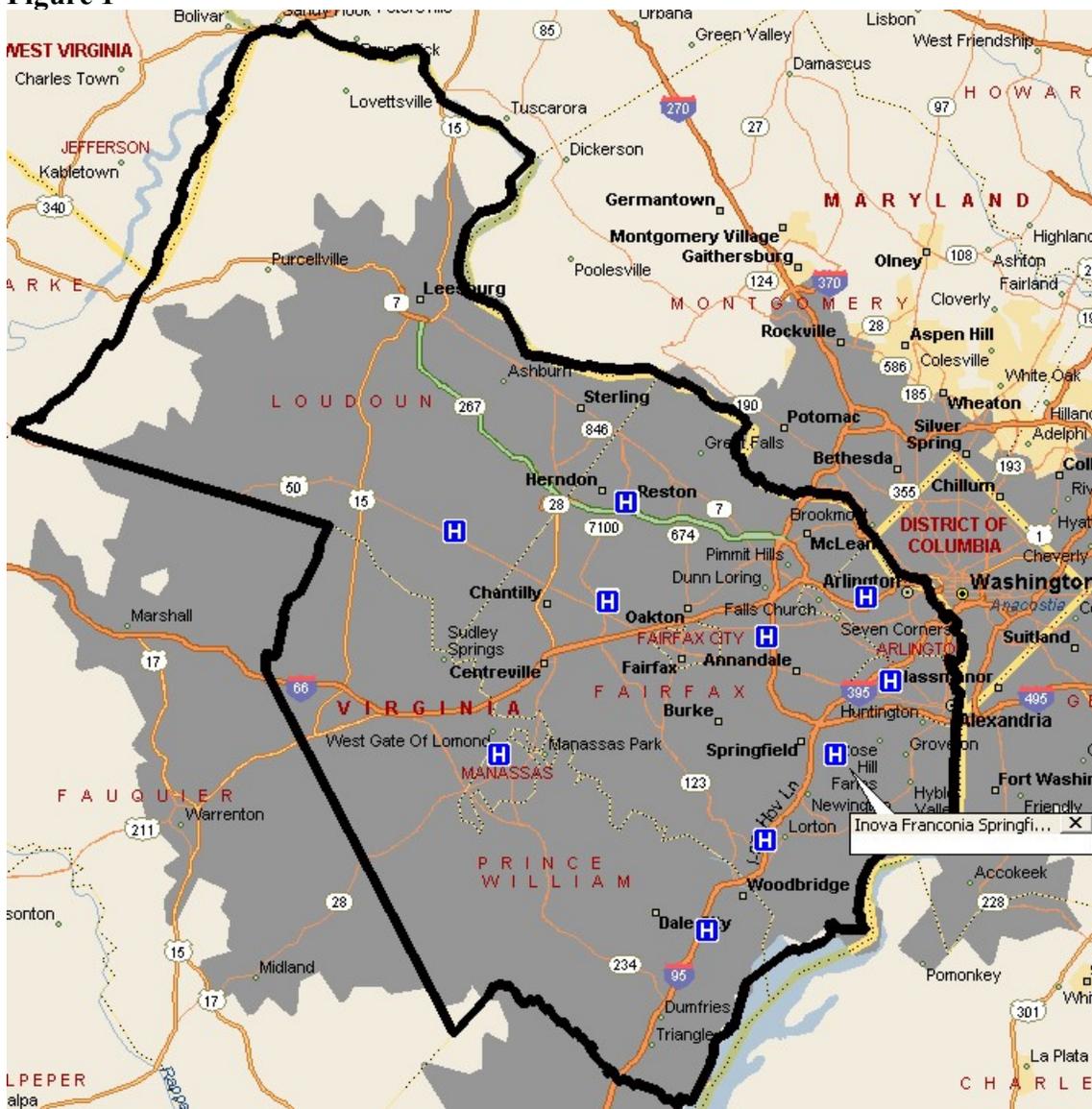
Part VIII. Lithotripsy Service

12VAC5-230-650. Travel Time.

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

The heavy dark line in Figure 1 identifies the boundaries of HPR II. The grey shading illustrates the area that is within a thirty-minute drive under normal driving conditions of all renal lithotripsy service providers in HPR II. Based on the shaded area in Figure 1, it is reasonable to conclude that 95% of the population of HPR II is within 30 minutes driving-time one-way under normal traffic conditions of renal lithotripsy services.

Figure 1



12VAC5-230-660. Need for New Service.

A. Preference may be given to a project that establishes new renal or orthopedic lithotripsy services at a new facility through contract with, or by lease of equipment from, an existing service provider authorized to operate in Virginia, and the facility has referred at least two appropriate patients per week, or 100 appropriate patients annually, for the relevant reporting period to other facilities for either renal or orthopedic lithotripsy services.

The proposed project seeks to establish a new renal lithotripsy service at an existing facility through contract with United Medical Systems, the current vendor of mobile lithotripsy services for other Inova facilities in HPR II. In both their application and their responses to the completeness questions, the applicant did not address any referrals by FSSC to any other locations, including Inova Lorton. As such, DCOPN cannot conclude that the applicant has met this threshold.

B. A new renal lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 750 renal lithotripsy procedures annually.

Based on the calculation for 12VAC5-230-70.A, the prorated minimum service requirement for FSSC's proposed mobile lithotripsy site is 150 procedures annually. As discussed above, the applicant stated that lithotripsy cases that historically were performed at Inova Lorton, would be performed at FSSC. In 2018, Inova Lorton performed 91 lithotripsy procedures. The applicant states that they anticipate performing 141 lithotripsy cases in their first year of operation and 144 cases in their second year of operation.

While this standard has not been formally set aside, it has not been applied in recent years. DCOPN observes that renal lithotripsy providers rarely meet this volume standard. DCOPN currently focuses its review of mobile renal lithotripsy projects on the public need for establishing a new site, rather than anticipated service volume. While DCOPN is not bound by precedent, similar projects have been recommended for approval by DCOPN, and subsequently approved by the Commissioner, because they had little or no capital cost and resulted in improved geographic access and timelier scheduling for renal lithotripsy services. Furthermore, the proposed project will not increase the inventory of lithotripsy sites in HPR II, because the applicant has proffered that, should the proposed project be approved, Inova Lorton will cease to offer mobile renal lithotripsy at that location once the proposed project is completed.

C. A new orthopedic lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 500 orthopedic lithotripsy procedures annually.

Not applicable. The applicant is not proposing to introduce or establish a new orthopedic lithotripsy service.

12VAC5-230-670. Expansion of Services.

A. Proposals to expand renal lithotripsy services should demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 75 procedures annually at all sites served by the vendor or provider.

Not applicable. FSSC is proposing to establish a new renal lithotripsy service.

B. Proposals to expand orthopedic lithotripsy services should demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 500 procedures annually at all sites served by the vendor or provider.

Not applicable. FSSC is proposing to establish a new renal lithotripsy service.

12VAC5-230-680. Adding or Expanding Mobile Lithotripsy Services.

A. Proposals for mobile lithotripsy services should demonstrate that, for the relevant reporting period, at least 125 procedures were performed and that the proposed mobile unit will not reduce the utilization of existing machines in the health planning region.

Not applicable. TOA currently does not provide mobile renal lithotripsy services.

B. Proposals to convert a mobile lithotripsy service to a fixed site lithotripsy service should demonstrate that, for the relevant reporting period, at least 430 procedures were performed and the proposed conversion will not reduce the utilization of existing providers in the health planning district.

Not applicable. The proposed project is to establish a new mobile renal lithotripsy service.

12VAC5-230-690. Staffing.

Lithotripsy services should be under the direction or supervision of one or more qualified physicians.

As discussed above, the proposed lithotripsy service will be operated by qualified technicians supplied by the mobile vendor and will be supervised by a board-certified urologist who is already on the staff at FSSC.

Required Considerations Continued

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

HSANV asserts, and DCOPN agrees that, as the proposed project would effectively serve as a replacement for the service that is being discontinued at Inova Lorton, there is no indication that the proposed project would introduce beneficial competition for patients in HPR II.

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

The applicant asserts, and DCOPN agrees, that approval of the project is unlikely to impact existing services or facilities. The proposed project is neutral in regard to mobile renal lithotripsy sites as Inova Lorton, which is located 8.3 miles from FSSC, will cease to offer lithotripsy services should the proposed project be approved. Moreover, the applicant intends for FSSC to assume all of the mobile renal lithotripsy cases that are currently being treated at Inova Lorton. Based on the information above, DCOPN concludes that the proposed project is highly unlikely to materially affect the utilization and efficiency of existing services and facilities.

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

DCOPN concludes that the proposed project is feasible and would have no effect on the availability of financial or human resources. As discussed above, there are no capital costs associated with the proposed project. The proposed project would not require any special construction, remodeling, or purchase of equipment. The mobile lithotripsy equipment would be operated by qualified technicians supplied by the mobile vendor and would be supervised by a board-certified urologist who is already on the staff at FSSC.

7. The extent to which the project provides improvements or innovations in the financing and delivery of health 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 services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

DCOPN and HSANV did not identify any improvements or innovations in the financing or delivery of health services, as demonstrated by the introduction of new technology, the potential for the provision of outpatient services, any cooperative efforts to meet regional health care needs, or any other factors as may be appropriate. HSANV determined, and DCOPN concurs, that mobile renal lithotripsy is widely available within HPR II and neighboring health planning regions.

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.

FSSC is not a teaching hospital or affiliated with a public institution of higher education or medical school 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 Staff Findings and Conclusion

DCOPN finds that the proposed project to establish lithotripsy services at the Inova Franconia-Springfield Ambulatory Surgery Center is consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia.

Moreover, DCOPN finds that the project is more favorable than the alternative of the status quo. The proposed project would improve access to mobile renal lithotripsy for residents of Fairfax County without materially effecting the utilization of existing providers or increasing the number of mobile renal lithotripsy sites within the HPR. Additionally, DCOPN did not receive any letters of opposition and no attendees at the public hearing voiced opposition to the proposed project. Moreover, DCOPN notes that HSANV voted unanimously to recommend approval to the proposed project.

Finally, DCOPN finds that the proposed project does not entail a capital expenditure or other investment. No special construction, remodeling, or purchase of equipment are required. The mobile lithotripsy equipment would be operated by qualified technicians supplied by the mobile vendor and would be supervised by a board-certified urologist who is already on the staff at FSSC.

Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of the applicant's COPN request to introduce mobile renal lithotripsy at Inova Franconia-Springfield Ambulatory Surgery Center for the following reasons:

1. The proposed project is consistent with the applicable criteria and standards of the State Medical Facilities Plan, or is in harmony or general agreement with the SMFP, and the Eight Required Considerations of the Code of Virginia.
2. The project is more favorable than the alternative of the status quo.
3. Approval of the project is unlikely to affect materially the underutilization of existing facilities and services in the planning district.
4. Approval of the project will not increase the number of mobile renal lithotripsy sites in Health Planning Region II.
5. The Health Services Agency of Northern Virginia voted unanimously to recommend approval and there is no known opposition to the project.

6. The project does not entail a capital expenditure or other investment.

Recommended Condition

Franconia-Springfield Surgery Center, LLC will provide mobile renal lithotripsy services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 4.1% of Franconia-Springfield Surgery Center, LLC's total patient services revenue derived from mobile renal lithotripsy services provided at Inova Franconia-Springfield Ambulatory Surgery Center 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. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Franconia-Springfield Surgery Center, LLC 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. The value of charity care provided to individuals pursuant to this condition shall be based on 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.