

# **VIRGINIA DEPARTMENT OF HEALTH**

## **Office of Licensure and Certification**

### **Division of Certificate of Public Need**

#### **Staff Analysis Report**

March 30, 2020

COPN Request No. VA-8485  
Tidewater Orthopaedic Associates, Inc.  
Hampton, Virginia  
Replace existing extremity MRI with a full-body MRI

#### **Applicant**

Tidewater Orthopaedic Associates, Inc. (“TOA”) is a Virginia corporation that was formed in September 1975. TOA is located in Hampton, Virginia, Planning District (“PD”) 21, Health Planning Region (“HPR”) V.

#### **Background**

TOA is an orthopedic practice located in Hampton, Virginia. TOA that treats a wide range of conditions affecting the musculoskeletal system, including arthritis, rotator cuff and SCL tears, carpal tunnel syndrome, Achilles tendonitis, and more. On May 4, 2007, the Virginia State Health Commissioner (“Commissioner”) issued COPN No. VA-04093 to TOA authorizing the addition of one extremity MRI (“E-MRI”) unit. On the certificate, the commissioner limited the replacement under the registration process of the E-MRI unit to one that is a comparable extremity unit. As explained in greater detail below, the proposed project was reviewed out of cycle due to a waiver given by the Commissioner.

There were 14 COPN authorized fixed MRI units in PD 21 in 2018, the last year for which DCOPN has data, which have a utilization rate of 61.6% (Table 1). DCOPN records show that there are two fixed MRI units that were approved by DCOPN that had not commenced operations when VDH collected the 2018 data.

**Table 1. PD 21 COPN Authorized Fixed MRI Units: 2018**

<b>Facility</b>	<b>Number of Scanners</b>	<b>Number of Scans</b>	<b>Utilization Rate</b>
Bon Secours Mary Immaculate Hospital	1	2,610	52.2%
Hampton Roads Orthopaedics and Sports Medicine (Newport News)	1	4,350	87.0%
Orthopaedic Surgery and Sports Medicine Specialists (Newport News)	1	5,326	106.5%
Riverside Diagnostic & Breast Imaging Center (Riverside Diagnostic Center - Oyster Point)	1	2,055	41.1%
Riverside Diagnostic Center - Williamsburg	1	2,370	47.4%
Riverside Regional Medical Center	2	8,043	80.4%
Sentara Careplex Hospital	2	6,021	60.2%
Sentara Geddy Outpatient Center	1	1,496	29.9%
Sentara Port Warwick II	1	2,342	46.8%
Sentara Williamsburg Regional Medical Center	1	5,772	115.4%
Tidewater Orthopaedic Associates	1	1,254	25.1%
Tidewater Physicians Multispecialty Group <sup>1</sup>	1	1,513	30.3%
<b>2018 TOTAL and Average</b>	<b>14</b>	<b>43,152</b>	<b>61.6%</b>
<b>Current Total<sup>2</sup></b>	<b>16</b>	<b>n/a</b>	<b>n/a</b>

Source: VHI and DCOPN Records

### **Proposed Project**

The applicant proposes to replace their existing E-MRI with a full-body MRI. The applicant states that they are no longer able to secure maintenance or replacement parts for their existing E-MRI. Moreover, the applicant states that replacement of the existing E-MRI with a newer E-MRI is not feasible because there is only one provider that produces an E-MRI and the 0.31T magnet on this MRI is vastly below both the 1.0T magnet on TOA's current model and the 1.5T current industry standard. TOA has proffered that, should the proposed project be approved, the use of the new full-body MRI will be limited to solely orthopedic indications. This means that TOA will only image the musculoskeletal system, including bones of the skeleton, and joints, and the muscles, nerves, cartilages, ligaments, and other connective tissue that stabilize or connect the bones. The total capital and financing cost of the proposed project is \$1,584,211 (Table 2). The project will be paid for through a conventional 10-year low with a fixed interest rate. The applicant asserts that the proposed project will not have any impact on the cost of TOA providing care.

<sup>1</sup> The Commissioner issued COPN No. VA-04665 to Tidewater Physicians Multispecialty Group on September 3, 2019, which authorized the conversion of the mobile MRI unit at their Williamsburg location to a fixed MRI unit. The applicant asserted that the project would become operational on December 31, 2019, but DCOPN has not received an indefinite extension from the applicant.

<sup>2</sup> The Commissioner issued COPN No. VA-04664 to Hampton Roads Proton Beam Therapy Institute at Hampton University, L.L.C. on September 3, 2019, which authorized the addition of one fixed MRI unit. The project is expected to become operational on March 1, 2020.

**Table 2. Capital and Financing Costs**

Direct Construction Costs	\$510,000
Equipment Not Included in Construction Contract	\$793,940
Conventional Loan Financing	\$280,271
<b>TOTAL Capital and Financing Costs</b>	<b>\$1,584,211</b>

Source: COPN Request No. VA-8485

### **Project Definition**

Section 32.1 of the Code of Virginia defines a project, in part, as the “[i]ntroduction into an existing medical care facility of any new... magnetic resonance imaging (MRI)..., which the facility has never provided or has not 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... magnetic resonance imaging (MRI)...”

### **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 replace their E-MRI with a full-body MRI. The applicant has proffered that, should the proposed project be approved, the use of the new full-body MRI will be limited to solely orthopedic indications. While this would significantly limit the use of the proposed full-body MRI, it would expand the scope of TOA's MRI scanning capabilities. The current E-MRI cannot perform scans on shoulders, hips, and spines. TOA would be able to perform scans on all of these areas if the proposed project is approved. Currently, these patients must schedule three separate appointments before receiving treatment. Following their initial appointment at TOA, the patient must receive an MRI at another location. Once the MRI is completed, the patient must schedule a follow up appointment at TOA before receiving treatment. Approval of the project would decrease the amount of copays for these patients as well as time away from work. Moreover, approval of the project would limit the amount of painful and difficult travel that is required for patients with hip and spinal issues.

Geographically, TOA is located less than a mile from I-64 and is easily accessible from Hampton Roads Center Parkway and SR 134. Public transportation is available via a Hampton Roads Transit bus located half a mile away from TOA.

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 eight letters of support, including one from a Virginia State Senator, Senator Mason, and three Virginia state Delegates, Delegates Simonds, Mugler, and Mullin. Collectively, these letters articulated the need for continuity of care for patients, particularly those with lower body issues that may have trouble traveling. Additionally, these letters stated that TOA is the only non-hospital provider of MRI scans on the peninsula. The letters go on to state that, because of Anthem's policies, patients would be required to travel a significant distance or pay high out-of-pocket expenses should TOA cease to offer MRI services. DCOPN received no letters of opposition for the proposed project.

**Public Hearing**

DCOPN conducted the required public hearing on February 19, 2020. A total of 9 individuals were in attendance. Five individuals indicated that they were in support of the proposed project and four individuals did not indicate if they supported or opposed the project. The project was presented by three individuals representing TOA. No members of the public spoke in support or opposition of 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;**

The status quo is not a viable alternative to the proposed project. As discussed throughout this staff report, TOA's current E-MRI is at the end of its life and are no longer able to secure repairs or replacement parts for the model. Additionally, replacement E-MRIs are virtually non-existent and use 0.31T magnets, which is drastically lower than TOA's current 1.0T magnet machine. Maintenance of the status quo effectively means either TOA losing their imaging capabilities when their machine ceases to function or purchasing a machine that would provide lower quality scans than both TOA's current machine and the full-body MRI machines in the planning district. As such, DCOPN concludes that the status quo is not a viable alternative to the proposed project.

**(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;**

Currently there is no organization in HPR V designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 21. Therefore, this consideration is not applicable to the review of the proposed project.

**(iv) any costs and benefits of the project;**

As discussed above, the total capital costs of the proposed project are \$1,584,211 (Table 2), which would be paid for through a conventional 10-year low with a fixed interest rate. The costs for the project are reasonable and consistent with previously approved projects to add one MRI scanner. For example, COPN VA- 03906 issued to Odyssey IV, LLC, dba the Center for Advanced Imaging, to add an MRI unit, which cost approximately \$1,598,550; and COPN VA- 04380 issued to InSight Health Corporation d/b/a InSight Imaging Woodbridge, to add an MRI unit, which cost approximately \$1,589,352. The proposed project to replace TOA's E-MRI with a full-body MRI would offer several benefits. First, as discussed above, maintenance of the status quo would either lead to TOA ceasing to be able to provide MRI services when their machine next breaks down or forcing them to purchase a machine that provides scans of a lower image quality than they are currently producing or are produced by other facilities in the PD. As such, approval of the proposed project would allow TOA to continue to provide MRI imaging of the level of quality that is provided by their current E-MRI machine. Moreover, as previously discussed, the full-body MRI would allow TOA to provide an increased continuity of care for patients that require treatment for their spine, shoulder, or hip by enabling TOA to provide MRI scanning services to them in the same location where they receive treatment.

**(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 V that reported such charity care for that year was 5.1% of all reported total gross patient revenues. DCOPN is unable to confirm the level of charity care provided by TOA because, in the most recent data available to DCOPN, TOA did not report any charity care contributions to VHI. Additionally, TOA did not supply a condition compliance report for COPN No. VA-04093 in 2017 or 2018. As such, should the proposed project receive approval, TOA 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 V.

**Table 3. HPR V 2018 Charity Care Contributions**

Health Planning Region V			
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:
Bon Secours DePaul Medical Center	\$698,996,618	\$53,230,518	7.62%
Sentara Careplex Hospital	\$889,460,665	\$64,660,889	7.27%
Riverside Tappahannock Hospital	\$162,491,011	\$11,307,825	6.96%
Riverside Regional Medical Center	\$1,861,151,990	\$126,769,911	6.81%
Bon Secours Maryview Medical Center	\$1,273,955,832	\$85,038,667	6.68%
Sentara Obici Hospital	\$825,126,790	\$54,851,619	6.65%
Riverside Walter Reed Hospital	\$252,673,741	\$16,571,599	6.56%
Sentara Virginia Beach General Hospital	\$1,210,282,480	\$67,107,518	5.54%
Riverside Doctors' Hospital Williamsburg	\$124,258,743	\$6,791,596	5.47%
Sentara Norfolk General Hospital	\$3,313,578,465	\$168,093,514	5.07%
Riverside Shore Memorial Hospital	\$235,708,877	\$11,934,270	5.06%
Sentara Leigh Hospital	\$1,182,257,169	\$55,810,160	4.72%
Bon Secours Mary Immaculate Hospital	\$675,071,989	\$29,896,497	4.43%
Sentara Princess Anne Hospital	\$967,617,447	\$38,069,270	3.93%
Sentara Williamsburg Regional Medical Center	\$659,049,590	\$24,789,255	3.76%
Chesapeake Regional Medical Center	\$900,598,911	\$15,330,992	1.70%
Hampton Roads Specialty Hospital	\$25,627,019	\$433,771	1.69%
Southampton Memorial Hospital	\$209,949,572	\$3,282,979	1.56%
Bon Secours Rappahannock General Hospital	\$71,220,177	\$1,107,592	1.56%
Children's Hospital of the King's Daughters	\$1,009,437,096	\$6,094,726	0.60%
Lake Taylor Transitional Care Hospital	\$46,761,019	\$0	0.00%
Hospital For Extended Recovery	\$25,515,975	-\$252,369	-0.99%
<b>Total \$ &amp; Mean %</b>	<b>\$16,620,791,176</b>	<b>\$840,920,799</b>	<b>5.1%</b>

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.**

In September 2019, the current E-MRI required major service to replace the cold head, which is an integral part of the magnet's cooling system. GE, with whom the applicant had a comprehensive support agreement, had to obtain replacement parts from deactivated units since parts for the applicant's E-MRI are no longer manufactured. The total repair time required to effectuate these repairs, because of the need to salvage parts from deactivated units, was almost a full month.

Following these repairs, GE gave TOA a 30-day notice that they would no longer honor the comprehensive service agreement because the machine had reached the end of its life. The

comprehensive service agreement was not slated to end until November 2021. The reasoning provided by GE was that parts for the E-MRI were no longer produced and would difficult, if not impossible, to procure.

Based on these events, on November 18, 2019, the applicant requested that the Commissioner waive the review schedule requirements of 12VAC5-220-200, including the batch cycle process and the 30-day period between a Letter of Intent and submission of the application, and that DCOPN accelerate its review of TOA's application. On December 9, 2019, the Commissioner determined that an emergency does exist and approved TOA's request to waive the schedule requirements of 12VAC5-220-200.

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

The SMFP contains criteria/standards for the establishment or expansion of MRI services. They are as follows:

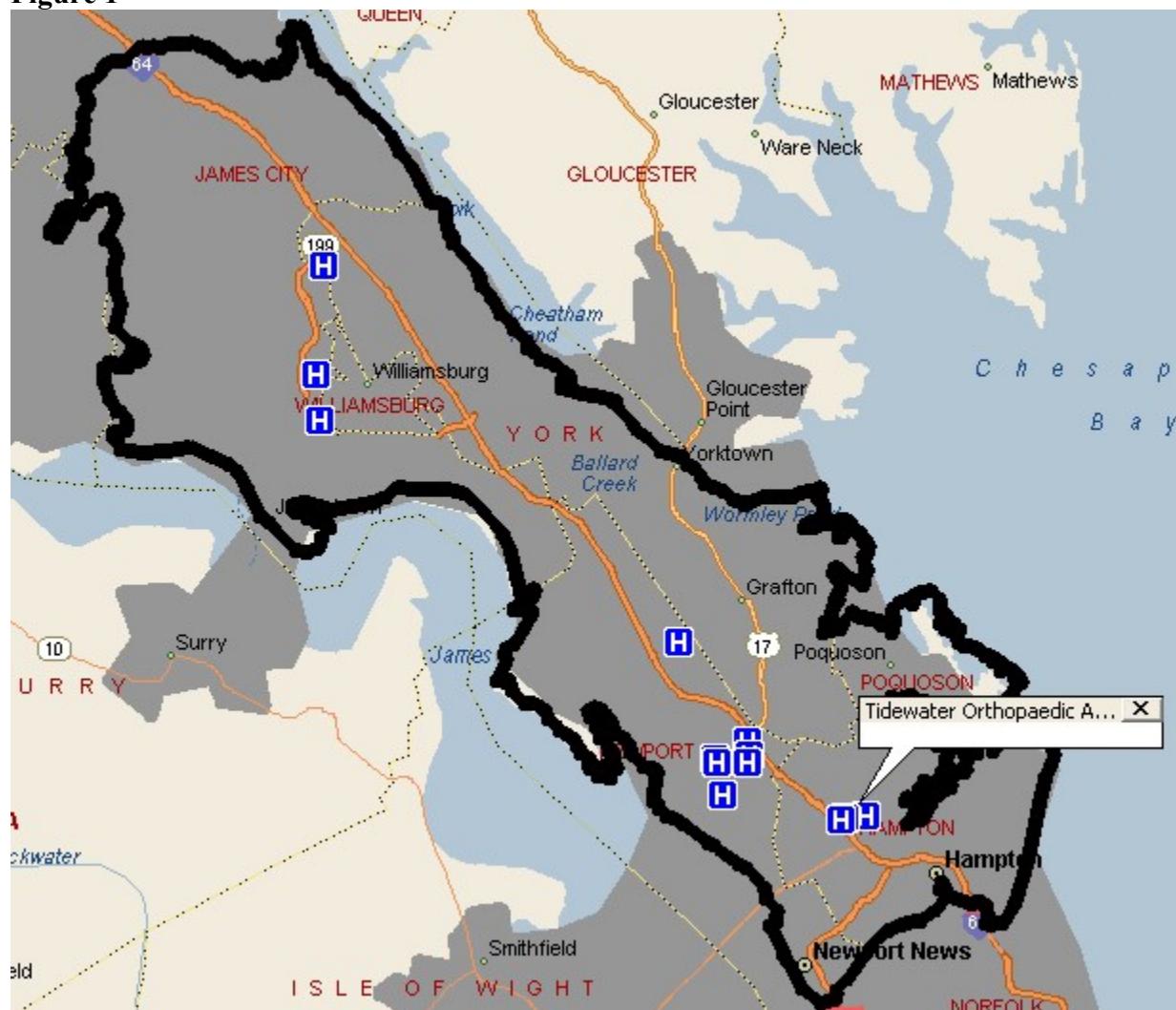
**Part II**  
**Diagnostic Imaging Services**  
**Article 2**  
**Criteria and Standards for Magnetic Resonance Imaging**

**12VAC5-230-140. Travel time.**

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

The heavy dark line in Figure 1 identifies the boundaries of PD 21. The grey shading illustrates the area that is within a thirty-minute drive under normal driving conditions of all MRI service providers in PD 21. Based on the shaded area in Figure 1, it is reasonable to conclude that 95% of the population of PD 21 is within 30 minutes driving-time one-way under normal traffic conditions of MRI services.

Figure 1



**12VAC5-230-150. Need for new fixed site service.**

No new fixed site MRI service should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service may be disregarded in computing average utilization of MRI scanners in such planning district.

As noted in Table 1 above, the utilization of existing MRI services in the planning district was only 61.6% of the 5,000 procedures per scanner necessary to introduce a full body MRI scanner under this section of the SMFP. DCOPN notes that the proposed project does not seek to establish a new MRI where none previously existed, but rather to replace an existing COPN

authorized E-MRI with a full-body MRI scanner. Moreover, the applicant has proffered that, should the proposed project be approved, the use of the new full-body MRI will be limited to solely orthopedic indications. This will still increase the scope of TOA's MRI services, as they will now be able to perform MRI scans on hips, shoulders, and the spine. Despite this increase in scope, DCOPN concludes that the proposed project is highly unlikely to reduce materially the utilization of providers in PD 21.

**12VAC5-230-160. Expansion of fixed site service.**

**Proposals to expand an existing medical care facility's MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant's existing medical care facility, or at a separate location within the applicant's primary service area for MRI services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health-planning district.**

Not applicable. The applicant is not proposing to expand the number of MRI scanners at their facility.

**12VAC5-230-170. Adding or expanding mobile MRI services.**

**A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health-planning district.**

Not applicable. The applicant is not proposing the addition or expansion of a mobile MRI service.

**B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health-planning district.**

Not applicable. The applicant is not proposing the conversion of a mobile MRI service to a fixed site scanner.

**12VAC5-230-180. Staffing.**

**MRI services should be under the direct supervision of one or more qualified physicians.**

The applicant stated that MRI services are, and will remain, under the direct supervision of a qualified physician.

### **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;**

TOA is an existing provider of orthopedic MRI scanning. As discussed above, the applicant has proffered that, should the proposed project receive approval, the use of the new full-body MRI would be limited to solely orthopedic indications. While it is true that this would allow for scanning of certain body parts, such as shoulders, hips, and spines, that the current E-MRI is unable to accommodate, DCOPN concludes that this minor expansion would not materially affect existing providers of MRI services in the area. As such, DCOPN concludes that it is unlikely that the proposed project would foster institutional competition that benefits the area to be served.

**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 proposed project, which seeks to replace a COPN authorized E-RMI with a full-body MRI, would not increase the number of fixed MRI scanners in the planning district. As discussed above, while the proposed project marginally increases the scope of MRI scanning at TOA, the proffered limited use of the proposed full-body MRI are sufficiently narrow in scope that approval of the project would not materially affect the utilization of existing services.

**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;**

As discussed above, the total capital costs of the proposed project are \$1,584,211 (Table 2), which would be paid for through a conventional 10-year low with a fixed interest rate. The applicant asserts that the proposed project will not have any impact on the cost of TOA providing care. The costs for the project are reasonable and consistent with previously approved projects to add one MRI scanner. For example, COPN VA- 03906 issued to Odyssey IV, LLC, dba the Center for Advanced Imaging to add an MRI unit, which cost approximately \$1,598,550; and COPN VA- 04380 issued to InSight Health Corporation d/b/a InSight Imaging Woodbridge to add an MRI unit, which cost approximately \$1,589,352. The required staffing for the proposed project, consisting of one full time FTE for a nurse and one FTE for a radiologic technologist, is

relatively minor. The applicant asserts, and DCOPN agrees, that the proposed project is unlikely to impact the staffing at other facilities in the PD.

**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**

The proposed project would improve the delivery of health services on an outpatient basis by allowing TOA to provide MRI scans to patients with shoulder, hip, and spinal issues that are not currently able to receive scans from TOA's E-MRI. As mentioned above, this would reduce the number of copays for the patient, reduce the time between their initial appointment and the start of treatment, and limit travel that would be difficult and painful for patients with hip and spinal issues. DCOPN did not identify any other improvements or innovations in the financing or delivery of health services offered by the proposed project.

**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.**

TOA 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 replace an extremity MRI scanner with a full-body MRI scanner at Tidewater Orthopaedic Associates is consistent with the applicable criteria and standards of the SMFP, or is in harmony or general agreement with the SMFP, and the Eight Required Considerations of the Code of Virginia

Moreover, DCOPN finds that the status quo is not a viable alternative to the proposed project. Maintenance of the status quo would either lead to TOA ceasing to be able to provide MRI services when their machine next breaks down or forcing them to purchase a machine that provides scans of a lower image quality than they are currently producing or are produced by

other facilities in the PD. Additionally, DCOPN finds that the proposed project would reduce the number of copays for the patient, reduce the time between their initial appointment and the start of treatment, and limit travel that would be difficult and painful for patients with hip and spinal issues. Moreover, DCOPN finds that the proposed project is unlikely to affect materially existing providers in the PD. The proposed project, which seeks to replace an E-MRI scanner with a full-body MRI scanner, would be inventory neutral. Additionally, the applicant has proffered to limit the use of the proposed full-body MRI to orthopedic indications. This means that TOA “will only image the musculoskeletal system, including bones of the skeleton, joints, muscles, nerves, cartilages, ligaments, and other connective tissue that stabilize or connect the bones.”

Finally, DCOPN finds that the total capital costs of the proposed project are \$1,584,211 (Table 2), which would be paid for through a conventional 10-year low with a fixed interest rate. TOA asserts that the proposed project will not have any impact on the cost of providing care at the facility. The costs for the project are reasonable and consistent with previously approved projects to add one MRI scanner. For example, COPN VA- 03906 issued to Odyssey IV, LLC, dba the Center for Advanced Imaging to add an MRI unit, which cost approximately \$1,598,550; and COPN VA- 04380 issued to InSight Health Corporation d/b/a InSight Imaging Woodbridge to add an MRI unit, which cost approximately \$1,589,352.

### **Staff Recommendation**

The Division of Certificate of Public Need recommends **conditional approval** of the applicant’s COPN request to add one MRI scanner for diagnostic use at Tidewater Orthopaedic Associates, Inc. for the following reasons:

1. The 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 status quo is not a viable alternative to the proposed project.
3. The project is inventory neutral.
4. The project is unlikely to affect materially the utilization of existing providers in the Planning District.
5. The capital costs are reasonable and consistent with the projects of this type.

**Recommended Condition**

Tidewater Orthopaedic Associates, Inc will provide MRI 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 5.1% of Tidewater Orthopaedic Associates, Inc's total patient services revenue derived from MRI services provided at Tidewater Orthopaedic Associates 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. Tidewater Orthopaedic Associates, Inc 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.