

**Health Systems Agency of Northern Virginia
Board of Directors Meeting
Video Conference Meeting
May 9, 2022**

Members Present

Michael Carrasco
Sahil Chaudhry
Linda Cook
Tom Fonseca
Pamela Kincheloe, RN
Patrice Lepczyk
Michelle Kimmel
Lydia Lawrence, RN
Sally Patterson
Douglas Samuelson
Andrew Wankum
Terry West
Maria Zlotnick

Staff Present

Ann McFeeley
Dean Montgomery

Guests (Partial List)

Elizabeth Breen, Counsel, Inova Health System
Paula Ferrada, MD, Division Chief, Trauma and Acute Care Surgery, Inova Health System
Andrew Gill, Vice President, Administrator, Inova Heart & Vascular Institute
Peter Mellette, Attorney, Williamsburg, VA
Jessica Parker, Senior Director of Strategy & Planning, Inova Health System
Alan Speir, MD, Medical Director, Cardiac Surgical Services, Inova Health System
Thomas Stallings, Counsel, HCA of Virginia
Adrian Stanton, Vice President and Chief Marketing Officer, Virginia Hospital Center
Alexander Truesdell, MD, Interventional Cardiologist, Virginia Heart

I. Call to Order

Tom Fonseca, Chairperson, Health Systems Agency of Northern Virginia (HSANV), called the meeting to order at 7:32 PM. He welcomed those present, including Lydia Lawrence a new member from Fairfax County, and reviewed the agenda.

Fonseca indicated that, among other matters, the Board would consider a certificate of public need (COPN) application from Reston Hospital Center:

- Reston Hospital Center, Establish Open Heart Surgery Service, COPN Request VA-8621.

II. Previous Minutes

Minutes of the March 14, 2022 meeting were approved as written.

III. Conflicts of Interest

Fonseca followed established HSANV conflict of interest procedures to determine whether any member of the Board had a conflict of interest on the Reston Hospital Center (RHC) application. No conflicts were declared, alleged, or otherwise identified.

IV. Review: Reston Hospital Center Establish Open Heart Surgery Service, COPN Request VA-8621

Staff Review/Report

Dean Montgomery discussed the HSANV staff evaluation of the Reston Hospital Center application. He observed that the current application is similar to and raises essentially the same planning and service development questions as RHC's 2017 and 2019 open heart surgery COPN proposals. Both were denied as not necessary to meet a public need. The 2017 application was denied in 2018, the 2019 proposal in 2020.

Examination of the RHC proposal, in the context of required COPN planning considerations and the local cardiovascular services market, found that:

- Though there have been recent increases in specialized cardiovascular service volumes at Inova Fairfax Hospital and Virginia Hospital Center, the two local cardiovascular surgery services, since RHC's 2017 and 2019 applications were considered, Northern Virginia resident service volumes and population based use rates have not increased significantly and remain far lower than Virginia, Washington metropolitan area and national levels.
- Northern Virginia has been served well by the Inova Fairfax Hospital and Virginia Hospital Center cardiovascular surgery programs. Reported costs (charges) are much lower in PD 8 than in any other planning region of the state, and among the lowest of the nearly two dozen open heart surgery services in the state.
- Contrary to RHC's assertions, existing open heart surgery programs and capacity are not poorly or inappropriately distributed. Residents of the region (PD 8) have access to quality high volume, low cost cardiovascular surgical services in less than 60 minutes travel time. Most residents have access to both programs in less than 30 minutes travel time.
- Though population based use rates remain low, there is no evidence or other indication of unmet need or suppressed demand for cardiac surgery in PD 8.

Based on these considerations and findings, and on the data and argument discussed in the staff report on the application, there is no evident public need for an additional open heart surgery service in the region.

Reston Hospital Center Presentation

Tom Stallings, legal counsel to Reston Hospital Center, presented the hospital's proposal. The principal RHC arguments offered in support of the application are summarized in the set of slides Stallings used in the presentation (Attachment 1).

Among other considerations, Stallings stated that:

- Previous RHC proposals to establish an open heart surgery service were found to satisfy all but one of the service development criteria specified in the Virginia State Medical Facilities Plan (SMFP), namely the potential negative effect on demand and service volumes at Inova Fairfax Hospital (IFH) and Virginia Hospital Center (VHC).
- Increases in surgery volumes at IFH and VHC since 2015 show that increasing demand for open and closed cardiovascular surgery shows that RHC's argument that it can establish a successful high volume program without affecting the existing services negatively was correct in 2017 and 2019. That assessment is correct today.
- It is now evident, contrary to claims of the existing services, HSANV, DCOPN and a number of interest individuals that another program is warranted and would not have negative effects on existing services.
- The need for and potential value of another cardiovascular surgery program is indicated and attested to by Anthem's support for and endorsement of the RHC proposal, holding that an additional program would be positive, resulting in lower costs and better care.
- Compared with other parts of the state, Northern Virginia is underserved in cardiovascular surgery services. The RHC program is needed to help cure this deficiency.
- An open heart surgery service is required at RHC to complement the array of services offered by the hospital, as indicated by its Level II trauma center designation and case mix index.
- RHC is the appropriate location for an additional open heart surgery service in the region. It is located near Dulles International Airport, with its potential for mass casualties, and would be the nearest service for about one-third of local residents.
- Contrary to the assumption of HSANV and other critics, RHC plans to offer transcatheter aortic valve replacement (TAVR) and other endovascular services and expects to do so by the third year of operations.
- RHC expects to develop an efficient, high volume program that will expand service choices in the region and improve access to care for much of the local population. RHC expects its cardiovascular surgery caseload to be equal to that of Virginia Hospital Center within three years.
- The RHC proposal satisfies all of the planning and service development requirements specified in the Virginia SMFP.

Board Questions, Discussion

In response to questions from the board, Stallings indicated that

- RHC has not specified, or otherwise identified, clinical leadership of the service, but will have no difficulty retaining highly qualified staff and clinical leaders when it is time to select them.
- A cardiovascular surgery program at RHC would improve geographic access, as measured by potential average travel time, for about one-third of the Northern Virginia population.
- RHC charges will be competitive with, not notably higher than, those of existing services.

- RHC will actively work to eliminate disparities in the provision of cardiovascular care and will agree to a charity care commitment equal to the regional hospital level, now about 3.4% of inpatient charges.
- Though its service volume projections and *pro forma* budget for the first two years of operations do not include potential TAVR procedures, RHC anticipates getting Medicare authorization to offer TAVR as soon as possible and plans to provide significant numbers of endovascular procedures within the third year of operations.

Public Comment

Six speakers addressed the Reston Hospital application. Two represented organizations, Inova Health System and Virginia Health (Virginia Hospital Center). Four spoke as interested individuals. All six spoke in opposition to the RHC application.

Jessica Parker, Senior Director of Strategy & Planning, Inova Health System (Inova), spoke on behalf of Inova. She argued that, as was the case with the two previous applications, the current RHC proposal is deficient in many respects and does not warrant approval. She stated that:

- The current RHC open heart surgery proposal is essentially a repeat of the 2017 and 2019 applications that were denied because there is no public need for an additional program. Nothing has changed to justify another application or program.
- RHC’s analytical approach is flawed and inflates current and projected demand for the procedures the hospital can and proposes to perform. It assumes that the increase in cases at IFH and VHC reflect increased demand for open heart surgery in PD 8. This is incorrect. Open heart surgery demand is not growing in Northern Virginia.
- RHC’s demand projections appear to be driven by a desire to meet the service volume thresholds specified in the Virginia SMFP. They are not plausible. As with its earlier proposals, an open heart surgery program at RHC is likely to be a low volume, high cost service that increases risk to some patients.
- RHC estimates and projections are sharply inconsistent with metropolitan Washington, DC, Virginia, Maryland and national open heart surgery demand and trends.

Parker’s comments are attached (Attachment 2).

Alan Speir, MD, Medical Director, Cardiac Surgical Services, Inova Health System, spoke as an interested individual. Speir opposed the RHC open heart surgery proposal, emphasizing the notable clinical and economic benefits of having two efficient, high volume services (IFH and VHC) in the region and the risk inherent in disrupting these successful programs. Speir recounted his experience in providing cardiovascular surgical care locally and his knowledge of services and practices elsewhere in Virginia. He called attention to the patient care and economic benefits of large, efficient open heart surgery programs, compared with smaller programs, which are well documented and should be taken into account. He stressed that additional low volume programs are not in the public interest; not needed locally or elsewhere in Virginia.

Speir submitted a number of professional studies and articles to the record supporting his comments and experience.

Paula Ferrada, MD, Division Chief, Trauma and Acute Care Surgery, Inova Health System, spoke as an interested individual. She opposed the application on the grounds that an RHC open heart surgery is likely to be a low volume, high risk service. Ferrada described her experience as a trauma surgeon and supervisor of trauma services. Ferrada said that virtually all cardiovascular surgery are scheduled cases. Trauma patients rarely need open heart surgery. There is no link between trauma center designation and on site availability of open heart surgery services. Cardiovascular surgery programs are not justified on the basis of emergency department service volume or trauma service availability.

Adrian Stanton, Vice President and Chief Marketing Officer, Virginia Hospital Center, spoke on behalf of Virginia Hospital Center, which opposes the RHC application. VHC opposes the application on the grounds that there has been no significant change in local conditions or circumstances since the 2017 and 2019 RHC applications were denied that warrant a third application or the approval of an open heart surgery service at RHC.

Among other considerations VHC argues that

- There is no evidence of unmet need for open heart surgery services in PD8. Approval would adversely impact use of existing services and threaten quality and patient safety.
- An open heart surgery program at RHC would not significantly improve geographic or financial access. The project is duplicative of existing, accessible open heart surgery services in PD 8 both of which are within the SMFP 60 minute driving time standard.
- Reston's proposal is not fully consistent with the SMFP, even if it is consistent with certain SMFP provisions. The status quo is a less costly, more effective, and more efficient alternative.
- Demand has not increased. Based on VHC's experience, Reston's data are over-inclusive and yield inflated estimates and projections of demand. It appears to include a variety of procedures not properly classified as open heart cases and some that RHC would not perform.

Virginia Hospital Center's comments are attached (Attachment 3).

Alexander Truesdell, MD, Interventional Cardiologist, Virginia Heart, spoke as an interested individual. Truesdell opposed the RHC proposal on the grounds that there are serious quality and related operational issues at the RHC cardiac catheterization service. Virginia Heart, one of the largest cardiology groups in the region, does not schedule therapeutic catheterization (PCI) cases at the hospital because of the problems there. Truesdell noted that he and others raised this question during the review of the 2019 proposal and emphasized that these problems are likely to carry over to a more complex cardiovascular surgery program. An open heart surgery program at RHC is likely to be a risky, low volume, high cost service.

Andrew Gill, Vice President, Administrator, Inova Heart & Vascular Institute, spoke as an interested individual. Gill opposed the RHC proposal. In discussing the changing mix of heart surgery patients, he noted that the number of coronary artery bypass graft (CABG) patients is decreasing and the number of endovascular patients is increasing. These and related patient mix considerations indicate the region is well served by the two relatively large, efficient programs now available. Adding a duplicative low volume program poses clinical and management risks that are likely to increase patient risk, increase operating costs and make staffing, already difficult, more problematic.

Final (Summary) Presentation

Stallings restated RHC's view of and rationale for the proposal. He disputed the criticism of the application by those speaking in opposition to it and rejected the critical analytical assessments of the proposal by HSANV staff, Inova Health System, and Virginia Hospital Center.

Stallings again argued that

- Current demand, recent service volumes increases, and RHC projections of likely future demand show that at least one additional program is need in PD 8.
- Existing open heart services are poorly distributed. An additional program is necessary to ameliorate this deficiency.
- RHC estimates and projections of the growth in, and demand for, cardiovascular surgery have proven superior to those of HSANV and other critics of the hospital's COPN proposals to establish an open heart surgery program.
- Reston Hospital Center is the appropriate location for a third open heart surgery service in Northern Virginia.
- Virginia Health Information (VHI), the health service data authority in Virginia, has shown that demand for cardiovascular surgery in growing rapidly in Northern Virginia.
- A Reston Hospital Center program would quickly be an efficient, high volume service, with caseloads comparable to those at Virginia Hospital Center within three years.
- Increasing demand for open heart surgery in Northern Virginia is such that RHC can attain high service volumes without reducing demand at the existing services.

Stallings concluded by asserting that the current RHC application is consistent with all applicable planning requirements, including those specified in the Virginia SMFP.

Staff Recommendations

Based on the information presented in the agency staff report on the application, on the comments and critiques submitted by opponents of the proposal, and on the problematic assumptions and assertions in the application, Montgomery recommended denial of the application. He stressed several basic facts and considerations in support of the recommendation:

- Cardiac catheterization and open heart surgery use rates are far below, 30% to 40% lower than, state and national rates. This pattern is endemic. It has been in place for more than three decades. Other than the ongoing shift to highly specialized services such as TAVR, there is little reason to expect large near term increases in open heart surgery demand, with or without an additional surgery program (or programs).
- Contrary to RHC assertions, existing cardiovascular surgery services in PD 8 are not poorly or mal distributed. They are located the region's two community hospitals which serve as regional referral centers. These programs are within reasonable travel times, 30 to 60 minutes, of all residents and have demonstrated a willingness to serve Medicaid patients and the medically indigent.
- Recent and projected use of the region's open heart operating rooms, less than one case per day on average, is far below nominal capacity. Existing programs and capacity are more than adequate to meet projected demand.

- Northern Virginia has been served well with two efficient, high volume, low cost (charge) services for several decades. Local open heart surgery charges are the lowest in Virginia, far lower than elsewhere. The 2020 PD 8 average charge of \$170,191 was only 68% of the statewide average of \$255,331.
- Average charges in Northern Virginia are a fraction of the charges for open heart surgery at RHC's sister HCA facilities with open heart surgery programs. Average 2020 charges at Henrico Doctors Hospital (\$612,371), CJW Medical Center (\$590,678) and LewisGale Medical Center (\$364,142) are more than two and three times higher than at Inova Fairfax Hospital (\$173,807) and Virginia Hospital Center (\$159,807). This pattern has held for many years. These data, and RHC's standing as the highest average charge facility in PD 8, calls into question the economic elements and projected charges in the current application.
- As was the case with RHC's 2017 and 2019 COPN applications, the project is not consistent with key elements of the Virginia State Medical Facilities Plan (SMFP), notably Subsection 12VAC5-230-450.A.3, and the regional planning principles that underlie it.

Montgomery's comments are attached (Attachment 4).

Board Deliberation and Votes

Sally Patterson offered a motion to recommend denial of the application. Lydia Lawrence seconded the motion. The motion passed by a vote of eleven in favor (Carrasco, Chaudhary, Cook, Fonseca, Kimmel, Kincheloe, Lawrence, Patterson, Samuelson, West, Zlotnick) and two (Lepczyk, Wankum) opposed.

V. Other Business

Tentative board meeting dates were set for June 13, 2022 and June 20, 2022.

VI. Adjourn

Fonseca adjourned the meeting 9:55 P.M.

Respectfully submitted,



Dean Montgomery

Attachments (4)