



COMMONWEALTH of VIRGINIA

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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February 25, 2020

Thomas J. Stallings, Esquire
McGuireWoods
800 East Canal Street
Richmond, Virginia 23219

Elizabeth A. Breen, Esquire
Hunton Andrews Kurth
951 East Byrd Street
Richmond, Virginia 23219

**RE: CERTIFICATE OF PUBLIC NEED
(COPN) REQUEST NUMBER VA-8436
Reston Hospital Center
Fairfax County, Planning District (PD) 8
Health Planning Region II
Introduction of Open Heart Surgery Services
(the "Reston Hospital project")**

**Good Cause Party:
Inova Health Care Services**

Dear Mr. Stallings and Ms. Breen:

In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et seq.*) of the Code of Virginia, I have reviewed the application submitted and record compiled in relation to the above-referenced proposed project. As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters, listed therein, that must be taken into account in making a determination of public need.

I have received, reviewed and adopted the enclosed findings, conclusions and recommended decision of the adjudication officer who convened the informal fact-finding conference to discuss the application, and who reviewed the administrative record pertaining to the proposed project.



Based on my review of the project and on the recommended decision of the adjudication officer, I am denying the proposed project captioned above. The project does not merit approval and should not receive a Certificate. It is not necessary to meet a public need.

The reasons for my decision include the following:

- (i) The Reston Hospital project is not fully consistent with the SMFP;
- (ii) There is no evidence of an unmet need for open heart surgery services in PD 8;
- (iii) The less costly, more effective and more efficient alternative reasonably available is maintaining the status quo in PD 8;
- (iv) Approval of the Reston Hospital project would likely decrease utilization at existing providers of open heart surgery services – a type of surgery that consists of a highly-specialized, high-acuity, and utilization-sensitive subset of cardiac surgery procedures;
- (v) The project is unnecessarily duplicative of two existing and accessible open heart surgery services in PD 8;
- (vi) The project would not significantly improve geographic or financial access for residents of PD 8 to open heart surgery services;
- (vii) Open heart surgery services are fully accessible and available in PD 8, in a timely manner and within an applicable driving time standard;
- (viii) Inova and Virginia Hospital Center, the existing providers of open heart surgery in PD 8, oppose the Reston Hospital project; and
- (ix) If approved, the Reston Hospital project would likely be a low-volume program.

In accordance with Rule 2A:2 of the Rules of the Supreme Court of Virginia, any aggrieved party to an administrative proceeding choosing to appeal a case decision* shall file, within 30 days after service of the case decision, a signed notice of appeal with “the agency secretary.” I would consider such a notice sufficiently filed if it were addressed and sent to the Office of the State Health Commissioner, and timely received by that office, at the James

* In accordance with Va. Code § 2.2-4023, the signed original of this final agency case decision “shall remain in the custody” of the Department, while the applicant is receiving a photocopy of the original letter and attachment.

Thomas Stallings, Esq.
Elizabeth Breen, Esq.
February 25, 2020
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Madison Building, Thirteenth Floor, 109 Governor Street, Richmond, Virginia 23219. Under the Rule, when service of a decision is "accomplished by mail," three days are added to the 30-day period.

Sincerely,

A handwritten signature in blue ink that reads "M. Norman Oliver MD". The signature is fluid and cursive, with the "MD" at the end being more distinct.

M. Norman Oliver, MD, MA
State Health Commissioner

Encl.

cc (via email):
Gloria Addo-Ayensu, MD, MPH
Director, Fairfax Health District
Amanda Lavin, Esq.
Assistant Attorney General
Dean Montgomery
Executive Director, Health Systems Agency
of Northern Virginia
Deborah Waite,
Virginia Health Information
Erik O. Bodin, III
Director, Division of Certificate of Public Need
Douglas R. Harris, JD
Adjudication Officer

**RECOMMENDATION
TO THE STATE HEALTH COMMISSIONER
FOLLOWING AN INFORMAL FACT FINDING
CONFERENCE REGARDING CERTIFICATE
OF PUBLIC NEED (COPN) or “Certificate”
REQUEST NUMBER VA-8436
RESTON HOSPITAL CENTER, LLC
Fairfax County, Planning District (PD) 8
Health Planning Region (HPR) II
Introduction of Open Heart Surgery Services**

**Good Cause Party to the Proceedings:
Inova Health Care Services**

I. Introduction

This recommended case decision is submitted to the State Health Commissioner (hereinafter, the “Commissioner”) for his consideration and adoption. It follows an informal fact-finding conference (IFFC) conducted in accordance with the Virginia Administrative Process Act (APA), Virginia Code § 2.2-4000 *et seq.*,¹ and is made upon a review of the Virginia Department of Health’s (the “Department”) administrative record of the above-captioned application for a COPN.

This recommended decision discusses the statutory considerations set forth in Virginia Code § 32.1-102.3, which the Commissioner must consider in determining whether to grant a COPN.

II. Authority

Article 1 of Chapter 4 of Title 32.1 (§ 32.1 – 102.1 *et seq.*) of the Virginia Code (the “COPN law”) addresses medical care facilities and provides that “[n]o person shall commence any project without first obtaining a [Certificate] issued by the Commissioner.”

This article defines “[p]roject” to include, in part, the “[i]ntroduction into an existing medical care facility of any new . . . open heart surgery . . . [services], which the facility has never provided or has not provided in the previous 12 months.” The COPN law defines “[m]edical care facility” to include, in part, a “[g]eneral hospital[.]”² The project proposed in the above-captioned application falls within these statutory definitions and the COPN law is applicable.

¹ *Specifically*, Va. Code § 2.2-4019.

² Va. Code § 32.1-102.1, definitions of “[p]roject,” items 5 and 7, and “[m]edical care facility.”

III. Preliminary Findings of Fact; Procedural Background

1. Reston Hospital Center is a 231-bed hospital located in northwest Fairfax County, PD 8, HPR II. It is operated by Reston Hospital Center, LLC ("Reston Hospital"), a limited liability company formed under the laws of Delaware. The ultimate corporate parent of the limited liability company is HCA Healthcare, Inc.
2. Reston Hospital has submitted an application for a COPN proposing to introduce open heart surgery services at Reston Hospital Center. Reston Hospital's application was given the identification of COPN Request Number VA-8436. The total capital cost of the project is \$2,482,404. These costs would be covered by accumulated reserves.
3. On May 22, 2019, the Health System's Agency of Northern Virginia (HSANV), a regional health planning agency existing pursuant to Virginia law to cover HPR II,³ forwarded its staff report (the "HSANV staff report") on the application submitted by Reston Hospital (the "Reston Hospital project"), recommending that its board of directors recommend that the Commissioner deny the project, and informed the Department's Division of Certificate of Public Need (DCOPN)⁴ that HSANV's board of directors had voted to recommend denial of the project.
4. On May 30, 2019, DCOPN issued its staff report (the "DCOPN staff report") recommending that the Commissioner deny the Reston Hospital project.
5. On June 3, 2019, Inova Health Care Services ("Inova"), which operates several hospitals and other facilities in PD 8, submitted a petition seeking to show good cause as to why it should become a party to the proceedings on the Reston Hospital project pursuant to the COPN law.⁵
6. On December 11, 2019, two informal fact finding conferences were held. The first gave Inova an opportunity to be heard on its petition seeking to show good cause and the second gave Reston Hospital the opportunity to present its case that its application be approved. The executive director of HSANV attended the IFFC and discussed his agency's recommendation that the Reston Hospital project be denied. A health facilities planning analyst from DCOPN also attended the IFFC and presented that division's staff report. The close of the adjudicatory record on the project occurred on January 30, 2020.
7. On February 5, 2020, the Commissioner issued a case decision, finding that Inova has shown good cause and is a party to the proceedings on the Reston Hospital project.
8. The factual basis underlying the present recommended decision consists of evidence in the administrative record, including information contained in the application, the HSANV staff report, the DCOPN staff report (both of which are incorporated into this document in order to provide evidence and argument that corroborates the recommendation made below), the transcript of the IFFC, and IFFC-related submittals made by the parties, i.e., Reston Hospital by counsel, Inova by counsel, and HSANV, as well as submittals made by DCOPN.

³ Va. Code § 32.1-122.05

⁴ DCOPN is the work unit, or division, within the Department that is composed of the Commonwealth's professional facilities planning staff.

⁵ Va. Code § 32.1-102.6 (D).

IV. Findings of Fact and Conclusions of Law

A. The Proposed Project in Relation to the Eight Statutory Considerations. Facts and conclusions about the project regarding each statutory consideration include:

- 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 access to care.**

Reston Hospital asserts that approval of it project

is necessary to improve access to lifesaving care for PD 8 residents. Heart disease remains the leading cause of death in America. . . . Existing open heart surgery services are not well distributed in PD 8. [Virginia Hospital Center] is located outside of the Capital Beltway, and Inova Fairfax is located immediately outside the Beltway.⁶

Inova states that PD 8 residents “continue to have *geographic* access to open heart surgery services well within the drive time standard set forth in the applicable provisions of the SMFP (12 VAC 5-230-440).”⁷ HSANV observes that “a new program is not necessary to assure or otherwise permit reasonable geographic access to the service.”⁸ DCOPN concludes that the driving time standard is met, despite frequent traffic congestion, and that “[t]here is no evidence of an unmet need for open heart surgery services in PD 8.”⁹ I agree.

Regarding financial access, there is little evidence to suggest that approval of the project would increase access for indigent residents of PD 8. HSANV observes that Reston Hospital “serves relatively few Medicaid and other medically indigent persons” and

[t]he argument that a Reston Hospital [open heart surgery] program would enhance economic access is . . . problematic. Reston Hospital Center, and other Hospital Corporation of America hospitals in Virginia, have a long history of high charges and of relatively low levels of charity care and service to the medically indigent.¹⁰

No evidence suggests that PD 8 cannot continue to meet the public need with the effective operation of its current armamentarium of open heart surgery services. PD 8 is well served by two existing open heart surgery providers, both of which are within 60 minutes’ driving time for the overwhelming majority of PD 8 residents.

⁶ Reston Hospital Proposed Findings and Conclusions at 14.

⁷ Inova Proposed Findings and Conclusions at 6. Italics in original.

⁸ HSANV Staff Report at 10.

⁹ DCOPN Staff Report at 3, 22.

¹⁰ HSANV Proposed Findings and Conclusions at 4, 5.

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;

Reston Hospital states that its project “has broad support, including support from Virginia legislators, Virginia’s largest insurer, and many well-respected physicians.”¹¹

HSANV observes that

[a]s with nearly all COPN proposals, [Reston Hospital] presents evidence of some community support for the project. In comparison with other COPN proposals, community knowledge of and support for the project appears to be modest but positive.¹²

DCOPN both lists both letters supporting the Reston Hospital project and lists letters opposing it.¹³

Consideration of popular support, which is to be expected for new health care services, should yield when unneeded proliferation of a high acuity service, with a recognized volume-quality correlation,¹⁴ is being proposed.

(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;

Reston states that

[t]here are no reasonable alternatives to the project. The status quo is not a reasonable alternative. The population per open heart program in PD 8 is significantly higher than in any other planning district and is growing. The volume of open heart procedures in PD 8 is projected to increase significantly for the foreseeable future.¹⁵

Inova states that “[t]he most reasonable and better alternative is to deny [the Reston project] and maintain the status quo.”¹⁶ HSANV observes that

[t]here are two open heart surgery programs in Northern Virginia. Both are successful, high volume services that have average charges per discharge that are considerably lower than those reported elsewhere in Virginia. In addition, Inova Fairfax Hospital and Virginia Hospital Center serve medically indigent patients

¹¹ Reston Proposed Findings and Conclusions at 15.

¹² HSANV Proposed Findings and Conclusions at 6.

¹³ DCOPN Staff Report at 4-5.

¹⁴ See Inova Supplemental Exhibits 12, 13.

¹⁵ Reston Proposed Findings and Conclusions at 15.

¹⁶ Inova Proposed Findings and Conclusions at 11.

equitably and provide substantial amounts of charity care. Both of these services have capacity to accommodate increased demand.¹⁷

Maintaining the status quo is the only reasonable alternative. Maintaining the status quo would meet the needs of the population in a less costly, more efficient, and more effective manner.

(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;

HSANV is a regional health planning agency that covers HPR II (coterminous with PD 8). HSANV recommends that the Commissioner deny the Reston Hospital project for the reasons listed in the DCOPN staff report.¹⁸

(iv) Any costs and benefits of the project;

The actual capital costs of the Reston Hospital project – less than \$2.5 million – would not be unreasonable if the project would meet a public need.

Reston asserts that the benefits of the Reston Hospital project are improved access, without delay, to lifesaving medical services, and the benefit of collocating open heart surgery services with a Level II Trauma center, continuity of care, market competition and greater access for women to open heart surgery.¹⁹

These benefits, if they exist, are outweighed by the general conclusion that no need for the project exists. Timeliness is not the benefit it seems, as most open heart surgery cases are not emergent cases. No law requires a Level II trauma center to have open heart surgery available. Inova observes that “the fact remains that trauma patients almost never require cardiac surgery.”²⁰

Existing services are within access-based standards contained in provisions of the SMFP. Further, the need to protect the proficiency and quality of existing programs performing exacting high-acuity, acute-care services, such as open heart surgery services, suggests that some apparent benefits come at a cost.

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

Reston Hospital states that it

accepts all patients regardless of ability to pay or payment source. Reston has a generous charity policy under which medically necessary services are provided at no charge to uninsured patients whose income is at or below 200% of the federal poverty income guidelines. Furthermore, Reston discounts medically necessary

¹⁷ HSANV Proposed Findings and Conclusions at 6.

¹⁸ DCOPN Staff Report at 6.

¹⁹ Reston Hospital Proposed Findings and Conclusions at 17.

²⁰ Inova Rebuttal at 6.

care for all patients without insurance who do not otherwise qualify for charity care by 88%, regardless of their income level.²¹

HSANV states that Reston Hospital

professes a willingness to serve the medically indigent and Medicaid patients equitably. Nevertheless, the hospital routinely reports low levels of charity care and relatively small Medicaid patient caseloads. Coupled with the highest charges [in] the region, the [Reston] operating environment is not conducive to enhancing or otherwise facilitating financial access to care.

There is nothing in the [Reston] application, or in recent [Reston] operations, to support the argument that an open heart surgery program at the hospital would improve economic access to care for anyone.²²

Further, HSANV states that “[i]n 2016 the overall [Reston Hospital] charity care level was 0.6% of gross charges and 0.4% for surgery patients.”²³ Based on the facts, I do not believe the Reston Hospital project would be financially accessible to residents of PD 8 to an appropriate degree.

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

No additional factors relating to the review of this project are clearly remarkable or appear to call for the exercise of the Commissioner’s discretion in identifying or evaluating them in relation to the proposed project.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

The COPN law requires that “[a]ny decision to issue . . . a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan [“SMFP”]”²⁴ The SMFP, found in the Virginia Administrative Code (VAC) at 12 VAC 5-230-10 *et seq.*, includes several provisions applicable to a project such as the Reston Hospital project, discussed below.

1. Driving Time. The SMFP’s provisions relating to open heart surgery services includes a driving time standard calling for such services to be within 60 minutes driving time of 95 percent of the population of a PD.²⁵

DCOPN found that “open heart surgical services are already well within a one-hour drive under normal conditions for nearly all resident of the planning district.”²⁶ HSANV states that “[a] new service delivery site at Reston Hospital [], or elsewhere in the planning region, would

²¹ Reston Proposed Findings and Conclusions at 16.

²² HSANV Proposed Findings and Conclusions at 7.

²³ HSANV Staff Report at 10.

²⁴ Va. Code § 32.1-102.3.

²⁵ 12 VAC 5- 230-440.

²⁶ DCOPN Staff Report at 8.

reduce average travel times slightly for some. But an additional program . . . is not needed to assure or enhance geographic or economic access.”²⁷ I agree.

This section of the SMFP also requires all-time availability. Reston Hospital represents that the service that would result from the proposed project would be available “24 hours a day, seven days a week.”²⁸

2. Determining Need for a New Service. The SMFP contains several provisions relating to whether a new open heart surgery service should be established. The first is that a candidate hospital should not be allowed to establish open heart surgery services unless it has an existing cardiac catheterization service that has “performed an average of 1,200 [diagnostic equivalent procedures (DEPs)]” annually.²⁹ Reston Hospital states that it performed 1,587 DEPs in 2018 – “the fifth consecutive year Reston [Hospital] exceeded 1,200 DEPs.”³⁰ Reston Hospital appears consistent with this standard.

The SMFP contains a key standard that

[n]o new open heart services should be approved unless . . . [o]pen heart surgery services located in the [PD] performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period . . .³¹

Disagreement exists over what constitutes a “procedure” for purposes of applying this provision. The SMFP defines “procedure” as “a study or treatment or a combination of studies and treatments identified by a distinct ICD-9 or CPT code performed in a single session on a single patient.”³² Reston Hospital believes that each ICD or CPT code performed should be counted, resulting in an apparent total of 3,025 procedures in 2018. The average between the two open heart surgery services in PD 8, then, would be 1,513 – 378 percent of the standard.³³

Inova states that

[t]he SMFP’s definition of “procedure” does not define nor otherwise contemplate treating each ICD procedure code performed during a surgical case as a separate “procedure.” If that is what the definition required, all that would have been needed is a simple directive to count the relevant codes; there would have been no reason to refer to studies or treatments or combinations of studies or treatments, or to include a limitation that they be “performed in a single session on a single patient. The language of the definition cannot be reconciled with the tortured reading suggested by Reston.”³⁴

It would seem logical that complex procedures, or surgical cases, can and often do have multiple procedure codes, as contemplated by the definition of “procedure.”

²⁷ HSANV Rebuttal at 11.

²⁸ Reston Hospital Proposed Findings and Conclusions at 17.

²⁹ 12 VAC 5-230-450 A.1.

³⁰ Reston Hospital Proposed Findings and Conclusions at 18.

³¹ 12 VAC 5-230-450 A.2.

³² 12 VAC 5-230-10.

³³ Reston Proposed Findings and Conclusions at 18.

³⁴ Inova Argument in Support of the Good Cause Petition at 3.

Regardless, DCOPN and Reston appear to agree that 1,579 open and closed heart cases were performed in PD 8 in 2017. This leads to an average of 789 per service,³⁵ exceeding the 400-procedure threshold. Reston Hospital appears to be consistent with this standard.

The SMFP contains an additional standard that

[n]o new open heart services should be approved unless . . . [t]he proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without significantly reducing the utilization of existing open heart surgery services in the health planning district.³⁶

As Inova observes,

Reston Hospital states it will perform 268 open heart procedures in the first year of operation of its open heart surgery program and 277 open heart procedures in the second year of operation. But Reston's projections identify the total number of ICD billing codes it anticipates will be associated with open heart surgeries performed on patients at Reston Hospital. Its projections do not identify projected open heart surgery patients (i.e., with a trip in and out of the operating room for open heart surgery counting as one procedure). As the HSAHV Staff Report observes, "Reston's argument . . . is based on a redefinition of open heart surgery capacity and service volume metrics used in determining public need for such services" that is "[c]ontrary to the understanding and practice throughout the history of COPN service planning and regulation in Virginia."³⁷

Reston Hospital's reliance on counting all ICD billing codes substantially inflates its projected surgery volume. As HSAHV observes, "[b]ecause several coded procedures may be performed during a single patient visit to the operating room, a shift from a patient visit count to a coded procedure count more than doubles the surgery volume counts and projections for [Reston Hospital]."³⁸ HSAHV maintains that Reston Hospital's "argument that its proposal is consistent with the Virginia SMFP is flawed in that it is grounded in a quixotic revision (reinterpretation) of established open heart service planning metrics and standards."³⁹

As Inova observes, "[c]onverting ICD billing code to patients (i.e., open heart surgery cases) results in projections of just 134 open heart surgery patients in year one and 138.5 open heart surgery patients in year two." Inova believes Reston Hospital is likely to perform "far fewer than even the 134 and 138.5 surgeries that result from converting Reston's projected ICD

³⁵ Due to a recent circuit court decision (*Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner et. al.*, Civil Docket No. CL18-6997), as Inova states, ". . . there has been a change in how the Commissioner is to determine the denominator when calculating average open heart surgery utilization in the planning district under this particular subsection." Inova Rebuttal at 3. Essentially, reaching the average among existing services, or programs, not operating rooms, in a planning district is the purpose of applying this standard.

³⁶ 12 VAC 5-230-450 A.3.

³⁷ Inova Proposed Findings and Conclusions at 18; quoting HSAHV Staff Report at 7.

³⁸ HSAHV Staff Report at 8.

³⁹ HSAHV Rebuttal at 3.

billing code to open heart surgery patients.”⁴⁰ HSANV states that “[i]t is evident from [Reston Hospital’s] procedure volume projections that the program would be a low volume service.”⁴¹ I agree.

Cardiac surgery volume has remained stagnant over the last decade. According to HSANV, reported cases for operating rooms used to perform open heart surgery decreased by about 6.5 percent from 2008 to 2017.⁴² Further, Inova states that “[c]oronary artery bypass graft (“CABG”), which would comprise the majority of any open heart surgeries performed at Reston Hospital, actually has declined by 22% over the last decade.”⁴³ If open heart surgery utilization is declining, as HSANV’s review indicates, the utilization of an open heart surgery program at Reston Hospital would likely harm the utilization at existing providers of open heart surgery services, yet it would likely be a low-volume program, as well. Each of these two likelihoods stands to affect quality of patient outcomes. The Reston Hospital project is inconsistent with this standard.

3. Staffing. Reston Hospital represents that open heart surgery services at Reston Hospital Center would be under the direction of a qualified medical director, complying with the SMFP’s applicable provision regarding staffing.⁴⁴

4. Summary of the Project’s Overall Consistency with the SMFP. After reviewing the administrative record, including the application, the completeness question responses, the transcript of the IFFC, the HSANV staff report, the DCOPN staff report, and the applicant’s and good-cause party’s post-IFFC submissions, I conclude that the Reston Hospital project is not fully consistent with the SMFP.

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.

Reston Hospital states that its project will foster beneficial institutional competition and that a

lack of competition allows the dominant provider to increase costs and hamstrings managed care companies, who must accept the dominant provider’s demands for reimbursement.⁴⁵

HSANV observes that,

[g]iven market conditions, cardiovascular service trends, and endemic low use rates and demand, those served at [Reston Hospital] would be drawn from the caseloads of Inova Fairfax Hospital and Virginia Hospital Center. In this sense, and to this extent, there would be increased competition for patients.

⁴⁰ Inova Proposed Findings and Conclusions at 19.

⁴¹ HSANV Rebuttal at 9.

⁴² HSANV Staff Report at 6. HSANV Rebuttal at 3.

⁴³ Inova Rebuttal at 3.

⁴⁴ Reston Hospital Proposed Findings and Conclusions at 21.

⁴⁵ Reston Proposed Findings and Conclusions at 22.

It should be understood and appreciated, however, that competitive effects can be both positive and negative, and claims of prospective beneficial competition are often fanciful. Reston Hospital Center projections and assertions notwithstanding, there is no indication, and no reason to believe, that the [Reston Hospital] project would result in beneficial price competition. [Reston Hospital] charges are likely to be much higher than those of Inova Fairfax Hospital and Virginia Hospital Center. Nor is there likely to be competition to serve Medicaid and other indigent patients.⁴⁶

HSANV states further that

[a]n examination of PD 8 demography, expressed demand for cardiovascular care, and cardiovascular service use rates and trends show that an additional open heart surgery program is not needed or warranted.⁴⁷

I believe that the competitive effect of approving the Reston Hospital project would not be beneficial.

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 or facilities.

No evidence in the record indicates that the two existing providers are not able to meet the public need for open heart surgery services in PD 8. HSANV states that “[d]emand for the specialized cardiovascular services subject to COPN regulation is inherently low in northern Virginia.”⁴⁸

HSANV observes that

[Reston Hospital] and its consultant Sg2 include pediatric open heart surgical cases and transcatheter aortic valve replacement (TAVR) cases in the baseline data they use to document and project demand for open heart surgery in Northern Virginia. Reston Hospital [] does not propose to offer pediatric open heart surgery or perform TAVR procedures.⁴⁹

The Reston Hospital project would be unnecessarily duplicative of two efficient area services, and would likely be a low-volume service.⁵⁰

Inova raises concerns over the effect on the positive relationship between high volume and quality outcomes, and has placed several scholarly articles to back its position into the record.⁵¹ Exacting surgical procedures, such as open heart surgical procedures, require a high level of clinical skill and depth to the surgical team. Normally, such services, when regulated, have been protected from proliferation, based on the demonstrated positive linkage of reasonably

⁴⁶ HSANV Proposed Findings and Conclusions at 7.

⁴⁷ HSANV Rebuttal at 6.

⁴⁸ HSANV Rebuttal at 11.

⁴⁹ HSANV Rebuttal at 4.

⁵⁰ A third open heart surgery service, at Inova Alexandria Hospital, recently ceased operations due to “[i]nsufficient demand and low service volume,” according to HSANV. HSANV Staff Report at 8.

⁵¹ Inova Supplemental Exhibits 12, 13.

high utilization with proficiency, good outcomes and lessened instances of mortality and morbidity.

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.

The feasibility of the Reston Hospital project is probable, although it would likely be a low-volume service. The project may come at the considerable expense of staffing or utilization at area open heart surgery services. Inova states that its cardiac surgery program, at Inova Fairfax Hospital, requires 49.4 clinical FTEs, and has a 32.4 percent vacancy, "meaning that 16 of the 49.4 positions are open."⁵² Reston Hospital would likely realize considerable financial benefits from the project. There are no costs of construction, as the project involves retrofitting existing space in a surgical suite. Reston Hospital states that

HCA has a multi-faced approach to staff development that places particular emphasis on expanding the pool of new staff. Reston intends to staff its open heart surgery services by training its own staff and through transfers within HCA, which is how HCA has successfully started all of its programs.⁵³

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.

Not applicable.

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 serve (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.

Not applicable. But Reston draws attention to a list containing over a dozen local and regional schools and institutions of higher learning with which it "has [clinical training] affiliations."⁵⁴

B. Conclusion. Based on the findings of fact made above and in light of applying the eight statutory considerations, as a whole, I conclude that Reston Hospital **has not** demonstrated a public need for the open heart surgery project it has proposed.

⁵² Inova Proposed Findings and Conclusions at 25.

⁵³ Reston Proposed Findings and Conclusions at 23-24.

⁵⁴ Reston Proposed Findings and Conclusions at 25.

V. Recommendation

Based on my overall assessment, I conclude that the proposed project does not merit approval. Reston Hospital should not receive a Certificate authorizing its proposed project. The Reston Hospital project is not necessary to meet a public need.

In addition to conclusions drawn throughout this document, specific reasons for my recommendation include:

- (i) The Reston Hospital project is not fully consistent with the SMFP;
- (ii) There is no evidence of an unmet need for open heart surgery services in PD 8;
- (iii) The less costly, more effective and more efficient alternative reasonably available is maintaining the status quo in PD 8;
- (iv) Approval of the Reston Hospital project would likely decrease utilization at existing providers of open heart surgery services – a type of surgery that consists of a highly-specialized, high-acuity, and utilization-sensitive subset of cardiac surgery procedures;
- (v) The project is unnecessarily duplicative of two existing and accessible open heart surgery services in PD 8;
- (vi) The project would not significantly improve geographic or financial access for residents of PD 8 to open heart surgery services;
- (vii) Open heart surgery services are fully accessible and available in PD 8, in a timely manner and within an applicable driving time standard;
- (viii) Inova and Virginia Hospital Center, the existing providers of open heart surgery in PD 8, oppose the Reston Hospital project; and
- (ix) If approved, the Reston Hospital project would likely be a low-volume program.

Respectfully submitted,



Douglas R. Harris, JD
Adjudication Officer

February 12, 2020