

VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification
Staff Analysis

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Azura Vascular Care and National Cardiovascular Partners

Azura Vascular Care River City
Richmond, Virginia

Temporarily Add Six Beds at Azura Vascular Care

Hospital

Azura Vascular Care and National Cardiovascular Partners (Azura) is a Virginia licensed outpatient surgical hospital located in Richmond, Virginia in Planning District (PD) 15, Health Planning Region (HPR) IV. Azura opened in July 2018 with two operating rooms. Certificate of public need number VA-04570 authorized the establishment of Azura with two operating rooms (ORs) specifically limited to performing outpatient surgeries for vascular access.

Background

During the COVID-19 Public Health Emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) is allowing Ambulatory Surgery Centers (ASCs) to enroll as hospitals. The purpose is to provide additional inpatient and outpatient hospital services to help address any urgent need to increase hospital capacity to take care of patients. Azura received notice from CMS of their enrollment as a hospital on 12 January 2021.

On 12 March 2020, Governor Ralph Northam issued Executive Order 51 (amended 26 May 2020) declaring a state of emergency throughout Virginia in response to the coronavirus pandemic. Executive Order 51 (EO 51) authorized "...the heads of executive branch agencies, on behalf of their regulatory boards as appropriate, and with the concurrence of their Cabinet Secretary, to waive any state requirement or regulation,..." On 23 April 2020 Dr. Norman Oliver, State Health Commissioner, under his EO 51 authority, issued a waiver to the Regulations for the Licensure of Hospitals in Virginia at 12VAC5-410-10. Specifically the waiver allows Medicare certified ambulatory surgical centers licensed as outpatient surgical hospitals that are temporarily enrolled with the CMS 1135 emergency declaration blanket waiver as a hospital to be classified as general hospitals. The waiver remains effective for the duration of the emergency declared by EO 51.

Subsequent to the initial declared state of emergency, on 20 March 2020, Governor Northam signed Executive Order 52 (EO 52) providing that notwithstanding the provisions of Article 1.1 of Chapter 4 of Title 32.1 of the Code of Virginia the State Health Commissioner (Commissioner), at his discretion, may authorize any general hospital or nursing home to

increase licensed bed capacity as determined necessary by the Commissioner to respond to increased demand for beds resulting from COVID-19. Such beds authorized by the Commissioner under EO 52 would, notwithstanding Virginia Code § 32.1-132, constitute licensed beds that do not require further approval or the issuance of a new license. EO 52 was amended on 22 June 2020 to extend the expiration of EO 52 to when EO 51 is rescinded. Both EO 51 and EO 52 remain in effect.

There are 3,226 existing licensed acute care hospital beds in PD 15, which is the Richmond metropolitan area. An additional 828 temporary acute care hospital beds have been authorized under EO 52 in PD 15, none of which have been placed into service. In total there are 4,054 acute care hospital beds available in PD 15. Current census data for those beds is not available.

Request

Azura cites a desire to help address a need to increase inpatient hospital capacity to take care of patients during the COVID-19 pandemic. Consistent with that desire, Azura offers their ability to contribute its capacity as a hospital site of service, thereby increasing hospital capacity in the community. Specifically, Azura requests authorization to temporarily add six medical/surgical (med/surg) beds. The requested beds will be in Azura's pre-op and post-op areas. The resulting bed configuration at Azura is shown in **Table 1**.

Table 1: Azura Requested Temporary Bed Inventory

Bed Type	Existing Beds	Requested Additional Beds	Resulting Available Beds
Adult ICU	0	0	0
Med/Surg	0	6	6
Total	0	6	6

It is our understanding Azura intends to retain and provide inpatient care for their post-op patients who otherwise would have required transfer to a general inpatient hospital for care due to post-op complications or need for extended recovery. Azura notes that in doing so they will reduce the inpatient burden on general inpatient hospitals in PD 15.

Azura also requested authority to "...extend the range of services provided in the ASC [Ambulatory Surgery Center]..." beyond the limitation to surgery for vascular access.

Considerations

In determining whether a need exists for the requested additional bed capacity, the State Health Commissioner established the following factors for consideration, when applicable.

1. Ongoing efforts to increase the availability of existing beds, such as suspension of elective procedures:

Azura has no existing inpatient beds. Azura provided no indication of their intention to suspend or reduce the number of surgeries performed to make the pre-op and post-op areas available or to reduce the number of patients ultimately requiring inpatient care.

Acute care hospitals in PD 15 have, at times during the declared public health emergency, suspended elective outpatient surgeries and other elective procedures to reduce the burden on the health care system to preserve resources for response to the COVID-19 pandemic.

2. The availability of professional and ancillary staff to provide care in the additional beds:

Azura has made assurances that by establishing expanded “on call” services for nurses, technicians, and physicians they will create the capability of servicing patients on a 24 hour basis, 7 days per week, it has the necessary professional staff to provide care in the added beds and throughout the facility.

3. The availability of medical supplies and personal protection equipment in the facility:

Azura did not address the availability of medical supplies and personal protection equipment (PPE) in the facility.

4. The specific plan for increasing bed capacity:

Azura has requested six med/surg beds. The additional med/surg beds will be used to retain post-op patients that would otherwise be transferred to other inpatient acute care hospitals for overnight stays due to complications. Azura did not address any reduction in surgical volume or other factors that would result in the availability of the space.

5. Where the beds will be located and the life safety code considerations of the location:

The requested beds will be located in the first floor suite of the outpatient surgical hospital in the existing pre-op and post-op spaces. Therefore, the space meets life safety code requirements for the type of patients or residents expected to occupy the space.

6. The availability of beds at other community hospitals and nursing homes in the community:

Per the current licensure data, there are 3,180 licensed inpatient acute care beds in PD 15. Nine of the ten hospitals in PD 15 have authorization to add a total of 828 more beds under EO 52. The overall bed capacity data does not inherently take into account the extent to which, due to the rapid rate of infection of COVID-19, how many new cases may arise, and thereby overwhelm the area’s capacity to treat patients, thereby jeopardizing the quality of care for residents of PD 15. However, as none of the 828 beds authorized under EO 52 in PD 15 have been opened and placed into service it would appear that there are an adequate

number of beds, at least for now. Azura's proposed increase of bed capacity by six beds is a 0.1% increase in available bed capacity in the planning district.

Azura proposes to reduce the inpatient burden on existing inpatient acute care hospitals in PD 15 by retaining their post-op patients who would require transfer to one of those other hospitals. Azura reports a transfer rate of 0.32% of their patients.

Azura has not been operational long enough to have reported their patient volume to Virginia Health Information (VHI), so no public record of Azura volume exists to which to apply the transfer rate. The most recent year for which patient volume is available from VHI for outpatient surgical hospitals is 2018. In 2018 the busiest outpatient surgical hospital in the Commonwealth performed 6,330 surgical cases per OR. At a patient transfer rate of 0.32% and adjusted to two ORs the busiest reporting (in 2018) outpatient surgical hospital in the Commonwealth would have transferred less than one (0.78) patients per week to a general acute care hospital.

Azura's webpage advertises that they are currently open nine and half hours per day (7:00am – 4:30pm), Monday – Friday. That equates to 95 available OR hours per week for two ORs. If one hour per case is allowed, which given the types of surgeries performed at Azura and the need for OR preparation and cleanup is generous, Azura has capacity to perform 95 surgical cases per week. At a patient transfer rate of 0.32% Azura would transfer less than one (0.3) patients per week to a general acute care hospital.

7. Other alternatives to adding bed capacity:

Maintain the status quo at Azura and within the community.

8. The current state of COVID-19 in the community:

At the time of this writing, the Virginia Department of Health reports that Virginia has 516,398 cases of COVID-19, and 6,650 deaths.¹ To date, the Centers for Disease Control and Prevention has confirmed 26,055,512 current cases in the United States, with 439,830 deaths.² There have been 59,943 reported cases of patients with COVID-19 in PD 15. COVID-19 remains a significant threat.

Additional Information

Currently Azura is limited by their certificate of public need (COPN no. VA-04570) to performing surgeries dedicated to vascular access. The restricted use limitation was placed on the certificate of public need (COPN) because Azura "...demonstrated a public need to provide dedicated vascular access surgical services to ensure continuity of care, timely patient access, and a lower cost patient option for ESRD patients" and that "[t]he proposed project is unlikely to have a significant negative impact upon the utilization, costs or charges of other facilities in PD

¹ <http://www.vdh.virginia.gov/coronavirus/coronavirus/covid-19-in-Virginia-cases/>

² <https://www.cdc.gov/covid-data-tracker/#global-counts-rates>

15.” The unique unmet need for vascular access surgery justified the need to add two ORs in a planning district with an existing surplus of ORs.

Because of the accepted restriction on the face of the COPN, Azura is barred from performing surgeries other than those needed to provide vascular access. EO 52 allows for the temporary addition of beds in response to the pandemic, but does not address changing the scope of services set on a COPN. A process and application form exists that changes the “services proposed to be offered” by making a “significant change” to the COPN (12VAC5-220-10). While not explicitly prohibited, the significant change process does not contemplate temporary changes to the scope of a COPN. Azura has not requested a significant change to their COPN.

Now that the early pandemic prohibition on elective surgeries has been lifted the OLC is unaware of a shortage of surgical services in the PD 15 area. Therefore there does not appear to be a need for the temporary lifting of OR use restrictions in the planning district.

Findings and Conclusions

Azura proposes to temporarily add six med/surg beds. The requested beds are to be located on the first floor suite of the outpatient surgical hospital, space that currently meets all life safety code requirements. The potential for a sudden and overwhelming increase in inpatient acute care cases resulting from COVID-19 infection remains throughout the Commonwealth. Azura has offered to temporarily add six beds in which to retain as inpatients the less than one patient per week that they historically transfer to acute care hospitals for complications. In so doing Azura’s assistance will reduce the inpatient census (at licensed capacity) of PD 15 hospitals by 0.03%. Azura, by temporarily becoming a six bed acute care hospital, will be able to bill at inpatient rates which are substantially higher than outpatient hospital rates, negating a significant cost advantage of having outpatient surgical hospitals. While there is little doubt that local inpatient hospitals are stretched thin, but since no other PD 15 EO 52 authorized beds have been opened, it is clear that inpatient capacity remains in the planning district.

A mechanism other than EO 52 exists for changing the scope of services authorized by COPN. There does not appear to be a current need for additional non-vascular access surgical capacity in PD 15 such that a change, even temporary, to the restrictions on the face of COPN number VA-04570 is warranted.

Staff Recommendations

The staff recommends the **denial** of Azura Vascular Care and National Cardiovascular Partners’ request to temporarily add six beds and increase the scope of surgical services offered at Azura. The staff’s recommendation is based on the following findings.

1. Azura has not demonstrated that, due to the reasonable expectation of a sudden and overwhelming increase in acute care patients resulting from COVID-19 infection, either

Azura or Planning District 15 has an immediate need to add six temporarily licensed inpatient beds to accommodate fewer than one patient per week.

2. There appears to be, at least for now, adequate physical inpatient bed capacity in PD 15.
3. Azura's plan and ability to obtain equipment and supplies was not addressed.
4. Azura's plan to expand bed capacity will result in a higher cost of outpatient care in return for a very small number of patients kept from being transferred to an existing acute care hospital.
5. Executive Order 52 authorization is not the appropriate vehicle for changing the scope of COPN authorized services.
6. There has not been a full review and determination of public need for, and there does not appear to be an anecdotal need for, additional outpatient surgical capacity in PD 15 at this time.