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July 31, 2024

Via Federal Express

Eric Baker, Program Manager
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: SurgCenter at National Harbor, LLC dba Harborside Surgery Center
**Application for Certificate of Need to Convert a Procedure
Room to an Operating Room**

Dear Mr. Baker;

On behalf of SurgCenter at National Harbor, LLC dba Harborside Surgery Center (“Harborside”), I am responding to your letter of June 28, 2024, requesting additional information regarding the Certificate of Need (“CON”) application requesting approval for Harborside to operate the center as an ambulatory surgical facility (“ASF”) with three total operating rooms and two procedure rooms through the conversion of one procedure room to an operating room.

General

1) Provide a response for the following:

- A. On p. 12, clarify if this is a new health care facility, or a change in the type or scope of any health care service offered by a facility.**

Response:

Based on our discussions with the Maryland Health Care Commission (“The Commission”) prior to submitting the application and review of completeness questions in the prior CON review of the Chesapeake Eye Surgery Center application in Docket No. 22-02-2461, and Section .02D(1)(e) of the General Surgical Services chapter of the State Health Plan, it is our understanding that changing Harborside’s licensure from an ASC-2 to an ASF constitutes the establishment of a new ASF, and

the continued provision of surgical procedures is not a change in scope or type of health care service.

B. The current hours and days of operation at Harborside Surgery Center.

Response:

The center is operational 6am-6pm Monday thru Friday.
Surgeries are scheduled between the hours of 7am – 4:30pm
Total Joint Arthroplasties are scheduled 7am – 3:00pm

C. On p. 14, provide documentation or cite the source that supports the statements that “ambulatory surgery facilities are increasing becoming the site of choice by patients, payors, and surgeons for more complex cases...” and for the statement “increase patient satisfaction, decrease 30-day readmission rates, decrease infection rates, and decrease post-acute care stays in SNFs and rehabs.”

Response:

The statement was derived from a series of published studies, white papers and articles. The trend in site of service shift has been evolving over the last several years with focus on experience, outcomes and costs. Below are highlighted articles, and studies supporting these statements.

Patient Choice

The Leap Frog Group: Spring 2022. Part One: Outpatient Surgical Care, Patient Experience at Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs) (Attachment 27)

Report Highlights

Patients who had a same-day surgery are more favorable about care in ASCs than hospital outpatient departments on all four domains of patient experience, especially in their willingness to recommend the facility.

Payer Choice

1. Newitt, Patsy (2022) “Insurers want more surgeries in ASCs”, Beckers ASC Review (Attachment 28)

Excerpt:

However, many ASC leaders are seeing a shift in payer behavior — with insurers beginning to favor ASCs. And while some ASC owners are reporting

efforts by insurers to increase prior authorization requirements and ramping up denials, others are seeing evidence of payers advocating for ASCs.

"With the continued rising cost of patient care in the hospital setting, ASCs have become many insurance companies' preference for outpatient surgery," Dianna Reed, administrator of Sani Eye Surgery Center in Templeton, Calif., told *Becker's*.

2. Newitt, Patsy (2022) "Payers are pushing physicians to ASCs", Beckers ASC Review (Attachment 29)

Excerpt:

"With the continued rising cost of patient care in the hospital setting, ASCs have become many insurance companies' preference for outpatient surgery," Dianna Reed, administrator of Sani Eye Surgery Center in Templeton, Calif., told *Becker's*.

Patient Safety and Outcomes

1. Steven Young, Brian Osman, Fred E. Shapiro Published online: March 10, 2023

DOI: <https://doi.org/10.4097/kja.23078>

Safety considerations with the current ambulatory trends: more complicated procedures and more complicated patients (Attachment 30)

Conclusions:

The landscape of surgical and noninvasive procedures being performed has been evolving and shifting over the last quarter century. Anesthesiologists are constantly being challenged to maintain patient safety commensurate with this exponential growth. The literature supports the trend of higher ASA PS scored patients and more complicated procedures shifting towards the outpatient arena (i.e., ASCs and offices). Several reasons that may account for these include cost incentives (for patients and healthcare systems), advancement in anesthesia techniques, ERAS protocols, and increased patient satisfaction.

2. J Arthroplasty. 2020 January; 35(1): 7–11. doi: 10.1016/j.arth.2019.08.041. Patient Outcomes Following Total Joint Replacement Surgery: A Comparison of Hospitals and Ambulatory Surgery Centers (Attachment 31)

Results:

Readmissions, post-surgical complications, and payments were lower for outpatients than inpatients. Within outpatient settings, readmissions and post-surgical complications were lower in ASCs than in HOPDs but payments for ASC patients were higher than payments for HOPD patients.

3. World Neurosurgery [Volume 129](#), September 2019, Pages e233-e239
"A Comparison of 30-Day Hospital Readmission and Complication Rates After Outpatient Versus Inpatient 1 and 2 Level Anterior Cervical Discectomy and Fusion Surgery" _ An Analysis of a Medicare Patient Sample (Attachment 32)

Conclusion:

The results from the present study suggest that outpatient ACDF appears to be safe and effective with low complication and readmission rates in a Medicare patient sample.

D. Regarding the Project Budget (Attachment 4, Table E), provide the calculations used for the \$23,043 in Contingency Costs.

Response:

The contingency is a 20% contingency of total construction dollars and is based on historical budgeting practices, 15% of total project costs until the projects is formally bid and an additional 5% to account for inflationary trends.

E. Will Harborside keep procedure room 235 in service or take it out-of-service during the four weeks of renovations?

Response:

Procedure Room 235 will be out of service during the period of the renovations.

F. Will the renovations to the procedure room include upgrades to meet ASHRAE operating room standards for ventilation systems?

Response:

Procedure Room 235 already meets the current FGI and ASHRAE Standard 170 requirements for an Operating Room. ASHRAE calls for a minimum total Air Change Rate in ORs of 20. Room 235 has 24. ASHRAE calls for a minimum Outside Air Change Rate of 4. Room 235 has 4.2. The outside air intake is at least 25 feet from all exhaust and vent discharges, the supply air has two filter beds with the final filtration exceeding MERV 14, the airflow is unidirectional and there are two low side-wall return grilles at opposite corners of the room. Controls are in place to always maintain a positive pressure in the room. The Procedure Room was designed to meet or exceed the ventilation requirements for an Operating Room.

Applicant History, Statement of Responsibility, Authorization and Release of Information, and Signature (Currently in Process – Marshall completing should have by end of week)

- 2) Clarify the relationship of P. Marshall Maran, Managing Member, who signed the affirmation on p. 23 for the CON application. The table listing the Harborside ownership on p. 21 does not list P. Marshall Maran as an owner. Please include an ownership chart that shows all parties with a 5% ownership interest or greater in M2O.**

Response:

P. Marshall Maran is the CEO of M2 Orthopedic Partners Holdings, LLC and the appointed, managing member of Harborside Surgery Center through M2O's ownership. Mr. Maran does not have a direct ownership in Harborside, so he is not listed as an owner on the capitalization table.

Table 1 – M2 Orthopedic Partners Holdings, LLC Capitalization Table

M2 Orthopedic Partners Holdings, LLC Capitalization as of December 31, 2023		
Name	Number of Units (#)	Ownership % Basic Interest
Anderson GW	11,611	19.2%
Anderson NCA	250	0.4%
Total Class A-1	11,861	19.6%
M2 Orthopedic Partners, LLC	32,217	53.2%
Total Class A-2	32,217	53.2%
Firmament Capital Partners SBIC III, L.P.	10,032	16.6%
Rare Partners 1, LLC	4,836	8.0%
Marshall Maran	125	0.2%
Total Class A-3	14,993	24.8%
M2 Orthopedic Partners, LLC	1,008	1.7%
Firmament Capital Partners SBIC III, L.P.	328	0.5%
Rare Partners 1, LLC	164	0.3%
Total Class A-4 Preferred	1,500	2.5%
Total M2 Orthopedic Partners Holdings, LLC	60,571	100.0%

3) More information is required regarding M2 Orthopedic Partners Holdings (M2O), LLC. Please provide:

A. What is M2O's level of expertise and its role in operating and/or owning ambulatory surgery facilities?

Response:

M2O was founded and formed in June of 2021, at the same time the company acquired its ownership position in Harborside Surgery Center. Members of M2O's team, including its CEO, SVP of Clinical Programs and its Vice President of Strategic Programs have, combined, more than a decade of experience and deep expertise developing and managing ambulatory surgery centers. Specifically, M2O's CEO, Marshall Maran, was the SVP of Operations for Health Inventures, where he had responsibility for operating a network of 36 ASCs in markets throughout the U.S. Additionally, the three M2O executives referenced above, constituted the founding team of Muve Health, an organization that developed, owned and operated a network of specialty ASCs focused solely on providing total joint replacement procedures.

- B.** Please document the quality performance of each ambulatory surgery facility owned or operated by M2O.

Response:

Not Applicable. Information about Harborside has been provided in the application.

- C.** List each of the other health care businesses and entities owned and/or operated by M2O.

Response:

Today, M2O owns or operates the following two healthcare businesses:

1. Harborside Surgery Center
2. The Anderson Orthopaedic Clinic

- 4) What is Archimedes Health Investors, which is a private equity firm, and its relationship with M2O? Provide information on the size of Archimedes portfolio and the health care companies in its portfolio.**

Response:

Archimedes Health Investors is a private equity firm focused on the healthcare industry, with specific expertise and experience in the provider services segment of the industry. M2O is a portfolio company of Archimedes. Today, Archimedes has the following four companies in its portfolio:

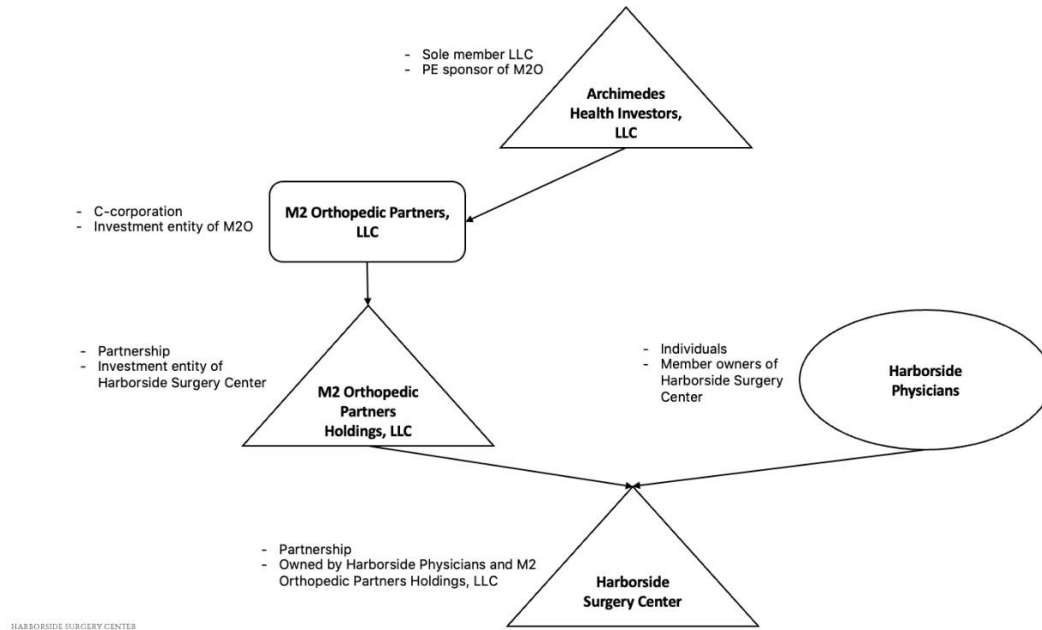
1. M2 Orthopedic Partners ("M2O") – an orthopedic physician practice management company
2. National Partners in Healthcare – an anesthesia services physician practice management company
3. Panorama Eyecare – an eyecare services physician practice management company
4. Apree Health – an integrated primary healthcare network

- 5) Is M2O incorporated within the State of Maryland? An organizational chart with the relationship between Harborside to both M2O and Archimedes Health Investors would be helpful.**

Response:

M2O is incorporated in the State of Delaware. Please see Figure 1 below for an organizational chart illustrating the relationship between Harborside, M2O and Archimedes Health Investors

Figure 1



State Health Plan

**COMAR 10.24.01.08G(3)(a), The State Health Plan
General Surgical Services COMAR 10.24.11**

Information Regarding Charges and Network Participation 05A (1)

6) Respond to the following:

- A. Regarding Subsections .05A(1)(a), (b), and (c), will Harborside provide a representative list of the charges for surgical services on its website and will Harborside post the health carrier networks in which Harborside and its physicians participates on its website? If not, please explain why not.**

Response: Standard .05(A) (1) Information Regarding Charges.

Information regarding charges for surgical services shall be available to the public.

(a) A physician outpatient surgery center, ambulatory surgical facility, or a general hospital shall provide to the public, upon inquiry or as required by applicable

regulations or law, information concerning charges for the full range of surgical services provided.

Per the regulation, Harborside shall provide to the public, upon inquiry, information concerning charges for the full range of services and participating networks. This practice is unchanged from prior Determination of Coverage approved by the Commission.

Surgeons practicing at the center is available on our website and posted in our waiting rooms. It can be found here: <https://harborsidesurgcenter.com/physicians/>

Prior to First Use, Harborside will list the participating health care networks on the website.

B. Regarding Attachment 5, please provide:

- 1) **A complete copy of the brochure that Harborside gives to its patients that shows Harborside's charity care and financial assistance policy.**

Response:

Prior to First Use, Harborside will amend its brochure and website to include a link to our financial assistance and charity care policy. The language is stated below:

NOTICE OF CHARITY CARE AND FINANCIAL ASSISTANCE PROGRAM

Harborside Surgery Center has a Charity care and Financial Assistance Program designed to provide surgical services on an uncompensated basis or at a reduced charge to uninsured, underinsured, and indigent persons, who meet eligibility criteria.

General Eligibility Criteria

- a) Persons with family income below 100 percent of the current Department of Health and Human Services Poverty Guidelines applicable to Maryland poverty level who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services at no charge. These guidelines can be found at:
<https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>
- b) Persons with family income above 100 percent of the Department of Health and Human Services Poverty Guidelines federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands according to the following table:

HHS Poverty Guideline	% Discount
100 - 149%	75%
150 - 174%	50%
175 - 199%	24%

- c) Proof of income and verification of the number of dependents based upon the previous year's tax return must be provided. If this is not available, the last two months paycheck stubs will be accepted. Dependents must meet the IRS definition of dependents to qualify as household members.
- d) Proof that medical assistance has been applied for and rejected. If the rejection is for non-compliance with all medical assistance paperwork requirements, reduced fee or charity will not be granted. If medical assistance rejection is based on income, disability, or assets, Harborside will review a person's medical financial assistance application and make a final determination of eligibility. Harborside staff will assist all persons to complete the application or identify alternative programs such as Medicaid.

To learn more about our financial assistance program or obtain a copy of our policy, ask your provider or one of our surgical coordinators. Additional information is available by calling 240-493-6110

2) Please show where in this brochure there is language regarding the provision of Harborside providing out-of-pocket charges to patients prior to arrival at the surgery center.

Response:

See Attachment 5, Harborside Brochure, in the original application. Language regarding patient responsibility is found under the section labeled Billing Information. The process is described below in 3).

3) Is this policy for out-of-pocket charges to patients on Harborside's website?

Response:

Our website, found at <https://harborsidesurgcenter.com/for-patients/billing-information/>, provides the patients with details of the process for out-of-pocket costs.

The section states:

You will be informed about any coinsurance due for your surgery during your preoperative call. This amount is due prior to, or on the day of your surgery.

Please remember to bring a form of payment with you. We accept cash, checks and major credit cards. The Surgery Center also participates with Care Credit, a health care expense financing company.

After surgery Harborside Surgery Center will submit your bill to your insurance company. You will receive a separate bill from your doctor, anesthesiologist and/or pathologist.

Please do not hesitate to contact our business office with any concerns or questions regarding your coinsurance obligation and/or payment options.

During the preoperative phone call, the patient is informed of their out-of-pocket costs, payment methods and business office contact if a payment plan is needed. The cost is derived by our business office specialist verifying with the provider the intended procedure to be performed and the associated CPT codes. The specialists then runs the procedure and codes via the insurance company portal which provides patient specific cost based on current benefit and deductible. This information is provided to the patient via phone call, email and/or postal mail based on patient preference.

Charity Care and Financial Assistance Policy 05A(3)

- 7) Regarding Harborside's response to Regulation .05A(3)(a) and Attachment 6, Charity Care and Financial Assistance Policy, please update this policy to provide the steps used by Harborside's staff to make a determination of probable eligibility¹ for charity care and financial assistance within two business days and the steps in notifying the patient of that determination.**

A determination of probable eligibility should only require the minimum amount of information needed by Harborside regarding whether the patient is eligible for charity care and financial assistance for the surgical services proposed by Harborside. This step would require such minimal information as an individual's annual salary or copies of the patient's most recent paychecks, the number of members in family, a patient's successful application for a determination of medical assistance or financial assistance for health care services, and/or any other information that would assist the Harborside business office or surgical coordinator in the determination of probable eligibility for charity care and financial assistance.

¹There is a difference in the determination of probable eligibility versus a final determination of financial eligibility for charity care and financial assistance.

A final determination of financial assistance may require the patient to submit a separate and completed financial assistance application with all the financial information necessary for Harborside to determine whether the patient will receive charity care and financial assistance for surgical services offered by Harborside. Please revise and update Harborside’s policy in Attachment 6 for making a final determination of probable eligibility for financial assistance.

A determination of probable eligibility should only require the minimum amount of information needed by Harborside regarding whether the patient is eligible for charity care and financial assistance for the surgical services proposed by Harborside. This step would require such minimal information as an individual’s annual salary or copies of the patient’s most recent paychecks, the number of members in family, a patient’s successful application for a determination of medical assistance or financial assistance for health care services, and/or any other information that would assist the Harborside business office or surgical coordinator in the determination of probable eligibility for charity care and financial assistance.

A final determination of financial assistance may require the patient to submit a separate and completed financial assistance application with all the financial information necessary for Harborside to determine whether the patient will receive charity care and financial assistance for surgical services offered by Harborside. Please revise and update Harborside’s policy in Attachment 6 for making a final determination of probable eligibility for financial assistance.

Response:

A copy of the revised financial assistance policy is included as Attachment 33 to this letter.

- 8) Please provide a copy of the financial assistance application form that the patient must complete to receive a final determination of charity care and financial assistance.**

Response: A copy of the Harborside financial assistance application form was included as Attachment 7 to the application.

- 9) Regarding Attachment 6, under Eligibility Criteria, please clarify the meaning of “current poverty level” or “federal poverty guideline”. Revise Harborside’s policy to indicate that the sliding fee scale identified in this policy will utilize the current federal poverty guidelines in determining eligibility for charity care and financial assistance, such as at: <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>.**

Response:

The revised financial assistance policy in Attachment 33 to this letter clarifies the poverty guidelines that will be used in determining eligibility for financial assistance.

10) Regarding Harborside's response to Regulation .05A3(b) and Attachment 6, please show:

A. Where on Harborside's website the policy on charity care and financial assistance is posted?

Response:

Prior to First Use, the policy will be posted as described above in B (1)

B. What other modes of communication Harborside will use to notify the public and patients of its charity care and financial assistance policy? Examples could be publication in local newspapers, public service announcement, inclusion in the Harborside patient brochure (Attachment 5), or notification to the Prince George's County Department of Health and other local health agencies and providers.

Response:

Education to the surgeons, staff and business office teams of the surgeons' offices will be completed to ensure they are familiar with the policy and process to access charity care and financial assistance. We will collaborate with Prince George's County Department of Health to provide brochures and contacts for patients in need.

C. Regarding Harborside's response to Regulation .05A(3)(f) and Attachment 6, please show the average amount of charity services provided by other Maryland ambulatory surgery facilities in the most recent year reported in comparison to Harborside.

Response:

Based on information provided by the Commission, the average amount of charity care provided by other Maryland ASFs was 0.8% of total operating expense. Harborside has not tracked charity in the past, but when approved as an ASF, it will do so. Harborside has set as its charity care of 1.0% as a minimum level of charity care.

11) Provide a response to the following:

- A. Regarding Harborside's response to Attachment 6 (paragraph 8.b) on p. 28, please provide further discussion as to how Harborside will meet its Charity Care Goals annually.**

Response:

Harborside will undertake a number of measures to ensure that it meets its charity care minimum annually. Its charity care policy will be posted on its website. Its goal will be communicated to all surgeons on its medical staff. The availability of financial assistance will also be posted in its lobby and patients will be informed of the policy in communications prior to the date of surgery.

- 12) The applicant indicates in Table 3, Revenues and Expenses – Entire Facility on p. 66-67 that the Patient Mix as a Percent of Total Revenue will include 0.0% Medicaid and 0.0% Self Pay. The table also shows the breakdown in revenue reimbursement for Harborside by either Medicare, Blue Cross, Commercial Insurance, or other payers (i.e., worker's compensation and Veteran's Administration).**

Response:

Table 3 does, in fact, contain a provision for self-pay. In the application as submitted percents were rounded to whole numbers, thus suppressing small fractions in the presentation. A revised Table 3 included as Attachment 34 to this letter has percents rounded to two decimal places and shows positive levels of utilization for self-pay in the historical and projected years.

Harborside does not participate in the Medicaid program. The absence of such participation does not create an impediment to, nor have an impact on, Harborside's commitment to the provision of Charity Care.

- A. Explain how Harborside will meet its annual charity care goal (defined by the applicant as one percent of total operating expenses, p. 30) if the patient mix does not include Medicaid and self-pay patients?**

Response:

As discussed in the preceding response, Harborside has served a small number of self-pay patients historically. It is expected that this number will increase with the posting of its charity care policy on its website and in its facility. In addition, the surgeons practicing at Harborside will be made aware of Harborside's charity care goal and process for patients requesting assistance.

- B. The applicant indicates in its response to Regulation .05A1(b) above (see page 25 of the application), that Medicaid is not included in the list of current health carrier networks under contract.**

Response:

As previously stated, the fact that Harborside does not participate in the Medicaid program will not be an impediment to reaching its charity commitment with the treatment of self-pay patients.

- 13) Please provide the historical level of charity care provided by Harborside for the years 2022 through year-to-date 2024. If not able to provide this information, then explain why Harborside cannot report the historical amount of charity care provided.**

Response:

As discussed above, Harborside has not tracked its charity care because as an ASC-2 it did not have a specific charity care goal. Charity care was included with bad debts and not separately recorded in its accounting system. There is no practical means of obtaining the historical charity care provided.

Attachment 6

- 14) Provide a copy of Harborside's Charity Care and Financial Assistance Policy in Spanish and show where this is posted on its website. Please state if this is also posted in all offices.**

Response:

As an ASC-2, Harborside is not required to have a charity care policy posted in English or Spanish. Prior to First Use, the charity care policy will be translated into Spanish and posted on its website and in its patient lobby.

Quality of Care 05A(4)

- 15) With regard to M2O, provide a response to Regulation .05A(4)(e) for the following:**

- A. As an applicant or a related entity that currently or previously has operated or owned one or more ASCs or ambulatory surgical facilities in or outside of Maryland in the five years prior to the applicant's filing of an application to establish an ambulatory surgical facility, shall provide details regarding the quality of care provided at each such ASC or ambulatory surgical facility including information on licensure, accreditation, performance metrics, and other relevant information.**

Response:

The Applicant or related entity has not operated or owned ASCs or ASFs in or outside of Maryland in the past five years besides Harborside.

Transfer Agreement 05A(5)

16) Provide a response for the following:

- A. Regarding Attachment 14, Harborside only has a transfer agreement with Inova Mount Vernon Hospital. Discuss why Harborside does not have a transfer agreement with an acute care hospital located in Maryland.**

Response:

Per regulation 10.24.11(5)(b), each ambulatory surgical facility shall have a process for assuring the emergency transfer of surgical patients to a hospital that complies with the requirements of COMAR 10.05.05.09(A)(B)(1).

A. The freestanding ambulatory surgical facility shall have an effective procedure for the transfer of patients to a hospital when care beyond the capabilities of the facility is required.

B. Procedures for emergency transfer to a hospital shall include, at a minimum:

(1) Having a written transfer agreement with a local Medicare participating hospital **OR** requiring all physicians, dentists, or podiatrists performing surgery in the freestanding ambulatory surgical facility to have admitting privileges at such a hospital;

Harborside has a well-defined procedure for patients requiring transfer as detailed in Attachment 13 of the application. Harborside requires all physicians performing surgery have admitting privileges at a Medicare participating hospital. All our surgeons meet this requirement. Out of an abundance of caution, Harborside has taken the extra step and engaged in a transfer agreement with Inova Mt Vernon, where the majority of our surgeons have privileges.

- B. Please explain whether Harborside discusses with patients and/or families before providing surgical services that the patient may be transferred to Inova Mount Vernon Hospital, especially for patients who are residents of Maryland.**

Response:

Patients are informed by their surgeons that if they require a higher level of care than can be provided at the center, they will be transferred to Inova Mount Vernon Hospital or if medically unstable to the closest hospital.

- C. Discuss whether Harborside has a contingency plan if the facility is not able to arrange transportation due to traffic complications, or that the patient and/or family prefers a transfer to an acute care hospital in Maryland.

Response:

When a patient is deemed in need of a higher level of care than can be provided at the center, a medical transfer is initiated. The 911 service is used to transfer medical patients between the center and the hospital. During the initial call, the ambulance dispatch is informed of the need for medical transport and whether this is an urgent or emergent situation. 911 Dispatch is also informed of our transfer agreement with Mt Vernon, any patient request and the patients' medical status. 911 Dispatch will take this all into account and will transport based on the medical need taking into account transfer agreement, traffic patterns, time of day, closest hospital and hospitals not accepting patients. 911 Dispatch determines the safest closest transport for on each case but takes into account all provided data as stated above.

Need – Minimum Utilization for Establishment of a New or Replacement Facility 05B(2)

- 17) Provide the Excel spreadsheet with the calculations for OR need included for Table 6 on p. 41, Table 7 on p. 42, and Table 8 on 43. Cite the source for the surgical cases and surgical minutes in these three tables.

Response:

An Excel spreadsheet is being provided separate from this letter that shows the calculations for Tables 6 through 8.

Design Requirements 05B(4)

- 18) Please have Harborside's architect attest that the design and construction for the third sterile operating room will comply with the latest FGI Guidelines.

Response:

Attachment 35 provides a letter from Harborside's architect attesting that the design and construction for the third sterile operating room will comply with the latest FGI Guidelines.

The letter states:

The design and construction for the third OR will meet the 2022 FGI Guidelines. It is a 524 sq. ft. OR. The clearance around the OR table is 8'-6" on each side, 6' x 8' at the head and 7'-0" at the foot to allow for circulation, the sterile field, anesthesia and movable equipment zones. There is no fixed equipment in required clearances. Documentation is provided by

a computer on wheels. An existing view box allows for visual information display. A scrub sink is currently provided with visual access near the door to the OR. Smooth scrubbable surfaces are provided on the walls and ceilings and monolithic flooring with an integral base is used in the OR. Med gas is provided per Table 2.1-2. Nurse call devices are provided per Table 2.1-3. At least 36 electrical receptacles are provided, with a minimum of 2 on each wall.

Support Services 05B(5)

19) Provide a response as to how Harborside will provide pathology services for its patients.

Response:

Harborside currently has a contract with Lab Corp to provide pathology services. See Attachment 36.

Please see Attachment 18 of original application Policy 12.01 Provision of Services, Pathology and Medical Laboratory Services

Impact 05B(9)

20) Provide a response for the following:

A. For the 19 physicians listed in Table 11 & 12, pp. 52-53,

1) Provide the surgical specialty for each physician.

Response:

Surgeon	Surgical Specialty
Azer, Nigel	Orthopedics
Branche, George	Orthopedics
Engh, Charles	Orthopedics
Fricka, Kevin	Orthopedics
Gallagher, Brian	Orthopedics
Gandhi, Rikesh	Orthopedics
Gebrelul, Aaron	Orthopedics
Hamilton, William	Orthopedics
Kittredge, Ben	Orthopedics
McAsey, Craig	Orthopedics
Nagda, Sameer	Orthopedics
Nathan, Michael	Otolaryngology
Narvaez, Michael	Orthopedics
Root, Cassie	Orthopedics
Saddler, Stephen	Orthopedics
Sershon, Robert	Orthopedics
Wallach, Corey	Orthopedics
Weinritt, David	General Surgery
Wolff, Andrew	Orthopedics

- 2) Clarify whether the reported surgical case volumes are for a calendar or fiscal year.**

Response:

Surgical case volumes are for calendar year.

- 3) Clarify whether the surgical case volumes reported in Tables 11 and 12 and in Attachment 17 are for surgical cases performed in operating rooms only.**

Response:

Tables 11 and 12 represent historical and projected activity in the operating rooms of Harborside and do not include activity in procedure rooms. The heading 'Operating Room (Surgery) Cases' in Table 11 reflects the number of surgical cases in the operating rooms of Harborside. The Operating Room (Procedure) Cases in Table 12 reflect the number of procedures performed in the operating rooms of Harborside given that a single surgical case often involves several procedures. The reference to operating room procedures is not the same as a case or a procedure performed in a procedure room. Tables 11 and 12 reflect only cases and procedures performed in an operating room.

- a) If these tables also include volumes for surgical cases performed in procedure rooms, please resubmit these two tables and Attachment 17 to report surgical cases performed in the operating rooms only.**

Response:

The case volumes reported in Attachment 17 and summarized in Table 14 are counts of the total number of cases that are performed in operating rooms and procedure rooms for each physician. Hence, the numbers in Table 14 do not correspond directly with the volumes in Table 11. Attachment 37 separates the volumes in Table 14 into cases performed in operating rooms and those performed in procedure rooms. The number of cases performed in operating rooms projected in the physician affidavits is the same as the volumes in Table 11.

- 4) Please cite the source for the projected surgical volumes reported in Attachment 17.**

Response:

The projected volumes reported in Attachment 17 are based on the historical volume of cases for physicians who are part of the Anderson Clinic. The Anderson Clinic maintains data on the number of cases performed by each physician by facility. Management of Harborside worked with the physicians to develop projections of future growth in their practices and the number of cases that they expected to redirect from other facilities to Harborside. Additional details about the projection methodology are included in the response to Question 6 below.

- 5) For Tables 11, 12 and Attachment 17, please clarify whether the utilization volumes are for (a) a 12-month period, (b) prorated for a twelve-month period (start of operations at Harborside's new location at National Harbor was February 17, 2023), or (c) from February through December 2023.**

Response:

In each instance the utilization volumes represent twelve-month periods, ended on December 31 for each referenced twelve-month period. Data are thus recorded for calendar years.

- 6) Based on the response to the previous question, discuss how the Historical 2023 volumes were used to calculate the projected surgical case volumes for the years 2024 through 2028.**

Response:

Historical 2023 volumes represent the aggregate of utilization for the individual physicians who utilize Harborside. Projected future utilization has been projected for each individual physician separately, based on the historical 2023 volumes. The projections employ assumptions about the potential increase in the number of cases which each physician is likely to serve at Harborside. In the case of physicians who are current high-volume users of Harborside and who will likely maintain their utilization of Harborside, the rate of growth is less than that assumed for a physician whose practice is less mature. For a physician in the latter category, the projections are based on a greater growth rate that depends on an assessment of that physician's future utilization of Harborside, taking into consideration the physician's organic increase in cases and the potential cases that will be transferred to Harborside from current sites.

- 7) In comparing the total historical and projected surgical cases reported in Tables 11 and 12 with Attachment 17, these projected total surgical case**

volumes do not agree. Please resolve any discrepancies in surgical cases reported between these two tables and Attachment 17.

Response:

As noted above in the response to Question 3, the data included in Tables 11 and 12 and Attachment 17 show distinct aspects of the projected utilization of Harborside. Table 11 shows the projected volume of surgical cases in the operating rooms, Table 12 the projected volume of procedures, and Table 14 and Attachment 17 the projected volume of operating room and procedure room cases.

- 8) Regarding Table 14 on pp. 55-56, please cite the source for the projected number of surgical cases at Harborside that were shifted from other surgical facilities.**

Response:

Table 14 is a compilation of the individual physician responses included in Attachment 17. As discussed in response to Question 20(4), The Anderson Clinic maintains data on the number of cases performed by each physician by facility. Management of Harborside worked with the physicians to develop projections of future growth in their practices and the number of cases that they expected to redirect from other facilities to Harborside.

- 9) Clarify the use of “HOPD” associated with Alexandria and Mount Vernon HOPD; does this represent the Inova hospitals located at these two locations?**

Response: The reference to HOPD does refer to the Hospital Outpatient Department associated with Inova Hospitals in Alexandria and Mount Vernon.

- 10) Regarding Regulation .04B(9)(b), provide a response that addresses the impact of shifting surgical case volumes from Inova Alexandria Hospital and Inova Mount Vernon Hospital to Harborside. Will these shifted surgical cases account for 18 percent or more of the operating room time in use at these two hospitals?**

Table 13, which is based on physician responses in Attachment 17, provides an assessment of the number of cases that would be able to be shifted to Harborside from providers in the service area of Harborside. The aggregated responses show that, based on 2023 data, a total of 3,040 cases of the Anderson Clinic physicians would be able to have been shifted to Harborside. Of these 3,040 cases, 1,732 (57.0%) and 624 (36.0%) would be shifted from Inova Mount Vernon Hospital

and Inova Alexandria Hospital, respectively. As noted in previous responses the physician survey data include both operating room cases.

The following table shows the potential impact of Harborside on Inova Mount Vernon Hospital and Inova Alexandria Hospital. The table is based on the following assumptions:

- Since the cases reported in Table 14 are combined operating room and procedure room cases. Attachment 37 presents the expected operating room only cases expected to be shifted to Harborside.
- Cases have been pro-rated to Inova Mount Vernon and Inova Alexandria based on the percentage of cases in 2023.
- The most recent data available for Virginia hospitals is for the fiscal years ending in 2022. These data include surgical cases at the two Inova hospitals. The impact will be based on the data for 2022.

Harborside Potential Impact				
On Inova Mount Vernon and Inova Alexandria Hospitals				
		2025	2026	2027
Cases Shifted to Harborside		561	906	1,241
Percent Surgical Cases		61.2%	62.6%	63.7%
Surgical Cases		343	567	791
Pro-rated				
Inova Mount Vernon (57.0%)		196	323	451
Inova Alexandria (20.5%)		70	116	162
Surgical Cases, 2022				
Inova Mount Vernon		4,513	4,513	4,513
Inova Alexandria		7,118	7,118	7,118
Harborside Impact				
Inova Mount Vernon		4.3%	7.2%	10.0%
Inova Alexandria		1.0%	1.6%	2.3%
<i>Source: 2022 data are from Virginia Health Information</i>				

As the information presented in the preceding table shows, the impact of Harborside, using Virginia hospital data from 2022, is less than the 18% threshold for both Inova facilities.

The population of Virginia Planning District 8, which includes the Alexandria and Mount Vernon hospitals is increasing more rapidly than the rest of Virginia

and much of the growth lies within the elderly population. The following table summarizes this projected growth.

Geography Name	Population, 2020		Population, 2030		AAGR, 2020-2023	
	Total	65+	Total	65+	Total	65+
Planning District 8	2,544,942	318,164	2,828,990	404,555	1.1%	2.4%
Virginia, Statewide	8,590,563	1,401,044	9,129,002	1,762,641	0.6%	2.3%
Note: 'AAGR' Average Annual Growth Rate.						
<i>Source: Demographics Research Group of the Weldon Cooper Center for Public Service, Aug. 2023.</i>						

It is likely, therefore, that demand for surgical services at Inova Alexandria and Inova Mount Vernon in future years will be greater than it was in 2022. The impact of Harborside presented in the previous table is likely to be less than the table suggests because of this population growth.

Other Criteria

Alternatives to the Project G3(c)

21) Regarding the alternative where there is no conversion of the procedure room, and instead an addition of a third OR- please provide further discussion as to where the addition of a new operating room would be located in the current layout of the surgery center, the total estimated project cost for adding a third OR, and the projected amount of time needed to construct this additional third OR.

Response:

When Harborside constructed its replacement facility, the procedure room that this application seeks to convert was built to operating room construction standards. As a consequence, there is a small capital expenditure required to convert this procedure room to an operating room and there will be minimal disruption to operations during the conversion.

In contrast, the construction of a third operating room would be highly disruptive to Harborside’s operations and require significant reconfiguration of its sterile corridor. Moreover, there is no need based on current and projected volumes of cases to add a third operating room and retain both procedure rooms. Given that the design of the current physical plant was previously approved by the Commission, and approval for the final step of conversion of a procedure room to an OR is now being sought, Harborside did not undertake a renewed and detailed architectural review of the option of adding a third operating room when the conversion of an existing procedure room continues to be appropriate to address its needs in a more cost effective manner.

Project Financial Feasibility G3(d)

22) Regarding Table 3, Revenues and Expenses – Entire Facility, please discuss the basis for the loss of about \$744,000 in Net Income reported for the year 2022.

Response:

2022 was a transition year for Harborside. It relocated to its new facility and began to increase its surgical volumes with the availability of a second operating room. Harborside operated profitably in 2023 and is projected to operate profitably in future years.

23) Regarding Attachment 22, Table L, Workforce Information, discuss:

A. How Harborside will recruit 8.0 FTEs in Direct Care staff without negatively impacting staffing at existing hospitals and ambulatory surgical facilities in its service area?

Response: The 8.0 FTEs projected to be needed in the future is a small incremental change relative to the size of the health care market in the National Capital Region. Harborside will not restrict its search to only the service area but will recruit in Maryland, Virginia and other states to find qualified staff. The impact on any single local provider is expected to be small.

B. Why were no additional anesthesiologists added to the staff for the third OR? Are all anesthesiologists part of the medical staff, or do you also use certified registered nurse anesthetists (CRNAs)?

Response:

Harborside contracts for anesthesiologists and CRNAs with an outside contractor rather than employing these staff directly. The contractor is responsible for providing the necessary personnel consistent with the volume of cases to be performed.

Project Impact G3(f)

24) Provide a response that addresses the impact of shifting surgical case volumes from existing hospitals and ambulatory surgical facilities located in Virginia, as indicated in Table 14, pp. 55-56 of the CON application.

Response:

As discussed previously, Harborside does not have access to detailed surgical information for Virginia providers. Given the size of the organizations from which these cases are being redirected, the impact should not be significant.

Health Equity G3(g)

25) Harborside needs to address the health care disparities in availability, accessibility, and quality of care among different populations within its service area. As stated in the criterion, provide a response that addresses questions A-C regarding the following:

Standard 10.24.01.08G(3)(g) Health Equity in the State Health Plan indicates that in reviewing a project, the “Commission shall consider how a proposed project *will address*” a number of different facets of health disparities in the service area, and further *consider* how social determinants of health in the service area create disparities in health care delivery. (Emphasis added)

Harborside is committed to principles of Health Equity. It is important to note several aspects of this standard. First, there are no specific benchmarks that must be met in order for a finding of compliance with the standard to be made. Second, the regulation does not identify specific information the applicant must provide in order for the Commission to be able to consider Health Equity issues. Third, the Commission’s assessment of social determinants necessarily is focused on *historical* information, and it is up to the applicant to provide relevant information. And fourth, by using the words “will address,” the standard is *future* oriented with respect to the Commission’s consideration of how a project is intended to address health disparities. This orientation of assessment of *past* social determinants, as contrasted with *prospective* expectations of addressing health care disparities, is especially important for an ASC seeking to become an Ambulatory Surgery Facility because ASCs traditionally have come into being as extensions of physician office practices.

While the Instructions for addressing these issues in the application form for the project are useful to an understanding of what the Commission would find helpful in the considerations it is required to make under the State Health Plan standard, in a practical sense much of this information is not typically available in the ASC context where the ASC is not a health care facility. Nonetheless, in our original submission, we were pleased to be able to demonstrate that notwithstanding what one might expect from a typical ASC with regard to Health Equity matters, Harborside has in fact historically had an early involvement and commitment in this regard that is unusual and noteworthy because there were no regulatory requirements to do so and it was a most uncommon practice in ASCs, thus distinguishing it from the experience of ASCs in general. Though we believe we have already provided a comprehensive and rather unique outline of information required by the Standard to enable the Commission to consider the issues identified in the Standard, we will provide some further information below to supplement our prior responses.

- A. With health equity in mind, the applicant shall identify the specific medically underserved area(s)/group(s)² within the designated service area and outline how the proposed project will address the unique health needs and quality of care for each identified group.**

Response:

On page 76 of the application, a review of the US Census data for our top 5 counties in Harborside Surgery Center service area, we found on average 8.5% of the population 65 and under are without health insurance and 7.7% persons in poverty.

As described in the application, Harborside Surgery Center has supported Operation Walk Virginia and members of our medical staff with in-kind contributions of medications, supplies, and staff to mission trips providing hip and knee surgeries to patients in Central and South America. This demonstrates our historical commitment to serving others.

To address the availability of access to the uninsured directly in our community, Harborside Surgery Center is partnering with our surgeon to identify underinsured, and uninsured patients in need and provide surgical services to this population through surgeon and office staff education, and education with local health departments. As you will see below, we are also exploring providing a musculoskeletal clinic annually to our community.

Further, the surgeons and Harborside are exploring a partnership with Operation Walk. Operation Walk USA is a medical charitable organization established in 2011, dedicated to assisting uninsured patients in the United States who require hip or knee replacement surgeries.

While historically, Operation Walk USA has collaborated with hospital partners, we are interested in exploring the possibility of extending this partnership to our ambulatory surgery center (ASC) setting. Our goal is to provide these critical services to uninsured patients within our service area.

- B. Applicants are expected to furnish a detailed overview of their organization's expertise and experience in health care access and service delivery. Emphasis should be placed on highlighting any relevant background that underscores the organization's commitment to equitable health care. This encompasses efforts to**

² According to HRSA, medically underserved populations and areas are identified as those which lack access to primary care services. These groups may face economic, cultural, or language barriers to health care. Some examples include: People experiencing homelessness, people who are low-income, people who are eligible for Medicaid, Native Americans and other historically disadvantaged populations of color, migrant farm workers, etc. (<https://bhwh.hrsa.gov/workforce-shortage-areas/shortage-designation#mups>)

integrate implicit bias and cultural competency training within the health facility and among current staff members.

Response:

As detailed on pages 72 - 75 of the application, the section on Diversity, Equity and Inclusivity details the organization commitment to equitable health care.

1. The US Census Report of the surrounding 5 counties comprising our service is used to understand the diversity of the community we serve. These counties include Maryland and Virginia.
2. Race and Ethnicity data was shared to demonstrate the diversity among our medical staff and work force.
3. Employee Manual and Code of Behavior was provided to demonstrate our commitment to equal opportunity employment, our commitment to equity, and our commitment to respect for the patient safeguarding their dignity, cultural, psychosocial and spiritual needs.
4. A detailed plan was provided of our commitment to staff and surgeon development in the areas of Social Determinates of Health, Implicit Bias and Cultural Competence by providing a detailed description of the annual competencies goal and objectives.

C. Please provide a comprehensive account of how the applicant planned with the community during the preparations for this project and how it will continue to engage with the community. Include a description of any specific initiatives and programs aimed at improving community well-being that are relevant to the proposed project. If applicable, the applicant should acknowledge any unintended barriers caused by the project that may have been identified through community discourse and propose proactive solutions to mitigate and rectify potential issues.

Response:

During the build out of Harborside, as it was a replacement facility for an already existing and operating ASC in the community, we did not reach into the community during the development. That said, we are committed to the community surrounding Harborside and as described below in section E, Harborside plans to plan with the community to improve community well-being by initiating musculoskeletal screenings in collaboration with the community.

D. Provide a copy of the policy that directs resources to address the issue of Health Equity at Harborside.

Response:

Prior to First Use, Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address our commitment to Health Equity.

- E. Please discuss whether Harborside conducts an outreach program with the community aimed at improving the health and well-being of the population within Harborside's service area.**

Response:

Harborside has not conducted outreach programs in the community. Harborside, in good faith, intends to develop an outreach clinic to perform annual musculoskeletal screening for arthritis and fall risk in our community. Risk screening and education would be provided. We will coordinate with Prince George's Department of Health and other Health clinics in our area to promote the screenings.

Character and Competence (G3(h))

26) Please address the following questions regarding character and competence:

- A. Discuss whether Harborside requires the physician and staff at Harborside to complete educational classes and training that address competency and quality in their interactions with both the patient and their families during the provision of health care surgical services.**

Response:

As stated on p. 74 of the original submission, Harborside Surgery Center recognizes the critical importance of providing ongoing competency training for its staff and medical professionals to ensure that our healthcare professionals possess the necessary competence to understand and effectively practice key concepts such as Social Determinants of Health (SDOH), Implicit Bias, and Cultural Competence.

As part of its commitment to fostering a workplace environment that values cultural competence and inclusivity, it requires all staff to complete a course on Social Determinants of Health (SDOH), Implicit Bias, and Cultural Competence during onboarding and on an annual basis thereafter. A full description of the courses content and objectives are outlined on page 74 and 75 of the original submission, for these three required competencies stated above.

- B. Is M2O involved in the ownership, development, or management of another health care facility? If so, please provide a complete list of its involvement.**

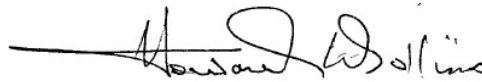
Eric Baker, Program Manager
Maryland Health Care Commission
July 31, 2024
Page 28

Response:

No, M2O is not involved in the ownership, development, or management of any other health care facility.

If any further information is required, please let us know, and it will be provided promptly.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard L. Sollins". The signature is written in a cursive style with a long horizontal line extending to the left.

Howard L. Sollins

HLS/tjr

Enclosures

cc: Jeanne-Marie Gawel, MHCC
Bill Chan, MHCC
Ruby Potter, MHCC
Deanna Dunn, MHCC
Matthew Levy, MD, MPH,
Health Officer Prince George's County Health Department
Jane Falk
Sandra Gateau
Daniel Sullivan
John Hill
John J. Eller, Esquire

LIST OF ATTACHMENTS

27. Outpatient Surgical Care, Patient Experience at Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs)
28. “Insurers want more surgeries in ASCs”
29. “Payers are pushing physicians to ASCs”
30. Safety considerations with the current ambulatory trends, more complicated procedures and more complicated patients
31. Patient Outcomes Following Total Joint Replacement Surgery: A Comparison of Hospitals and Ambulatory Surgery Centers
32. A Comparison of 30-Day Hospital Readmission and Complication Rates After Outpatient Versus Inpatient 1 and 2 Level Anterior Cervical Discectomy and Fusion Surgery
33. Charity Care and Financial Assistance Policy (Revised)
34. Tables 3 and 4 – Revenues and Expenses (Revised)
35. Letter from Architect re FGI Guidelines
36. Lab Corp Contract
37. Attachment 17 (revised) Historical and Projected Cases, Operating Room, Procedure Room, and Total
38. Affirmations

ATTACHMENT 27

Outpatient Surgical Care, Patient
Experience at Ambulatory Surgery
Centers (ASCs) and Hospital Outpatient
Departments (HOPDs)

Part One: Outpatient Surgical Care

Patient Experience at Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs)

Report Highlights

- Patients who had a same-day surgery are more favorable about care in ASCs than hospital outpatient departments on all four domains of patient experience, especially in their willingness to recommend the facility.
- Patients report less favorably about their experience with communications in both HOPDs and ASCs during the pandemic than in the year prior, an issue critical to ensuring patient safety.
- More transparency is essential: more HOPDs and ASCs need to publicly report on the experience of their same-day surgery patients, and the findings need to be published in a consumer-friendly manner.

Where the data comes from

This report analyzes patient experience data collected by hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) through a standardized survey called the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS). This report analyzes facilities that issued an OAS CAHPS Survey to their patients reflecting a time period of calendar year 2019 (pre-pandemic), as well as facilities that issued an OAS CAHPS Survey to their patients reflecting a time period of July 1, 2020 - June 30, 2021 (mid-pandemic), and then reported this data to the Centers for Medicare and Medicaid Services (CMS). More information on the content and interpretation of patient experience surveys can be found in [Appendix A](#).

Introduction

The COVID-19 pandemic has impacted health care delivery at every level and setting, from staffing shortages to increased infections to the very care patients receive. It has never been more critical to assess patient perspectives, both to assure that the patient voice is accounted for and heard, and to obtain vital information on the overall safety and quality of care being delivered. This report is the first in a three-part series from The Leapfrog Group examining patient experience during the pandemic.

Over 60% of all surgeries are performed on an outpatient basis (meaning that the patient is discharged on the same day the procedure is performed) either in a hospital outpatient department (HOPD) or ambulatory surgery center (ASC), and this continues to rise. The Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey ([OAS CAHPS](#)) measures the experience of patients undergoing same-day surgery in HOPDs or ASCs. Leapfrog asks facilities participating in the Leapfrog Hospital Survey and Leapfrog ASC Survey to report the results of the OAS CAHPS surveys administered to their patients, so that patients, employers, and purchasers can access this critical information. Leapfrog makes patient experience information available on its public reporting website, which allows users to search and compare patient experience at HOPDs and ASCs. Though CMS also publishes OAS CAHPS results for some facilities, they can only be accessed via a downloadable database that is not intended for layperson use.

The systematic collection of patient experience information after same-day surgery provides tremendous value for patients. Studies have shown that reliable patient experience data correlates significantly with safety and quality, and the collection and use of the data helps put patients at the core of health care delivery^{1,2}. Just as people seek out customer reviews and ratings before making online purchases, they can benefit from learning about patient perspectives on health care services before they decide where to receive care³. This is particularly the case for same-day procedures such as cataracts, hernia repair, or arthroscopic surgery for which patients almost always have the opportunity to research in advance where they would like to have their surgery performed. Without Leapfrog's public reporting of these [data](#), patients may struggle to find and compare information on the experience of other patients at an ASC or HOPD when choosing where to seek care. Leapfrog and its health care purchaser constituency call on all hospitals and ASCs across the U.S. to conduct the OAS CAHPS survey and report results to CMS and Leapfrog.

Adult Patient Experience in Hospital Outpatient Departments and Ambulatory Surgery Centers

The four areas of care covered on OAS CAHPS surveys include:

- General information about the facility and staff
Was the patient treated with respect by all staff and clinicians, was the facility clean, was the check-in process smooth?
- Communications from staff about the procedure
Was the patient given information on what to expect before, during, and after the procedure?
- Overall rating of the facility
How do patients rate the facility on a scale of 1 - 10?
- Willingness to recommend the facility
Would patients recommend the facility to friends or family?

Details about each measure and underlying questions, along with the response options, can be found in [Appendix B](#) of this report.

ASCs and HOPDs that voluntarily administered the OAS CAHPS survey and submitted their results to CMS were included in this analysis. It examines patient experience data from before the COVID-19 pandemic (January 1 to December 31, 2019) and during (July 1, 2020, to June 30, 2021).

Analysis

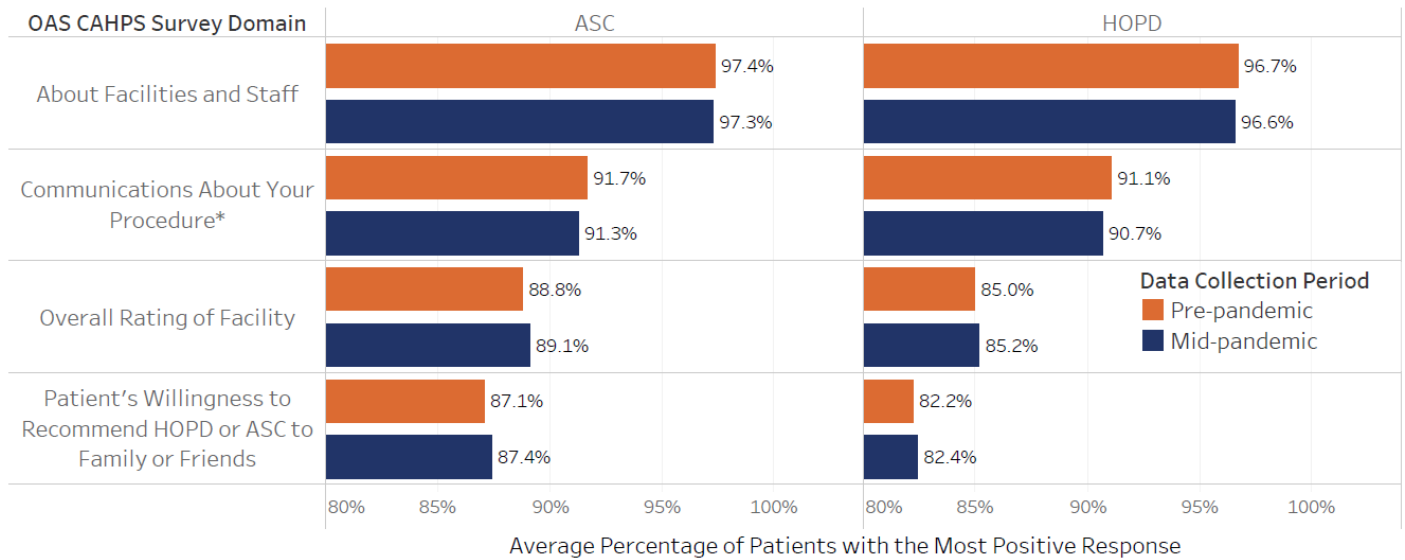
To evaluate ASC and HOPD performance on OAS CAHPS, Leapfrog looks at the percent of survey respondents who chose the most positive response for a given item. For example, a patient may indicate that nurses *always* listened carefully to them or that they would *definitely* recommend the facility to friends or family. Across all domains of patient experience examined through OAS CAHPS, a higher percentage of patients gave ASCs the most favorable response than those that gave the most favorable response to HOPDs. On average:

- Patients at both ASCs (97.3%) and HOPDs (96.6%) were more likely to give the most favorable responses to the **About Facilities and Staff** survey questions.
- Patients who selected the most favorable response for **Communications About Your Procedure** varies between ASCs (91.3%) and HOPDs (90.7%).
- Patients gave more favorable responses for **Overall Facility Ratings** at ASCs (89.1%) than at HOPDs (85.2%).
- Patients were least likely to give a favorable response on their **Willingness to Recommend** the facility, with an average of 87.4% of ASC patients and 82.4% of HOPD patients indicating that they would definitely recommend the facility.

The starkest difference between ASCs and HOPDs on patient experience is in Willingness to Recommend, with a five-percentage point difference favoring ASCs in the percent of patients who would definitely recommend the facility to family or friends in need of an outpatient procedure. ASCs also outperformed HOPDs on overall rating by a similar margin. This demonstrates that many ASC leaders have offered a positive experience to their patients that may give them a business advantage.

When comparing pre-COVID data to the most current data available, both facility types have shown the pandemic era brought with it a significant decline in patients' experience with communications about their procedure. This decline is more evident in HOPDs (90.7% vs. 91.1%) than ASCs (91.3% vs. 91.7%), though both have worsened. Clear communication from nurses and doctors about a patient's procedure is a crucial component of patient safety.

Average Percentage of ASC and HOPD patients who gave the most favorable responses on the OAS CAHPS survey pre-pandemic (2019; n=341 ASCs, 1064 HOPDs) and mid-pandemic (Mid-2020-Mid-2021; n= 392 ASCs, 1161 HOPDs).



Asterisk (*) denotes p-value < .05 for ASCs and HOPDs. Source: CMS (may include consolidated data from multiple hospitals)

Though the vast majority of patients gave positive feedback on their experience with outpatient surgical procedures despite the pressures of the pandemic, there remains significant room for improvement with both ASCs and HOPDs. While many elective procedures were delayed in 2020 and 2021, the data suggest that patients had a mostly positive experience when their surgeries were performed. Most of the patient experience reporting remained stable between the period prior to the pandemic and during the first COVID year, with statistically insignificant changes over the time period for all domains except communications about the procedure, a vital patient safety indicator. These findings suggest that outpatient surgical care may have escaped some, but not all, of the pandemic-era erosion of quality noted for inpatient care and other settings, according to national analyses by CMS and the CDC ⁴.

The Importance of Public Access to Patient Experience Data and Other Assessments of Quality and Safety

The OAS CAHPS survey is a useful tool for a variety of stakeholders, as long as the data is publicly available to them. Though CMS collects this data from ASCs and HOPDs, it is only made available to the public via a downloadable database which is challenging for consumers to use effectively. Furthermore, reporting OAS CAHPS to CMS is not yet mandated for HOPDs and ASCs, and therefore only available for facilities that voluntarily report this information.

Leapfrog reports patient experience for facilities that voluntarily report to the Leapfrog Hospital Survey and the Leapfrog ASC Survey. The Leapfrog Surveys are the only opportunities for facilities to report OAS CAHPS results in a consumer-friendly format. Results of same-day surgery patient experience surveys are available and accessible at Ratings.LeapfrogGroup.org. Results for the areas measured in this report are displayed under “Experience of Patients Undergoing Elective Outpatient Surgery.”

While all hospitals and ASCs can report to the Leapfrog Surveys at no cost to them, some decline to participate. If a hospital or ASC declines to report to Leapfrog, employers, patients, and community members are encouraged to contact facility leadership and ask them to do so.

For facilities that voluntarily participate in the Leapfrog Surveys, the act of public reporting is valuable not only for patients and families who entrust their lives to the facility’s care, but also for the facility’s physicians, nurses, staff, and leadership. They benefit from understanding how their patients experienced care in the facility and be able to identify gaps tied to safety and quality. Two ASCs, the [Center for Spine and Joint Replacement](#) in western Washington and [Coronado Surgery Center](#) near Las Vegas, highlighted the value that Survey participation has had on their quality improvement efforts in a series of [case studies](#).

Conclusion

Leapfrog’s assessment of the OAS CAHPS survey results between a pre-COVID and mid-COVID timeframe reveals that patient experience remained relatively stable with the advent of the pandemic, a potential contrast to indications that inpatient care saw sharp declines. Though patients at both ASCs and HOPDs generally provided favorable responses about their experience, same-day surgery centers continue to surpass hospital outpatient settings when it comes to reported patient experience. That said, the sample size for both facility types remains relatively small, with far fewer ASCs voluntarily completing OAS CAHPS surveys and then providing those results to CMS than HOPDs. This relative lack of transparency suggests the potential of selection bias influencing the results. Until more facilities are transparent, the contrast in patient experience between settings of care cannot be characterized as definitive. What’s more, the value of this information is undermined when patients and other stakeholders cannot easily access or comprehend the findings. Leapfrog’s efforts to expand quality and safety reporting in the outpatient surgical setting, including patient experience surveys, are critical to ensuring patients have the information they need to make the right health care decisions for themselves and their families.

Patient Experience During the Pandemic: A Three Part Series From The Leapfrog Group

Upcoming Reports

Part Two: Adult Inpatient Care (Early May)

Part Three: Pediatric Care (End of May)

Appendix A: How Patient Experience Surveys Work

A random sample of patients who have had specific surgical procedures performed in an outpatient setting (HOPD or ASC) are asked to complete an OAS CAHPS survey. Surveys are most often administered by an experienced survey vendor and are distributed by mail, telephone, or by mail with a telephonic follow-up.

Across all domains on OAS CAHPS surveys, participants are asked to check a box reflecting their experience with their care. Most frequently, these questions are phrased with response options like *Never*, *Sometimes*, *Usually*, *Always*; or *Strongly Disagree*, *Disagree*, *Agree*, *Strongly Agree*. Other times questions are phrased to ask for a 1 – 10 response, where 1 is the least favorable and 10 is the most favorable.

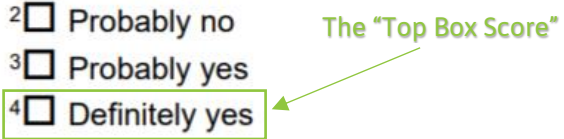
To evaluate overall facility performance on these surveys, Leapfrog looks at the “Top Box Scores,” which is the percent of survey respondents who chose the most positive response for a given item. For example, a patient may indicate that nurses *always* listened carefully to them or that they would *definitely* recommend the facility to friends or family. Looking at the Top Box Score is an approach to understanding responses reflecting the most positive sentiment. In this report, the Top Box Score is referred to as the most favorable response (e.g., *Always* or *Strongly Agree*). To analyze the data included in this report, Leapfrog calculated the average Top Box Score among facilities for which data is available.

Example of a HCAHPS Survey question. In this case “Definitely yes” is the top box.

19. Would you recommend this hospital to your friends and family?

- 1 Definitely no
- 2 Probably no
- 3 Probably yes
- 4 Definitely yes

The “Top Box Score”



Studies have shown that when used correctly, CAHPS results provide valid and reliable measures of quality and safety^{1,2}.

Appendix B: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS)

About Facilities and Staff	<ul style="list-style-type: none"> • Did the check-in process run smoothly? (Yes, definitely/ Yes, somewhat/ No) • Was the facility clean? (Yes, definitely/ Yes, somewhat/ No) • Were clerks and receptionists at the facility as helpful as they should be? (Yes, definitely/ Yes, somewhat/ No) • Did the clerks and receptionists at the facility treat you with courtesy and respect? (Yes, definitely/ Yes, somewhat/ No) • Did the doctors and nurses treat you with courtesy and respect? (Yes, definitely/ Yes, somewhat/ No) • Did the doctors and nurses make sure you were as comfortable as possible? (Yes, definitely/ Yes, somewhat/ No)
Communications About Your Procedure	<ul style="list-style-type: none"> • Before your procedure, did your doctor or anyone from the facility give you all the information you needed about your procedure? (Yes, definitely/ Yes, somewhat/ No) • Before your procedure, did your doctor or anyone from the facility give you easy to understand instructions about getting ready for your procedure? (Yes, definitely/ Yes, somewhat/ No) • Did the doctors and nurses explain your procedure in a way that was easy to understand? (Yes, definitely/ Yes, somewhat/ No) • Anesthesia is something that would make you feel sleepy or go to sleep during your procedure. Were you given anesthesia? (Yes/ No) • Did your doctor or anyone from the facility explain the process of giving anesthesia in a way that was easy to understand? (Yes, definitely/ Yes, somewhat/ No) • Did your doctor or anyone from the facility explain the possible side effects of the anesthesia in a way that was easy to understand? (Yes, definitely/ Yes, somewhat/ No)
Overall Rating of Facility	<ul style="list-style-type: none"> • Using any number from 0 to 10, where 0 is the worst facility possible and 10 is the best facility possible, what number would you use to rate this facility?
Patient's Willingness to Recommend HOPD or ASC to Family or Friends	<ul style="list-style-type: none"> • Would you recommend this facility to your friends and family? (Definitely no/ Probably no/ Probably yes/ Definitely yes)

Survey Source: [Agency for Healthcare Research and Quality](#)

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ATTACHMENT 28

“Insurers want more surgeries in ASCs”

Insurers want more surgeries in ASCs

Snagging profitable payer contracts and high reimbursements has historically been an obstacle for ASCs, particularly when competing with hospitals' big pockets.

However, many ASC leaders are seeing a shift in payer behavior — with insurers beginning to favor ASCs. And while some ASC owners are reporting efforts by insurers to increase prior authorization requirements and ramping up denials, others are seeing evidence of payers advocating for ASCs.

"With the continued rising cost of patient care in the hospital setting, ASCs have become many insurance companies' preference for outpatient surgery," Dianna Reed, administrator of Sani Eye Surgery Center in Templeton, Calif., told [Becker's](#).

Many payer policies in the past year have pointed to a growing interest in the migration of procedures from hospitals to the lower-cost ASC setting.

In April 2021, Empire BlueCross BlueShield in New York began [requiring](#) a medical necessity review to have certain procedures performed in the outpatient hospital setting instead of an ASC. In June, UnitedHealth Group made a commitment to [push](#) more surgeries to ASCs. According to a company report, the group aims to have more than 55 percent of its members' outpatient surgeries and radiology services delivered at cost-efficient sites of care by 2030, which means directing many patients to ASCs.

Some leaders are seeing payers deny coverage for procedures at a hospital. Barbara Clancy-Sweeney, administrator of gastroenterology and hepatology at Thomas Jefferson University in Philadelphia, told Becker's that insurance companies in her area are "no longer paying for a screening colonoscopy in the hospital."

"Healthy patients wanting to have a colonoscopy at their local hospital will have high out-of-pocket costs," she said. "[ASCs] ... usually only do healthy patients and do not have the regulatory requirements and overhead of a hospital unit."

ASCs can offer serious savings for payers. The potential savings of moving total joint replacements to ASCs, for example, is significant — with the cost of treatment being about [40 percent](#) less in an ASC compared with a hospital setting.

Surgery centers can also reduce the amount of time spent on-site by patients for a procedure, Ms. Reed said. In her market, wait times before and after procedures at a hospital surgery center can be up to two to three times greater than her ASC.

Insurers used to favor hospitals for internal workflow efficiencies, but in some markets, ASCs seem to be gaining the upper hand.

"The future is bright for ASC with commercial payers seeing the cost savings for themselves and their customers by moving cases to the ASC setting," said Chris Blackburn, BSN, administrator of South Kansas City SurgiCenter in Overland Park.

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ATTACHMENT 29

“Payers are pushing physicians to ASCs”

Payers are pushing physicians to ASCs

Payers are incentivizing physicians to perform procedures in low-cost settings, which means ASCs are becoming increasingly attractive, according to ASC leaders.

Insurers are finally seeing the cost savings potential in the outpatient setting. In the last decade, payers have caught on that ASC procedures are about half the cost of a hospital, according to a [report](#) from Regent Surgical Health.

"Many payers are developing steering mechanisms to shift cases to lower-cost settings which will result in more pressure on physicians to move cases to the outpatient ASC arena," Andrew Lovewell, administrator of the Surgical Center at Columbia (Mo.) Orthopaedic Group, told *Becker's*.

In November 2019, UnitedHealthcare [adopted](#) a policy that restricted sites of care for some nonurgent surgeries. The payer now reimburses for surgeries performed in hospital outpatient departments only if the setting is medically necessary based on the acuity of the patient.

In April 2021, Empire BlueCross BlueShield in New York began [requiring](#) a medical necessity review to have certain procedures performed in the outpatient hospital setting instead of an ASC.

"With the continued rising cost of patient care in the hospital setting, ASCs have become many insurance companies' preference for outpatient surgery," Dianna Reed, administrator of Sani Eye Surgery Center in Templeton, Calif., told *Becker's*.

There are also financial incentives for physicians to own and practice at ASCs. Physicians stand to win big with an ASC ownership stake.

"Physician ownership preserves efficiency, is a great recruitment tool and keeps costs down for our patients," Scott Thellman, MD, surgeon at Lawrence (Kan.) Plastic Surgery, told *Becker's*.

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ATTACHMENT 30

Safety considerations with the current
ambulatory trends, more complicated procedures
and more complicated patients



Review Article

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Safety considerations with the current ambulatory trends: more complicated procedures and more complicated patients

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In the last quarter of a century, the backdrop of appropriate ambulatory and office-based surgeries has changed dramatically. Procedures that were traditionally done in hospitals or patients being admitted after surgery are migrating to the outpatient setting and being discharged on the same day, respectively, at a remarkable rate. In the face of this exponential growth, anesthesiologists are constantly being challenged to maintain patient safety by understanding the appropriate patient selection, procedure, and surgical location. Recently published literature supports the trend of higher, more medically complex patients, and more complicated procedures shifting towards the outpatient arena. Several reasons that may account for this include cost incentives, advancement in anesthesia techniques, enhanced recovery after surgery protocols, and increased patient satisfaction. Anesthesiologists must understand that there is a lack of standardized state regulations regarding ambulatory surgery centers and office-based surgery centers. Current and recently graduated anesthesiologists should be aware of the safety concerns related to the various non-hospital-based locations, the sustained growth and demand for anesthesia in the office, and the expansion of mobile anesthesia practices in the US in order to keep up and practice safely with the professional trends. Continuing procedural ambulatory shifts will require ongoing outcomes research, likely prospective in nature, on these novel outpatient procedures, in order to develop risk stratification and prediction models for the selection of the proper patient, procedure, and surgery location.

Keywords: Ambulatory care facilities; Health care costs; Health care sector; Patient safety; Patient selection; Physicians' offices.

Introduction

The landscape of ambulatory and office-based surgeries has been changing over the last twenty-five years. Procedures that were traditionally done in hospitals are migrating to the outpatient setting at a remarkable rate. This rapid expansion, in turn, has increased awareness to patient safety considerations for outpatient procedures that includes understanding the appropriate patient, procedure, and location where the procedure will be performed. In addition, one must also consider the choice of anesthesia techniques, personnel, available resources, and emergency preparedness.

Surgical procedures within the United States (US) are increasingly shifting to outpatient or non-hospital locations, as seen in the expected 4% annual expansion rate of the ambulatory surgery center (ASC) market over the ten-year period from 2017 to 2027 [1–



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3]. In 2018, Young et al. [4] reported that there were millions of procedures performed annually in the ambulatory setting as of 2014. There is an expected increase to 144 million procedures by 2023 [5]. In 2005, hospital-based outpatient departments (HOPDs) were performing 59% of outpatient cases versus 41% by ASCs. By 2020, this proportion has reversed with HOPDs performing 40% of cases, ASCs with 36%, and offices with 24% [5]. On average, an important contribution towards the shift in procedural location is that surgeries performed at ASCs cost 60% of HOPDs. More complex patients (American Society of Anesthesiologists [ASA] Physical Status [PS] III or higher) are having their surgeries and procedures performed in the ambulatory setting as well [6]. The outpatient facility may be a stand-alone ASC, a facility attached to a hospital outpatient department, or even an office. Some of these environments may not have the necessary equipment to monitor complex patients or to deal with a medical emergency [7]. Understanding these factors within the outpatient procedural or surgical setting is the key to patient safety. Anesthesiologists play an important role in selecting patients that are appropriate for the outpatient setting that may reduce the likelihood of complications and readmission rates via adequate pain control, use of multimodal anesthesia, adequate post-operative nausea and vomiting (PONV), and ensuring that patients are medically optimized before their procedure.

Concurrently, several incentives have arisen to drive procedures from the ASC to the office-based surgery (OBS) center. According to the Healthcare Cost and Utilization Project, some of the most common ambulatory procedures include ophthalmologic lens and cataract procedures, musculoskeletal procedures, cholecystectomies, hernia repairs, breast procedures, tonsillectomies, myringotomies, hysterectomies, pacemaker management and implantations, vascular stent procedures, and spine laminectomies [8]. Another report by VMG Health on ambulatory centers performing 2 million cases in 2022 cited these top outpatient procedures: gastroenterology, 32%; ophthalmology, 26%; pain management, 22%; and orthopedics, 21% [9]. The largest drivers of this trend away from hospitals include increased patient satisfaction, reduced healthcare costs, and improved productivity [10–12]. Enhanced recovery after surgery (ERAS) protocols have helped enhance patients' experience and same-day discharge. For example, more orthopedic surgeries (total joints, minimally invasive spine surgery, and single and multi-level fusions) are being performed in the ambulatory setting [3]. As one report in 2021 estimated, patients may save about \$680 USD per procedure in the ambulatory setting when compared to inpatient procedures [13]. Over the next few years, outpatient orthopedic procedures are expected to grow at 6.5% compounded annual growth rate [14].

For cardiovascular procedures, there is less movement from the inpatient to outpatient setting as a result of the patients being older, having more comorbidities, and frequently requiring admission to the hospital. The patients need complex coordinated medical care and often intensive care units, and thus are less likely to be appropriate candidates for the outpatient setting. However, certain cardiology procedures could expand to ambulatory settings (electrophysiology and other interventional cardiology procedures), if there are coordinated guidelines and procedures in place to transfer patients to a tertiary care facility should they require a higher level of care. Similarly, vascular procedures are also being performed in the outpatient setting (inferior vena cava [IVC] filter placement and peripheral vascular interventions [PVI]).

Interventional radiology (IR) procedures have benefits like reduced hospital stays and costs, due to the minimally invasive nature of their procedures, with a projected growth of nearly 6.5% from 2023 to 2028 [15]. Examples of IR procedures include central venous line placements, arterial embolization, IVC filter placement, vascular interventions for fibroids and scrotal varicoceles, image-guided biopsy or drainage, image-guided approaches for cancer biopsy, treatment, and surveillance, and vertebroplasties and kyphoplasties for pain related to spinal metastases [16]. Gynecological procedures are expected to decline in the inpatient setting by nearly 30% as obstetricians and gynecologists are performing more procedures (hysteroscopies and sling procedures) in their offices [3]. Gastroenterology may be one of the fastest growing markets, with a 20% growth from 2015 to 2016 [3]. Upper endoscopies with anesthesia services represent about 7.3% of all procedures done according to one industry report [17]. Dental procedures have among the largest market share through 2023, the majority of which are performed in office-based settings [5]. Ophthalmology is growing their market by doing more procedures in the outpatient setting, with and without anesthesia services [18]. Plastic surgery has been one of the pioneers for performing outpatient procedures, and they continue to see exponential growth to the outpatient setting [19]. Urology is observing a shift in reimbursements from hospital-based procedures to office-based ones, resulting in changes in the types of procedures being performed in the office that were historically performed in ASCs or HOPDs [20].

Outpatient procedures by specialty

Gynecology

Khandwala and Jayachandran [21] performed a small prospective feasibility study in 2012 that demonstrated that office-based

sling procedures are safe and feasible. A recent retrospective analysis by Cappuccio et al. [22] from 2021 examined data from 2008 to 2015, consisting of over 41,000 patients undergoing hysterectomy for endometrial cancer. They discovered that there was a 41% shift in volume from inpatient to outpatient centers. This was associated with a cost reduction of \$2,500 per hysterectomy. The authors mentioned that performing hysterectomies robotically in mid-sized hospitals were important factors associated with same-day discharge. However, patients undergoing abdominal hysterectomy or other concomitant procedures, with advanced age, of African American race, and with higher co-morbidities were more likely to be admitted.

Morgan et al. [23] studied a large retrospective analysis from 2010 to 2013 from a national data set on inpatient and outpatient hysterectomies from over 386,000 patients. The authors identified an outflow of cases to the outpatient setting, with inpatient and outpatient rates of 26.6 per 10,000 and 13.3 per 10,000 women changing to 15.4 per 10,000 and 19.6 per 10,000 women, respectively.

In 2020, a retrospective military study by Fielden et al. [24] on the benefits of office versus operating room (OR) hysteroscopy was done on 280 patients from 2015 to 2018. They compared admission time, procedure time, reimbursement, and costs for each type of hysteroscopy treatment group to develop a time-cost-benefit-value (TCBV). The TCBV was defined as any cost savings plus difference in reimbursement rates when Medicare increased office reimbursements in 2017. On average, the office had a one-hour clinic time versus 6.2 h for admission in the hospital. The average procedure time was 41%–61% shorter in the clinic versus in the OR. The authors had limited data on total actual office appointment time (57 of 235 cases) whereas they had the entire data for the OR cases (45). On average, 11% (26 of 235) of patients in the clinic could not complete the procedure. This was due to extensive pathology (16 of 235 cases), inability to tolerate the procedure (6 of 235 cases), and inability to visualize (4 of 235 cases). However, they could not track all of the direct and indirect costs of the OR and clinic and therefore were unable to calculate true TCBVs. They focused on disposable costs and labor — places that employed civilian anesthesiologists would face higher costs than active-duty staff.

Spine surgery

Spine surgery is an incredibly lucrative procedure for spine surgeons and there is a desire to discharge patients on the same day to reduce hospital costs and hospital length of stay. However, same-day discharge for spine surgery is debatable. A 2018 large-

scale retrospective case control study review by Arshi et al. [25] examined a national private insurance database from 2011 to 2016 to analyze the inpatient versus outpatient complication rates of anterior cervical discectomy and fusion (ACDF) surgeries. The authors were able to identify 770 patients who were discharged on the same day versus 26,826 patients who were admitted after surgery. They reported that outpatient ACDF was associated with a greater risk of perioperative surgical complications, including revision posterior or anterior surgery, requiring postoperative laminectomy, and a higher risk of perioperative renal failure. They assert that proper patient selection is crucial to reduce the risk of these complications. Conversely, Yerneni et al. [26] performed a retrospective meta-analysis of outpatient ACDF articles and found no statistically significant differences between inpatient and outpatient ACDF in terms of overall complications such as stroke, thrombolytic events, dysphagia, and hematoma. They report that outpatient ACDFs were more likely to have lower reoperation rates, mortality, and hospitalization duration. Their analysis was limited by the lack of high-quality evidence in the literature.

Other authors reported a reduction in costs for outpatient ACDF, an increasing shift in outpatient ACDF volume, and low likelihood of complications. Martin et al. [27] performed a retrospective review of a national insurance database of outpatient ACDF trends and costs from 2007 to 2014, demonstrating lower costs for outpatient surgery at 90 days, lower incidences of 30-day complications, and a higher morbidity for inpatient surgery. Del-Sole et al. reported in a 2019 meta-analysis substantial growth in spine surgery from 1994 through 2016 [28]. Their data reflected low likelihood of complications after same-day discharge. A 2020 retrospective review of Medicare patients undergoing ACDF identified 264,000 surgeries from 2012 to 2017 [29]. Their data demonstrated a significant increase of 185% in ASC ACDF volume from 2015 to 2017.

Urology

A common urology procedure typically performed in the hospital is the ureteral (JJ) stent placement. There is a push in urology to move some of these stent placements in the clinic for the right patient. In 2019, Doersch et al. [30] examined clinic versus OR ureteral (JJ) stent placements (under nitrous oxide and/or local anesthesia [LA] versus general anesthesia [GA], respectively) in New York. Outcomes compared were complications, unanticipated hospitalizations, and stent failures. Overall, there were low complication rates (unanticipated hospitalizations or stent failures) — 4.1% in the clinic setting versus 7.9% in the OR setting. The authors could not find any identifiable risk factors that affect-

ed the complication rates; the clinic versus OR setting was not predictive of complications.

Another type of office procedure is the magnetic resonance imaging prostate partial gland cryoablation. A 2020 feasibility study by Basourakos et al. [31] examined patients who underwent this procedure under LA. The authors found adequate outcomes of cancer remission without an increase in urinary or sexual function compared to the baseline. Additionally, in-office costs were significantly lower than when doing the procedure under GA in the OR at an ASC (\$4,400 versus \$8,400). While disposable costs for both in-office and OR procedures were similar (\$3,086), the fixed costs for in-office procedures were \$305 while for OR procedures ranged from \$1,859 to \$6,049. The larger fixed costs for the OR were from driven from the need to perform the procedure under GA and longer operative times (90–150 min versus 16–58 min).

For women undergoing complex female pelvic floor reconstruction surgery, Dutta et al. [32] created in 2020 an ERAS protocol for same-day discharge and studied whether this would result in a reduction in hospital resources without compromising patient safety outcomes. Their ERAS protocol involved pre-operative hydration, urinary analgesia, non-narcotic analgesia, involvement of the family, and communication. The authors found no differences in demographics, operative details, complications, overall revenues or expenses, emergency room visits, or unexpected clinic visits when comparing pre-ERAS protocol versus post-ERAS protocol. They did find a significant difference in the bed-unit cost (\$210 versus \$533) and the amount of prescribed narcotics in favor of the post-ERAS group. The post-ERAS group did have significantly more patients undergo the procedure in an ambulatory setting (73.6% versus 48.8%) and who were discharged on the same day (80.2% versus 50%).

Partial nephrectomies are moving towards a same-day discharge. Wood et al. [33] conducted a retrospective analysis over six years from 2015 to 2021 comparing a before and after implementation of a same-day discharge protocol for partial nephrectomy. On a before and after same-day discharge protocol comparison, their study found 78% of post-anesthesia care unit (PACU) patients were discharged on the same day compared to 0%, had similar safety profile, and no difference in readmission rates, but same-day discharge patients were more likely to return to the office for an unplanned visit (17.8% versus 6.8%). On a cost basis, same-day discharge patients incurred higher costs from the lengthier PACU stay by \$1,622 per patient; on the other hand, total healthcare costs were lower for same-day discharge patients (\$5,222 versus \$8,425 per patient).

Vascular

Vascular surgery outpatient procedures have also increased while inpatient services have declined. Jones et al. [34] examined cases from 2006 to 2011, demonstrating a significant shift of PVI to the outpatient setting. The authors identified nearly 40,000 Medicare patients and found that there was a large reduction in the rate of PVIs in the hospital: 209.7 to 151.6 per 100,000 beneficiaries. Meanwhile outpatient hospitals and office-based laboratories (OBLs) saw a huge increase: 184.7 to 228.5 per 100,000 beneficiaries and 6 to 37.8 per 100,000 beneficiaries, respectively.

Looking at the trends of ambulatory shifts, Schramm et al. [35] reviewed Medicare claims from 2011 to 2017 for PVI, demonstrating a large increase in office-based billing and steep decreases in hospital inpatient and outpatient billing. Over this time period, the largest proceduralist growth was in the radiology group versus cardiology or vascular surgery. Overall, all OBL claims sent in by surgery, cardiology, and radiology showed significant advancement during this time.

Another report by Smith et al. [36] reviewed Medicare payments from 2013 to 2015 for vascular procedures (atherectomy, diagnostic angiography, stent placement, and percutaneous transluminal angioplasty) and found a 64% increase of procedure in office volume. A more recent study by Mukherjee et al. [37] surveying cases from 2011 to 2014 demonstrated a 60% increase in outpatient PVI, with office procedures increasing by as much as 298%.

An examination of 6,200 procedures on nearly 2,800 patients from 2011 to 2015 by Aurshina et al. [38] found that low risk patients were able to safely undergo minimally invasive, noncomplex vascular procedures with low risk for morbidity and mortality. The authors looked at procedures performed at an OBL. The majority of their patients were ASA PS I and II. They found no patients with any deaths, major bleeding, myocardial infarction, or stroke within 72 h of the procedure. A study in 2016 by Alsheekh et al. [39] reported that vascular surgeons were safely able to place IVC filters in patients in their offices.

Interventional radiology

IR procedures are also moving into the outpatient arena. Wang et al. [40] investigated the cost of endovascular intervention versus hysterectomy to treat uterine leiomyoma along with hospital length of stay. The authors examined outpatient data from over 227,000 patients from California (2005–2011) and Florida (2005–2014). They compared three groups: hysterectomy, myomectomy, and uterine artery embolization (UAE) for treatment of uterine leiomyoma. Patients who received a hysterectomy had slightly

longer mean length of stay versus the other two treatment groups. The cost of an UAE was significantly cheaper, \$3,772, versus hysterectomy, \$5,409, and versus myomectomy, \$6,318. Their study found that 75% of the patients undergoing an UAE were discharged on the same day versus 55% of the patients undergoing hysterectomy.

Ahn et al. [41] published a 2017 case series on 5,134 outpatients who underwent endovascular procedures. They examined the first 5,134 consecutive patients in the office from 2006 to 2013 to assess for complication and success rates. The five types of procedures in descending order of proportion were venous interventions, arterial interventions, diagnostic angiograms, dialysis access interventions, and venous catheter management. There were low complication rates: 1%, 1.5%, 3%, 1.1%, and 0.7%, respectively. Nine patients out of 5,134 died within 30 days of their procedure but were not deemed to be procedure-related.

Offices may provide improved patient satisfaction as there can be reduced delays for IR procedures. In 2020, Hickey et al. [42] studied the impact of an OBL versus hospital setting on procedure start delays. They looked at 176 mapping and treatment angiograms from 2019 to 2020. There were no differences in mapping or treatment angiograms between each site. There were longer start delays in the hospital versus the office (28.6 min versus 0.8 min). Procedures also took longer on average in the hospital versus the office (2 h, 1.8 min versus 1 h, 44 min). It follows that patients would have higher satisfaction since there were less delays and shorter procedure duration. Additionally, there were cost savings associated with office-based procedures as more of the procedure payment stays with the radiology practice rather than going towards the hospital facility fee.

Dental

Patient safety in dental offices has been wrought with controversy in the past. Specifically, pediatric deaths in dental offices from 1980 to 2011 were reported on by Lee et al. [43]. There were 44 deaths: two in ages 0–23 months, 21 in ages 2–5 years, eight in ages 6–12, 13 in ages 13–21 years, and. The type of anesthesia used was reported with the fatalities: 20 in a setting of moderate sedation, 10 in a setting of GA, 10 were not reported, and 4 with LA. The type of anesthesia provider was also reported- 25 deaths were in the setting of a pediatric/general dentist, 8 with an oral surgeon, 7 with anesthesia, and 4 were not reported. The procedure location was labeled with the fatalities: 31 deaths occurred in offices, six in hospital, and seven were not reported. However, a recent report by Gaiser et al. [44] examining online versus PubMed (<https://pubmed.ncbi.nlm.nih.gov/>, United States National Library of Med-

icine) published deaths in dental offices found that there may be an undercounting of deaths as well as underestimation of the risks from sedation and GA. More reported deaths under the age of 18 were seen in the non-expert online articles versus PubMed.

Within the adult world in the military health system, dental adverse event trends were examined by Stahl et al. [45]. They looked retrospectively from 2013 to 2016 and found a 32% increase in events in dentistry. Additionally, dental adverse outcomes were the highest compared to other specialties (32.7%). Of the adverse events, wrong-sided surgeries (WSS) and intraoperative/post-operative anesthesia or surgery issues were the highest fraction sentinel events (63% and 14%, respectively). Within WSS, wrong-sided anesthesia and wrong-tooth surgery comprised the largest percentages of events (40% and 32%, respectively). The dataset did not track total procedures, so no incidence rates were calculated. Root cause analyses (RCAs) performed afterwards found communication failure and inconsistent use of the universal protocol to be the leading reasons for WSSs.

A survey was conducted by Viswanath et al. [46] of 120 oral maxillofacial surgeons (OMFS) on ambulatory checklist adoption and malpractice claims in 2018. They found that 42% of respondents did not use a checklist in ambulatory surgery; even 45% of OMFS performing more than 30 procedures a week were not using a checklist. Up to 17% of OMFS nationally report at least one malpractice claim [47]. The authors concluded that OMFS should adopt ambulatory checklists more universally as well as conduct more research in this area.

A recent 2022 survey of American Association of Pediatric Dental program directors found that more than two-thirds of the program directors felt that there was a lack in safety knowledge and information among residents [48]. A limited number of program directors were familiar with tools associated with safety, such as RCA and situation-background-assessment-recommendation.

Otorhinolaryngology procedures

A recent retrospective study on office ear, nose, and throat (ENT) procedures was undertaken by Benito et al. [49] They examined sialendoscopies in the office versus sialolithotomies in the OR from 2011 to 2016. The authors found similar demographics, sialolith numbers, and sizes. There were similar symptom improvement as well as recurrence rates. However, within the office they found a significantly shorter duration of procedure compared to the OR (39 min versus 277 min). Additionally, there was a significant reduction in procedure and hospital charges (\$719 versus \$13,950).

Another study by Mastrodonardo et al. [50] examined the types

of anesthesia for OR sialendoscopies from 2017 to 2019. They found that when doing the procedure with monitored anesthesia care compared to GA, there was a decreased median hospital time (141 min), anesthesia time (46 min), operative time (24 min), time in the OR (43 min), and recovery time (56 min). There were no differences in the rates of symptom resolution, complications, and repeat medical or surgical interventions.

A contemporary review by Schimberg et al. [51] of laryngopharyngeal surgery cost comparison between the office and the OR was published in 2019. They found 13 studies to include, all of which described lower costs in the office, nearly 95% reduction per procedure. The types of surgeries included laser surgery, biopsy, vocal fold injection, or esophageal dilation. The lowest cost was associated with LA instead of procedures performed with an anesthesiologist. The added benefit was that the patients can often return to work the same day. The authors noted vast differences between charges that hospitals submitted for billing and the actual costs of the procedure, as well as wide variation on total costs per procedure. There appeared to be a lack of transparency with regards to this information within and across the healthcare systems internationally.

Ophthalmology

A retrospective cohort analysis conducted by Stagg et al. [18] of 531,000 ophthalmologic surgeries from 2001 to 2014 in the US reported that outpatient cataract surgery increased from 43.6% in 2001 to 73% in 2014. Current literature also shows reports that commonly performed ophthalmology procedures are also trending toward the office setting. As of 2019, office procedures are safe, more financially viable, and may offer more convenience for the proceduralists and better patient satisfaction [52].

Gastroenterology

Gastrointestinal (GI) procedures have served as one of the pioneers for procedures performed in the outpatient setting. Predmore et al. [53] reported Medicare data with respect to ASA PS I and II patients who received anesthesia for GI procedures. From 2010 to 2013, 6.6 million GI outpatient procedures showed an increase in the use of anesthesia from 33.7% to 47.6% among Medicare patients and 38.3% to 53% among private insurance patients. Another report by Adams et al. [54] demonstrated substantial growth of anesthesia services for GI procedures performed at the Veterans Administration hospital from 2000 to 2013. Similarly, a retrospective analysis by Eberth et al. [55] on the trend of gastroenterology procedures reported a substantial shift from hospitals

to ASCs from 2001 to 2010.

A major part of the shift towards outpatient gastroenterology cases is due to a reduction in healthcare costs. Blue Cross Blue Shield insurance-approved charges are shown in Fig. 1. Office-based procedures provided significant cost savings to the healthcare system. For a typical GI procedure, the reimbursement to the hospital or HOPD was \$2,753, to the ASC was \$2,277, and to the office was \$1,678.

Plastic surgery

Plastic surgery is another pioneer in outpatient and office-based procedures. Ballard et al. [56] reported in 2019 that the majority of breast surgery augmentation procedures were performed in freestanding outpatient (47%) and office (34%) centers from 2011 to 2015. The authors also reported a low rate of adverse events (7%) and reoperation rates (2%). Another retrospective analysis from 2011 to 2018 of aesthetic plastic surgery conducted by Khetpal et al. [19] also demonstrated the consistent trend of significant increases in breast reduction and abdominoplasty cases seen in the ASC.

Supporting the trend of plastic surgery cases being performed in the office, Osman and Shapiro [57] reported in their review that there were 72% of 17.5 million aesthetic procedures being done in the office-based setting annually. A common surgical technique is the use of tumescent lidocaine that has a somewhat large safety margin; however, fat embolism is a concern and has been associated with deaths [58]. A 2017 survey of plastic surgeons by Mofid et al. [59] found that out of 198,857 cases of glu-

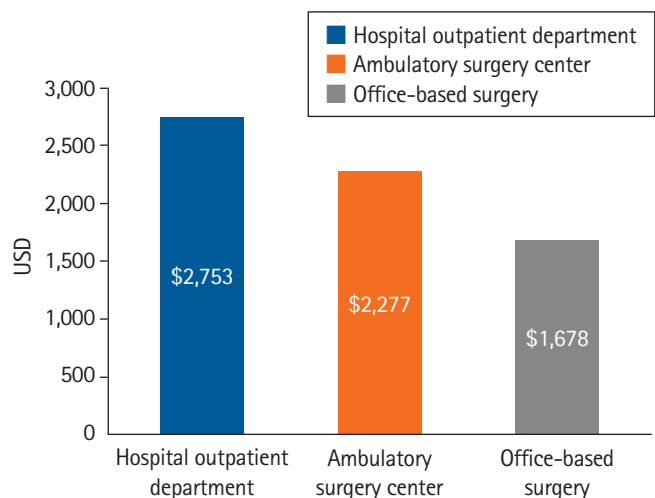


Fig. 1. Average Blue Cross Blue Shield approved charges (USD) for a typical GI procedure by site. USD: United States dollar, GI: gastroenterology.

teal fat grafting, there were 32 fatalities and 103 nonfatal pulmonary emboli. There may be a higher mortality incidence associated with gluteal fat grafting than with other cosmetic procedures.

Endocrine surgery

A 2018 retrospective analysis was conducted by McLaughlin et al. [60] of 76,000 patients who underwent partial or total thyroidectomy from 2005 to 2014. They uncovered a steady increase in patients undergoing outpatient surgery annually with a relatively low risk of complications. When comparing outpatient versus inpatient thyroid surgery, there are cost savings associated with outpatient surgery, decreased hospital length of stay, and increased patient satisfaction [61]. Proper patient selection was key to the success of creating and maintaining an outpatient program. The authors identified important contraindications to outpatient thyroid surgery that include complex medical problems, anticipated difficult surgical dissection, anticoagulated patients, lack of home support, and patient anxiety about same-day discharge. This, in turn, was used to develop a protocol to improve patient safety and satisfaction. In 2021, Rosen et al. [62] performed a retrospective analysis in Alabama analyzing outpatient versus inpatient thyroid surgery and associated costs and outcomes from 2011 to 2017. Of 870 isolated total thyroidectomies, 42% were outpatient surgeries

and there were no significant differences in complications between the two groups. The outpatient group had average cost savings of \$2,300 per patient compared to the inpatient group.

Mobile anesthesia

Most surgical procedures require the use of anesthesia services regardless of the location of the procedures being performed. As surgical procedures migrate from inpatient hospitals to outpatient centers and offices, anesthesia providers must follow suit. Mobile anesthesia is a relatively new concept that provides services to office-based surgery sites [63]. This concept brings the OR to the office and the patient. For instance, a medium sized mid-west anesthesia practice specializing in mobile anesthesia, called Mobile, provides offices with anesthesiologists and pre- and post-procedure nurses. They transport portable anesthesia machines with all of the ASA standard monitoring equipment, airway management supplies, anesthesia medications, emergency medications for advanced cardiopulmonary life support and malignant hyperthermia (MH), pediatric-related equipment, and anesthesia electronic medical record (EMR) documentation. Examples of specialties that perform procedures in the office include ENT, gastroenterology, pain medicine, gynecology, urology, dentistry, vascular surgery, orthopedic surgery, podiatry, and plastic surgery (Table 1).

Table 1. Examples of Procedures Done in the Office in the Mid-west USA

ENT	Gastroenterology	Pain medicine
Balloon sinuplasties	Upper endoscopies	ESI
Turbinates reduction	Flexible sigmoidoscopies	Medial branch blocks
Septoplasties		Radiofrequency ablations
Concha bullosa reduction	Gynecology	Urology
Maxillary anastrotomies	Essure, myosure, novasure	Cystoscopies
Myringotomy tube insertion	Hysteroscopies	Urolift
Ethmoidotomies	Dilation and curettage	Vasectomies
Coablation of the tongue base	Polypectomies	Lithotripsies
DISE	Hymen repairs	Bladder and prostate biopsies
Plastic surgery	Vascular surgery	Orthopedic surgery
Rhinoplasties	Endovascular laser treatments	Carpal tunnel release
Blepharoplasties	Phlebectomies	Knee arthroscopies
Breast augmentation	Podiatry	Shoulder arthroscopies
Face and/or brow lifts	Bunionectomy	Tendon and ligament repairs
Abdominoplasties	Hammer toe repair	Rotator cuff repairs
Liposuction		Ankle surgeries
Dental		
Extractions, implants		
Full mouth restoration		
Pediatric, special needs		

ENT: ear, nose, and throat, ESI: epidural steroid injection, DISE: drug-induced sleep endoscopy.

A large retrospective analysis of nearly 90,000 cases from 2016 to 2019 from a mobile anesthesia practice in New York was conducted by Shapiro et al. [63]. This practice staffed both ASC and OBS sites. Their four-year EMR data reflected a steady increase in OBS cases and an exponential growth in ASC volume. The top five procedures in the ASC were cataract removal, lumbar epidural steroid injections, shoulder arthroscopy, knee arthroscopy, and lumbar disc decompression (Table 2). The top five procedures in the OBS were colonoscopy, prostate biopsy, angioplasty, urethrocytostomy, and uterine fibroid embolization. The case mix was widely different between the two, almost exclusive of each other. OBS had slightly older group of patients and slightly higher classification with patients considered ASA III or greater. Overall complications in the OBS were zero in 89% of cases versus 83% of ASC cases, which was a significant difference. Major complications were rare and there was no significant difference between OBS and ASC sites. OBS had significantly fewer minor complications compared to ASCs. There was a low incidence of overall complications observed in the OBS procedures.

Complex patients

As demonstrated above, the scope of procedures being performed in the outpatient setting is becoming more complex. This, in turn, brings with it a patient population with more complicated medical issues. Just as cardiovascular risk factors and atherosclerotic cardiovascular disease have increased over time, Smilowitz et al. [64] assert that one can only assume the same for the outpatient population. While examining a US inpatient study sample from 2004 to 2013, the authors found that patients with more than two cardiovascular risk factors increased from 40% to 48%, the percent of patients with coronary artery disease increased from 17% to 18% over this time period, peripheral vascular disease increased from 6.3% to 7.4%, and patients with a reported prior stroke increased from 3.5% to 4.7%, respectively.

A 2021 study by Hajmohamed et al. [65] reported a changing landscape in outpatient surgery with regard to morbid obesity

and surgical complications. They conducted a retrospective analysis examining 7,100 patients from 2017 to 2018, reporting that a similar proportion of patients from each group had to be readmitted within three days (0.48% versus 0.46%). After multivariate analysis in which the body mass index (BMI) was evaluated as a continuous variable, a BMI of 40 + was not associated with medical complications, surgical complications, or readmissions. The authors state that there is insufficient evidence regarding postoperative complications in these patients undergoing GA for outpatient surgery.

The effect of increased BMI can be seen in anesthesia-related closed claims. A retrospective analysis by Ranum et al. [66] from 2007 to 2014 of nearly 1,000 closed claims at ASCs and hospitals found that 19% of ASC claims and 33% of hospital claims were high severity injuries. High severity included injuries like loss of one or two limbs, brain damage, paraplegia or quadriplegia, or severe brain damage, death, or lifelong care. The four top injury claims were dental injuries, perioperative pain, nerve damage, and death. While no comorbidity was implicated in the vast majority of the claims (71% and 65% for ASC and hospital, respectively), obesity (13% and 20% for ASC and hospital, respectively) was the most common comorbidity that impacted both ASC and hospital closed claims.

Patients with high BMI are also at high risk for obstructive sleep apnea (OSA) and are at increased jeopardy of suffering postoperative complications after receiving sedation or postoperative analgesia. Goldberg et al. [67] used the validated STOP-BANG (Snoring history, Tired during the day, Observed stop breathing while asleep, high blood Pressure, BMI more than 35 kg/m², Age more than 50 years, Neck circumference more than 40 cm, and male Gender) questionnaire to evaluate their patient population who required intravenous (IV) anesthesia or sedation for risk of OSA. Of the 153 patients, 12 (8%) were at moderate to high risk of OSA. With this new data, they changed the sedation plan for four patients due to the elevated OSA risk.

Bongiovanni et al. [68] appreciated the change of the overall health and comorbidities in patients undergoing outpatient procedures and performed an analysis of over a 1.2 million ambulatory surgeries in California taking place from 2009 to 2011. The authors analyzed the rate of 30-day unplanned hospital visits, emergency room visits, and hospital admissions. The data showed that the risk of unplanned hospital visits was 4.8%, ER visit was 3.1%, and hospital admission was 1.7%. The independent risk factors included increasing age, increasing comorbidities, location of procedure, and type of surgery. Cardiovascular and urological procedures had the highest rate of unplanned hospital visits at 30 days.

Table 2. Top Procedures from a Mobile Anesthesia Practice

ASC top five procedures	OBS top five procedures
Cataract removal	Colonoscopy
LESI	Prostate biopsy
Shoulder arthroscopy	Angioplasty
Knee arthroscopy	Urethrocytostomy
Lumbar disc decompression	Uterine fibroid embolization

ASC: ambulatory surgery center, OBS: office-based surgery center, LESI: lumbar epidural steroid injection.

Rajan et al. [7] performed a 2021 review of patient selection in ambulatory surgery and assert that many factors need to be considered in patient selection. This includes the type of procedure being performed, type of facility (hospital versus free-standing versus office), patient medical history, social history and non-medical factors, and the type of anesthesia being administered. Facility type and procedure type are important to consider because the facility may not be able to offer higher acuity services such as lab or blood bank services, expert consultation for the care of sicker patients, or formal transfer policies and procedures in the case of an emergency. The authors provide some recommendations for proper patient selection: ASA III patients who are stable, ASA IV patients who are stable undergoing low-risk procedures, graded consideration for obesity, screening for and optimizing patients with sleep apnea, asymptomatic cardiac patients who do not require testing, excluding patients with severe chronic obstructive pulmonary disease, excluding patients with end-stage renal disease not on dialysis, and ensuring that there is MH treatment cart and non-triggering agents if caring for patients with MH.

The use of regional anesthesia in ambulatory surgery provides clear benefits to the patient including lower pain scores, reduced narcotic pain medicine usage, shorter recovery times, and decreased hospital length of stays. Gabriel and Ilfeld [69] identified nearly 13 million ambulatory surgeries from 2010 to 2015 from the National Anesthesia Clinical Outcomes Registry (NACOR) that demonstrated that the employment of peripheral nerve blocks has rapidly increased over time. Uncontrolled pain can prevent timely discharge after recovery or even result in an unplanned hospital admission. Pavlin et al. [70] reported that high pain scores can lead to higher and more frequent doses of narcotics in recovery, increased risk of PONV, and a resultant delay in discharge. The authors stated that pain scores had a positive predictive effect on recovery times, with increasing times with increasing pain scores. Patients who received LA and ketorolac were less likely to have high pain scores, and patients received less fentanyl if they also received ketorolac intraoperatively.

In recent years the influence of pain on PACU stay and hospital length of stay has been confirmed with other types of surgeries that incorporate ERAS protocols, like non-opioid analgesics, dexamethasone, and regional anesthesia. Non-opioid analgesics like acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), ketamine, and dexmedetomidine have consistently positive effects on pain control and reducing hospital length of stay [71–74]. Dexamethasone has been shown to reduce pain as well as nausea incidence [75]. Use of regional anesthesia has good evidence to reduce pain scores, nausea and vomiting rates, and PACU length of stay [76]. High pain scores after breast surgery

have been associated with higher rates of post-discharge nausea and vomiting that Stjernberg et al. [77] thought was due to higher opioid consumption.

A 2016 retrospective study by Herzig et al. [78] analyzed adverse events among Medicare beneficiaries who were discharged with opioids versus NSAIDs (13,385 versus 4,677) and found that there were significantly more morbidity and mortality within 30 days of discharge. Specifically, among opioid users, there were significantly higher rates of death (1.8% versus 1.1%), healthcare utilization (19% versus 17.4%), and any potential adverse event (25.2% versus 21.3%) — higher relative risk [RR] of a fracture or fall (4.5% versus 3.4%, RR 1.3), nausea or vomiting (9.2% versus 7.3%, RR 1.3), and constipation (8% versus 6.2%, RR 1.3). There were no differences in the risk of delirium, acute kidney injury, or gastritis.

Conclusion

The landscape of surgical and noninvasive procedures being performed has been evolving and shifting over the last quarter century. Anesthesiologists are constantly being challenged to maintain patient safety commensurate with this exponential growth. The literature supports the trend of higher ASA PS scored patients and more complicated procedures shifting towards the outpatient arena (i.e., ASCs and offices). Several reasons that may account for these include cost incentives (for patients and health-care systems), advancement in anesthesia techniques, ERAS protocols, and increased patient satisfaction. Recently published literature shows positive patient outcomes or no difference in complication rates for patients to have same-day discharge procedures versus hospital admissions, but the appropriate patient and procedure has to be selected [4]. Additionally, the use of checklists and accreditation status of the surgical office plays an important impact on patient safety [79]. Anesthesiologists must understand that there is a lack of standardized state regulations regarding ASCs and OBSs. As of 2022, there is still wide variation per the Federation of State Medical Boards: 17 do not regulate OBS centers [80]. The next generation of anesthesiologists, as well as currently practicing anesthesiologists, should be aware of the safety concerns related to the various locations (HOPD, ASC, and OBS), the sustained growth and demand for anesthesia in the office, and the expansion of mobile anesthesia practices around the US in order to keep up and practice safely with the professional trends [81]. A critical factor to ensuring safety with the continued migration of procedures from the hospital to the outpatient and office-based setting is to establish a culture of safety. Multidisciplinary teams can come together, such as the Cincinnati Children's Hospital's endeavor to bring pediatric anesthesiologists to

the dental clinics. Their goal was to improve patient outcomes and access to in-office GA for dental procedures without increasing adverse events [82]. They increased the number of successful case completions, complete radiographs, and reduced the number of failed sedations.

Continuing growth trends will require ongoing research regarding patient safety, satisfaction, and outcomes, and efficiency costs between outpatient and inpatient procedures. Does the cost of the limited number of complications and readmissions outweigh the benefits of the shift from the inpatient to outpatient setting? Are we educating the next generation of anesthesiologists about the necessary safety measures when providing anesthesia in the varied non-hospital-based locations? Additional research outcomes, likely prospective in nature, must be performed on these novel outpatient procedures, to develop risk stratification and prediction models for the selection of the proper patient, procedure, and location, in order to ensure safety in anesthesia practice.

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ATTACHMENT 31

Patient Outcomes Following Total Joint
Replacement Surgery: A Comparison of
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Patient Outcomes Following Total Joint Replacement Surgery: A Comparison of Hospitals and Ambulatory Surgery Centers

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Abstract

Background—For several years, many orthopedic surgeons have been performing total joint replacements in hospital outpatient departments (HOPDs) and more recently in ambulatory surgery centers (ASCs). In a recent shift, the Centers for Medicare and Medicaid Services (CMS) began reimbursing for total knee replacement surgery in HOPDs. Some observers have expressed concerns over patient safety for the Medicare population particularly if CMS extends the policy to include total hip replacement surgery and coverage in ambulatory surgery centers (ASCs).

Methods—This study used a large claims database of non-Medicare patients to examine inpatient and outpatient total knee replacement and total hip replacement surgery performed on a near elderly population during 2014–2016. We applied propensity score methods to match inpatients with ASC patients and HOPD patients with ASC patients adjusting for risk using the HHS Hierarchical Condition Categories risk adjustment model. We conducted statistical tests comparing clinical outcomes across the three settings and examined relative costs.

Results—Readmissions, post-surgical complications, and payments were lower for outpatients than for inpatients. Within outpatient settings, readmissions and post-surgical complications were lower in ASCs than in HOPDs but payments for ASC patients were higher than payments for HOPD patients.

Conclusion—Our findings support the argument that outpatient total joint replacement is appropriate for select patients treated in both HOPDs and ASCs, although in the commercially insured population, the latter services may come at a cost. Until further study of outpatient total

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joint replacement in the Medicare population becomes available, how this will extrapolate to the Medicare population is unknown.

Keywords

joint replacement; hospital outpatient; complications; ambulatory surgery center

Introduction

More than one million patients receive total knee arthroplasty (TKA) or total hip arthroplasty (THA) every year in the U.S., a number expected to grow to nearly four million by 2030 [1]. While joint replacement has become a highly effective surgical intervention, it is also a costly one. Owing to improved surgical techniques, pressure from payers and patients' desire to return to activities, a number of commercial insurers have begun covering TKA and THA performed in outpatient settings, including hospital outpatient departments (HOPDs) and, more recently, ambulatory surgery centers (ASCs). The number of ASCs performing TKA and THA also has begun to rise. In 2017, over 200 ASCs were performing outpatient joint replacement compared to 25 in 2014 [2]. The trend away from the inpatient setting is expected to accelerate; greater than one half of primary joint replacement surgeries are predicted to take place in an outpatient setting by 2026 [3].

While prior studies of inpatient TKA and THA have shown considerable variation in post-operative complications including readmission, infections and revision surgery [4–8], studies based on small samples of outpatient TKA and THA found HOPD settings to be clinically feasible for select patients [9–10]. Other small sample studies used matched controls to compare inpatient and HOPD settings for TKA [11–12] and THA [13] and found comparable outcomes in the perioperative period. Measured differences in payments across settings also showed repeatedly that TKA and THA treatment in HOPDs translated into large cost savings to payers [12–14]. Studies of total joint replacement in freestanding ASCs have begun only recently, with the generally positive result that the ASC setting is safe for select patients [15–19]. One study showed greater patient satisfaction in ASCs compared to the traditional inpatient stay [20]. While ASCs are normally perceived as low cost settings, previous studies of total joint replacement have not conducted comparisons of hospital and ASC relative costs.

In this study, we contribute to the literature on total joint replacement by comparing TKA and THA across inpatient, HOPD, and ASC settings using a single large claims database of non-Medicare patients. We examine outcomes during the 90-day period following surgery. Additionally, we weigh the relative cost of providing these services across settings.

Methods

Data Source

We conducted quantitative data analysis using the Truven Health Analytics *MarketScan® Commercial Claims and Encounters* (MarketScan) database. MarketScan, which contains data on up to 50 million covered lives per year, is one of the few large commercial insurance

claims databases available to researchers. Data include detailed information on place of service, procedures, diagnoses, as well as actual payments to providers and allows tracking unique patients over time.

Study Population

We focused on the near elderly population, identifying all patients aged 55–64 who underwent TKA or THA in an inpatient, hospital outpatient, or ASC setting during calendar years 2014–2016, were enrolled for 12 months prior to the procedure and for 90 days following the procedure. Identification began with ICD-9 procedure codes 81.54 (TKA) and 81.51 (THA) and Current Procedural Terminology (CPT) codes 27447 (TKA) or 27130 (THA). Beginning in 2015, providers began transitioning to ICD-10 codes. Hence for 2015–2016, in addition to ICD-9 codes 81.54 and 81.51, we identified ICD-10 codes according to the CMS General Equivalence Mapping tool (GEMs) that matches ICD-9 and ICD-10 codes.

Patients undergoing TKA or THA in HOPD or ASC settings are carefully selected according to their relatively low risk and minimal likelihood of postoperative complications. In order to compare these patients with comparably low risk inpatients, we created four matched samples, comparing inpatient to ASC cases for TKA and THA, and HOPD to ASC cases for TKA and THA. The matching involved two steps. First, we created a propensity score, which is the likelihood of being in the ASC group versus inpatient or HOPD, based on two measures: risk scores and region of residence. We obtained risk scores using the HHS-Hierarchical Conditions Category (HHS-HCC) risk adjustment model which was designed by CMS to use claims data to risk adjust the population of individuals who purchased individual or small group commercial insurance under the Affordable Care Act [21]. The HHS-HCC model uses an individual's demographics and diagnoses captured over a 12-month period to determine a risk score, which is a relative measure of anticipated costliness of an individual, reflecting the individual's health risk. We used the 12-month period prior to the joint replacement procedure to determine individuals' risk. An individual's region of residence was defined as Northeast, North Central, South, or West. The propensity score balances our treatment selection so that individuals with similar HHS-HCC living in the same region will have similar propensity scores. We estimate the propensity scores with a logistic regression predicting treatment category (inpatient, HOPD or ASC) based on HHS-HCC risk score and region of residence.

Second, we applied the estimated propensity scores in a case-control match to create four samples. This process makes best matches first and next-best matches next, in a hierarchical sequence, selecting controls without replacement [22]. For a 1:N case-control match, sample size is important for two reasons: first, to ensure a sufficient number of individuals to match without replacement and second to ensure that the best, next-best, etc. match are reasonably close. For both TKA and THA, the large sample of inpatient procedures allowed for creation of a 3:1 matched sample of inpatients to ASC patients; the outpatient sample sizes allowed reasonable 1:1 matching of HOPD patients to ASC patients. We matched 2,574 TKA inpatients with 858 TKA ASC patients and 1,869 THA inpatients with 623 THA ASC patients. We further matched 450 HOPD TKA patients with 450 TKA ASC patients and 271 HOPD THA patients with 271 ASC THA patients.

Outcomes

For each case, we identified cases of 30-day readmission, 90-day readmission, and complications within 90 days including surgical site infection, deep-vein thrombosis, pulmonary embolism, dislocation/loosening/breakage of the prosthesis, and revision surgery. Consistent with the CMS Hospital Readmissions Reduction Program, we included readmissions for all causes. We also included cost outcomes: payment for the index hospitalization or index outpatient encounter, payments for all post-acute care to 90-days post-surgery and total episode payments.

Analyses

We examined rates of readmissions and complications following TKA and THA comparing inpatients with matched ASC patients and HOPD patients with matched ASC patients. We applied Chi-square tests for the equality of two proportions for independent samples. For the Chi-square test to be valid, cell counts must not be too small. In cases where the cell count was less than 5, we used Fisher's Exact test, which is a more conservative test of the difference between two proportions. Finally, we compared index, post-acute and total payments across samples in descriptive analyses. All analyses were conducted using SAS v9.4.

Results

As seen in Table 1, patients receiving TKA in ASCs had readmissions rates that were only about one-third as large as readmission rates for TKA inpatients: 1.98% compared to 5.56% for readmission within 30 days ($p<0.001$) and 3.15% compared to 9.87% for 90 days ($p<0.001$). Complication rates were low at both sites and did not differ substantially across sites (6.29% for inpatient and 5.48% for ASC; $p=0.387$). We observe similar yet very low rates of revision surgery, less than 1% for both inpatient and ASC ($p=0.221$).

Readmission rates and revision surgeries were somewhat lower for THA at both sites; however, there is a similar pattern of much lower readmission rates at ASCs (30-day readmissions; $p=0.011$) and (90-day readmission; $p<0.001$). Complication rates were also lower for THA compared to TKA, especially in ASCs where they averaged only 1.93% compared to 5.83% for inpatients ($p<0.001$).

Results for the HOPD to ASC comparisons are shown in Table 2. For TKA, readmission rates were again much lower for ASCs: 1.56% compared to 4.00% for readmissions within 30 days ($p=0.026$) and 2.89% compared to 6.22% for 90 days ($p=0.017$). Complication rates were only slightly higher in HOPDs compared to ASCs (5.33% versus 4.67%; $p=0.646$). There were no revision surgeries at either site. The HOPD to ASC comparison for THA patients shows the same general pattern. Readmissions were significantly smaller in ASCs compared to HOPDs (30-day readmissions 0.37% versus 2.95%; $p=0.038$) and (90-day readmissions 0.74% versus 2.95%; $p=0.001$). Complication and revision surgery rates were low at both sites, particularly in ASCs where the complication rate was only about 1% and there were no revision surgeries.

Finally, in Table 3 we display relative index, post-acute, and total average payments. For the TKA inpatient to ASC comparison, we see that the average payment to hospitals for the index stay was \$32,273, and to ASCs was \$27,839, or 13.7% lower than inpatient. Consistent with results of post-surgical outcomes and complication rate comparison, payments for post-acute care for inpatients exceeded post-acute care for ASC patients by 8.4%. The total episode cost was 12.8% lower for ASC patients. For THA, the index stay comparison is similar to THA: for ASCs the cost is 13.9% lower than the inpatient stay. Post-surgical costs are 20.5% lower in ASCs, and total episode costs are 14.8% lower.

Results for the HOPD to ASC cost comparison differ from the inpatient to ASC comparison. The index event costs in ASCs exceed those of HOPDs by 8.4% for TKA and 16.1% for THA. The post-acute care costs are lower in ASCs, by 5.5% for TKA and 34.4% for THA, reflecting the lower readmissions and post-surgical complication rates in ASCs. The total episode costs, however, are 5.3% and 5.1% higher in ASCs, for TKA and THA respectively.

Discussion

This analysis compared outcomes and costs following total joint replacement across three settings in a commercially-insured population of near elderly non-Medicare patients. Two themes emerge. First, we did not observe that transition of TKA and THA out of the traditional inpatient setting compromised patient safety. Readmissions were significantly lower for outpatients than for inpatients, particularly for ASC patients. Rates of revision surgery were in all cases extremely small or zero, within 90 days of surgery. ASC patients fared better than HOPD patients regarding complications and revision surgeries in all four cases. While our data and methods allowed us to match patients on overall risk, we were unable to capture any information on the environments to which patients were discharged. However, our results support an interpretation that clinicians were successful in incorporating such information into selection of appropriate candidates for outpatient surgery. We cannot rule out the possibility that some of the outpatients who did experience complications may have been better serviced as inpatients; however, the numbers of events are extremely small, diminishing this concern.

The second main theme relates to relative costs. The rationale for providing outpatient total joint replacement surgery is fixed in the value equation: for select patients, the outpatient setting is clinically appropriate, does not compromise patient safety and is much less expensive. Our results support that argument. Payments for both HOPD and ASC patients were lower than for inpatients. However, payments to ASCs exceeded payments to HOPDs by considerable margins. This is a notable result, since the broad rationale behind transition of services to the ASC is lower cost. Prior studies have found greater joint replacement patient satisfaction in ASCs [17, 20] and this may be a factor in driving up demand for ASC provision of these services. This result also aligns with an earlier study which found that relative ASC to HOPD payments by commercial insurers were considerably higher among ASCs that specialized in orthopedic surgery than ASCs in other specializations [23]. On the supply side, ASCs, which are primarily physician-owned and specialized, may be better positioned than hospitals to negotiate more aggressively around targeted surgical procedures and thus provide the appropriate services desired by patients.

The results of our analysis have implications for policymakers. In 2018, the Centers for Medicare and Medicaid Services (CMS) removed TKA from its inpatient-only (IPO) list. The change in CMS reimbursement rules has stirred standing concerns over the delivery of care in physician-owned specialty facilities. While current policy only permits outpatient TKA reimbursement for Medicare beneficiaries in HOPDs, many observers expect Medicare reimbursement for outpatient THA to follow [24], and CMS has sought comments on whether these procedures should be added to the ASC covered procedures list [25]. Since most ASCs are totally or partially physician-owned, provider incentives to perform TKA and potentially THA could lead to the unintended effect of higher overall utilization of these procedures. A Florida study of approximately 13,000 Medicare patients who received knee arthroscopy during 2006 found that the rate of procedures in hospital service areas with the highest one-third of ASC market share was more than twice that of hospital service areas with the lowest one-third [26].

CMS determined that appropriately selected patients could be successful candidates for outpatient TKA, a decision based on input from numerous stakeholders. However, movement of TKA from the IPO list has not been without its critics. Some state hospital associations, hospital systems and professional organizations representing orthopedic surgeons have expressed concern that TKA is an invasive procedure and that Medicare beneficiaries will face greater complications, recovery and rehabilitation needs than younger populations. Moreover, removal of TKA from the IPO list could lead commercial payers to implement coverage policies that would drive procedures toward outpatient settings that might not be sufficiently prepared to handle unforeseen complexities, raising patient safety concerns [27].

The patients studied here are near elderly and non-Medicare, such that results cannot be applied directly to the Medicare population of patients who are older and have more comorbidities. Yet our results supporting the contention that migration of total joint replacement surgery to outpatient settings is appropriate for some patients is encouraging, because a finding of patient safety failures in this age group would augur for even greater problems in an older population. It is important for future study that patient safety following outpatient joint replacement be monitored when data on Medicare patients becomes available.

There are limitations to our analysis. Our risk-adjustment was incomplete as we did not have information on follow-up protocol and adherence, or on social factors such as health habits or support at home that would allow more comprehensive control for selection. Moreover, the MarketScan database includes only claims that were voluntarily contributed from employer health insurance plans. While the data includes patients from all 50 states and the District of Columbia, it was not designed to be nationally representative.

Conclusion

A recent position statement on outpatient joint replacement by the American Association of Hip and Knee Surgeons emphasizes proper patient selection and states that an outpatient program should start with improved quality and safety outcomes [28]. Findings from this

study support the argument that outpatient total joint replacement is suitable for select patients, and the low rates of readmissions and complications observed suggest that physicians are exercising prudent judgment in selecting clinically appropriate candidates. Results are consistent with previous studies of outpatient joint replacement patient safety, although for ASCs in the sample we studied, it came at a cost.

Implications vary across stakeholders. For patients who prefer to return home as soon as possible after surgery, consultation with their physicians about same day surgery appears warranted. For payers, including both insurers and patients, differences in prices across settings should be considered. For CMS, the clinical outcomes in both HOPDs and ASCs are a positive finding. Yet a near elderly population is younger and likely more active with greater support at home than the population of Medicare beneficiaries. Going forward, it will be important to continually evaluate clinical outcomes as more joint replacements are provided in HOPDs and ASCs for Medicare as well as commercially insured patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Inpatient and Ambulatory Surgery Centers: Comparison of Total Joint Replacement Post-Surgical Events

	Total Knee Replacement				
	Inpatient (n=2,574)		Ambulatory Surgery Center (n=858)		p-value for equality of rates ^a
	# of Events	Rate (%)	# of Events	Rate (%)	
30-day Readmissions	143	5.56	17	1.98	<0.001
90-day Readmissions	254	9.87	27	3.15	<0.001
Post-Surgical Complications ^b	162	6.29	47	5.48	0.387
Revision Surgery	13	0.51	4	0.47	0.221
	Total Hip Replacement				
	Inpatient (n=1,869)		Ambulatory Surgery Center (n=623)		p-value for equality of rates ^a
	# of Events	Rate (%)	# of Events	Rate (%)	
30-day Readmissions	60	3.21	8	1.28	0.011
90-day Readmissions	143	7.65	10	1.61	<0.001
Post-Surgical Complications ^b	109	5.83	12	1.93	<0.001
Revision Surgery	4	0.21	1	0.16	0.396 ^c

^aChi-square test for the equality of two proportions from independent samples^bPost-Surgical Complications include surgical site infection, deep vein thrombosis, pulmonary embolism, and dislocation, loosening or breakage of prosthesis^cFisher's Exact test for the equality of two proportions from independent samples with small cell sizes

Table 2.

Hospital Outpatient Department and Ambulatory Surgery Centers: Comparison of Total Joint Replacement Post-Surgical Events

	Total Knee Replacement				p-value for equality of rates ^a
	Outpatient (n=450)		Ambulatory Surgery Center (n=450)		
	# of Events	Rate (%)	# of Events	Rate (%)	
30-day Readmissions	18	4.00	7	1.56	0.026
90-day Readmissions	28	6.22	13	2.89	0.017
Post-Surgical Complications ^b	24	5.33	21	4.67	0.646
Revision Surgery	0	0.00	0	0.00	-
	Total Hip Replacement				p-value for equality of rates ^a
	Outpatient (n=271)		Ambulatory Surgery Center (n=271)		
	# of Events	Rate (%)	# of Events	Rate (%)	
30-day Readmissions	8	2.95	1	0.37	0.038 ^c
90-day Readmissions	16	5.90	2	0.74	0.001 ^c
Post-Surgical Complications ^b	14	5.17	3	1.11	0.011 ^c
Revision Surgery	2	0.73	0	0.00	0.250 ^c

^aChi-square test for the equality of two proportions from independent samples

^bPost-Surgical Complications include surgical site infection, deep vein thrombosis, pulmonary embolism, and dislocation, loosening or breakage of prosthesis

^cFisher's Exact test for the equality of two proportions from independent samples with small cell sizes

Table 3. Total 90-Day Episode Costs (\$): Comparison of Hospitals and Ambulatory Surgery Centers (ASCs)

	Total Knee Replacement				Total Hip Replacement			
	Inpatient \$ (n=2,574)	ASC \$ (n=858)	Inpatient \$-ASC \$	Percent Difference	Inpatient \$ (n=2,574)	ASC \$ (n=858)	Inpatient \$-ASC \$	Percent Difference
Index	32,273	27,839	4,434	-13.7	33,469	28,821	4,648	-13.9
Post-Acute	7,293	6,683	610	-8.4	5,545	4,408	1,137	-20.5
Total Episode	39,566	34,521	5,045	-12.8	39,014	33,229	5,785	-14.8
	Total Knee Replacement				Total Hip Replacement			
	Outpatient \$ (n=450)	ASC (n=450)	Outpatient-ASC	Percent Difference	Outpatient (n=271)	ASC (n=271)	Outpatient-ASC	Percent Difference
Index	25,024	27,128	-2,104	+8.4	25,238	29,311	-4,073	+16.1
Post-Acute	7,078	6,687	391	-5.5	7,016	4,601	2,415	-34.4
Total Episode	32,102	33,815	-1,713	+5.3	32,254	33,913	-1,659	+5.1

ATTACHMENT 32

A Comparison of 30-Day Hospital Readmission and
Complication Rates After Outpatient Versus Inpatient
1 and 2 Level Anterior Cervical Discectomy and
Fusion Surgery



World Neurosurgery

Volume 129, September 2019, Pages e233-e239

Original Article

A Comparison of 30-Day Hospital Readmission and Complication Rates After Outpatient Versus Inpatient 1 and 2 Level Anterior Cervical Discectomy and Fusion Surgery: An Analysis of a Medicare Patient Sample

Syed I. Khalid ^{1,2}, Owoicho Adogwa ¹  , Amelia Ni ¹, Joseph Cheng ³, Carlos Bagley ⁴

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Background

Same-day surgery has been demonstrated to be a safe and cost-effective alternative to traditional inpatient surgery. Several studies have demonstrated no differences in the postoperative complication profile or 30-day hospital readmission rates with outpatient versus inpatient anterior cervical discectomy and fusion (ACDF). However, none of these studies compared the outcomes in elderly patients (aged >65 years) undergoing ACDF. Whether the results from previous studies can be applied to this subgroup of patients remains unknown. The aim of the present study was to compare the 30-day hospital readmission rates for Medicare patients (aged >65 years) undergoing outpatient versus inpatient ACDF.

Methods

We performed a retrospective analysis of a Medicare database, including data from 17,421 patients. Of the 17,421 patients, 16,386 had undergone inpatient ACDF and 1035, outpatient ACDF. Age, sex, comorbidities, postoperative complications, readmission rates, and overall financial costs were compared between the 2 cohorts.

Results

In a Medicare sample (aged >65 years), inpatient ACDF was associated with a greater incidence of postoperative complications compared with outpatient ACDF. Outpatient surgery was associated with significantly lower rates of postoperative complications (urinary tract infection, surgical site infection, deep vein thrombosis, pulmonary embolism, and myocardial infarction) and significantly lower treatment costs ($P \leq 0.001$). All-cause 30-day hospital readmission rates were also greater for inpatients (10.1% vs. 4%; $P = 0.17$).

Conclusion

The results from the present study suggest that outpatient ACDF appears to be safe and effective with low complication and readmission rates in a Medicare patient sample.

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Introduction

Anterior cervical discectomy and fusion (ACDF) procedures have been increasingly performed in an outpatient setting.^{1, 2, 3} Several studies have demonstrated that outpatient ACDF is safe and effective, with overall low complication rates compared with inpatient ACDF procedures.^{4, 5, 6} Outpatient ACDF has been associated with a decreased likelihood of developing perioperative durotomy, hematoma, neurological deficit, or cardiopulmonary complications.⁷ Previous studies, however, did not focus on the geriatric population; thus, it is unknown whether the results of these studies can be applied to this patient population.^{8, 9}

The present study assessed the outcomes, complication rates, and cost differences between inpatient and outpatient ACDF procedures in the geriatric population. To the best of our knowledge, the present study is the first to use the Medicare Standard Analytic Files database, derived from Medicare parts A and B, which include 100% of inpatient and outpatient facility records billed to Medicare and cover >51 million lives.

Section snippets

Methods

The institutional review board approved the present study (reference, PDRUNSG). Patients undergoing ACDF from 2007 to 2012 were identified retrospectively from the Medicare Standard Analytic Files using the International Classification of Diseases, 9th revision (ICD-9), diagnosis codes, ICD-9 procedure codes, and Current Procedural Terminology (CPT) codes....

Methods

Patients undergoing ACDF were identified by querying the database for 2 CPT codes: CPT code 22551 (arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy, and decompression of spinal cord and/or nerve roots] and CPT code 22554 (arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace [other than for decompression]). Only those cases with both codes plus ICD-9 code 81.62 for 1- or 2-level fusion were included in the...

Results

From 2007 to 2012, 17,421 geriatric patients who had undergone 1- or 2-level ACDF were identified. Of these 17,421 patients, 16,386 (94.1%) had undergone inpatient ACDF and 1035 (5.9%) had undergone outpatient ACDF.

The baseline comorbidities were similar between the 2 cohorts, although the inpatient cohort had a greater percentage of patients with a BMI of ≥ 30 kg/m². Men accounted for 50.0% ($n= 517$) of the outpatient population and 51.7% ($n= 8474$) of the inpatient population. For the entire...

Discussion

In the present Medicare patient sample of 17,421 geriatric patients who had undergone 1- or 2-level ACDF in either an inpatient or outpatient setting, we observed a significantly greater complications rate with the inpatient than with the outpatient procedures. The 30-day all-cause readmission rates were greater in the inpatient cohort, although the difference was not statistically significant (inpatient, 10.1% vs. outpatient, 4%; $P= 0.17$).

Previous studies of 1- and 2-level ACDF have shown its ...

Conclusion

The results from the present study suggest that outpatient ACDF appears to be safe and effective with low complication and 30-day readmission rates in a Medicare patient sample....

[Recommended articles](#)

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[Growing utilization of ambulatory spine surgery in Medicare patients from 2010–2021](#)

2024, North American Spine Society Journal

[Show abstract](#)

Outcomes following outpatient anterior cervical discectomy and fusion for the treatment of myelopathy

2021, Journal of Clinical Orthopaedics and Trauma

Citation Excerpt :

...Similarly, Khalid et al. and Martin et al. also report lower complication rates in outpatient ACDF's. However, these studies did not control for preoperative comorbidities/demographics, and the decreased complication rates may be attributed to the better overall health status of the outpatient cohort patients.^{17,30} Other studies and systematic reviews of the literature also report decreased complication rates for ACDF's in the outpatient setting as well.^{4,26,34...}

[Show abstract](#) 

Trends in National Use of Anterior Cervical Discectomy and Fusion from 2006 to 2016

2020, World Neurosurgery

Citation Excerpt :

...Our findings also demonstrate an increased rate of outpatient ACDF. This trend can be explained by the safety of outpatient ACDF on select patients^{11,22,26} and the adoption of outpatient surgery in many centers in conjunction with the evolution of surgery-centers over the past decade.²⁷ Our study demonstrates a trend toward decreased operative time and length of stay....

[Show abstract](#) 

Outpatient Prosthetic-Based Reconstruction during COVID-19 Pandemic Possible in Selected Patients without Increased Complications

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Is Complete Correction of Cervical Sagittal Malalignment Necessary During 4-Level Anterior Cervical Discectomy and Fusion Surgery in Patients With Kyphosis?



2023, Global Spine Journal

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2023, World Journal of Surgery



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Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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ATTACHMENT 33

Charity Care and Financial Assistance
Policy (Revised)

Policy and Procedure Manual	HARBORSIDE SURGERY CENTER
Chapter 2 GOVERNANCE	Effective Date: 4/25/2024 Revised Date: 7/27/24

2.14 Charity Care and Financial Assistance

POLICY:

To provide surgical services on an uncompensated basis or at a reduced charge to uninsured, underinsured, and indigent persons, who meet eligibility criteria. Harborside will establish an annual budget for Charity Care which shall not be less than the percentage committed to the Maryland Health Care Commission.

PROCEDURE:

1. Eligibility Criteria

- a. Persons with family income below 100 percent of the current Department of Health and Human Services Poverty Guidelines applicable to Maryland who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services at no charge. These guidelines can be found at <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>.
- b. Persons with family income above 100 percent of the Department of Health and Human Services Poverty Guidelines but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands according to the following table:

HHS Poverty Guideline %	% Discount
100 to 149%	75%
150 to 174%	50%
175 to 199%	25%

- a. Proof of income and verification of the number of dependents based upon the previous year’s tax return must be provided. If this is not available, the last two months paycheck stubs will be accepted. Dependents must meet IRS definition of dependents to qualify as household members.
- b. Proof that medical assistance has been applied for and rejected. If the rejection is for non-compliance with all medical assistance paperwork requirements, reduced fee or charity will not be granted. If medical assistance rejection is based on income, disability, or assets, Harborside will review person’s medical financial assistance application and make a final determination of eligibility. Harborside

Policy and Procedure Manual	HARBORSIDE SURGERY CENTER
Chapter 2 GOVERNANCE	Effective Date: 4/25/2024 Revised Date: 7/27/24

staff will assist all persons to complete the application or identify alternative programs such as Medicaid.

2. Public Notice and Program Information

Public Notices of Harborside’s charity care and financial assistance program shall be provided, or posted, in English and Spanish:

- In patient waiting and other common patient areas at the providers’ office
- In patient waiting and other common patient areas at the Harborside Surgery Center
- At provider office and surgery center business office and registration area
- On the Harborside website homepage
- As provided to the Prince George’s County Department of Health

3. Information about Harborside’s Charity Care and Financial Assistance program shall be made available prior to arrival for surgery.

Patients presenting to the provider’s office directly or through referral who inquire or demonstrate need for financial assistance are provided, through the provider or surgical scheduler, prior to arrival for surgery or consultation, with the policy and written information (description and application) about Harborside’s Charity Care and Financial Assistance Policy.

4. Program Monitoring

Harborside shall review the Charity Care and Financial Assistance program and monitor services provided as a standard agenda item at quarterly Quality Assurance and Performance Improvement (QAPI) meetings and reported to the governing body, annually. Data for reporting progress in meeting program goals shall be provided through the facility practice management system, which will provide documentation of the charity care results.

5. Approval Process

- a. A Harborside provider or designated representative shall provide a written copy of the Harborside Charity Care and Financial Assistance Policy, prepared in English and Spanish, when a patient presents to the providers office directly or through a referral and indicates need for financial assistance.
- b. Harborside surgical coordinator will serve as liaison and will assume, based on the patient’s verbal expressed request for financial assistance or verbal indication

Policy and Procedure Manual	HARBORSIDE SURGERY CENTER
Chapter 2 GOVERNANCE	Effective Date: 4/25/2024 Revised Date: 7/27/24

of no insurance, that the patient is eligible for application for free or low-cost surgery.

- c. A determination of probable eligibility will only require the minimum amount of information needed by Harborside regarding whether the patient is eligible for charity care and financial assistance for the surgical services proposed by Harborside. This step would require such minimal information as an individual's annual salary or copies of the patient's most recent paychecks, the number of members in family, a patient's successful application for a determination of medical assistance or financial assistance for health care services, and/or any other information that would assist the Harborside surgical coordinator in the determination of probable eligibility for charity care and financial assistance.
- d. A final determination of financial assistance may require the patient to submit a separate and completed financial assistance application with all the financial information necessary for Harborside to determine whether the patient will receive charity care and financial assistance for surgical services offered by Harborside.
- e. The surgical coordinator shall ensure the patient receives an application and is provided with assistance with completion and processing of the application. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital or ambulatory surgical facility shall make a determination of probable eligibility and notify the patient of that determination by telephone or other means specified by the patient.
- f. Patient shall provide, with the application, the required documents to support eligibility. Delays in receiving required documents may result in delays in the final determination of eligibility.
- g. Upon receipt of the required eligibility documents, a Harborside representative will submit the patient application and required paperwork to the business office for a final determination and convey this information to the patient by phone, email, or text (as agreed upon with the patient).
- h. If the patient is determined to be ineligible for uncompensated or reduced payment assistance, the patient is provided with information for Medicaid enrollment.

6. Post Approval Process

Policy and Procedure Manual	HARBORSIDE SURGERY CENTER
Chapter 2 GOVERNANCE	Effective Date: 4/25/2024 Revised Date: 7/27/24

- a. Present patient information to surgical provider and office scheduler.
- b. Notify all necessary departments, billing department, front desk, surgical scheduler, etc. Inform these departments and personnel of patient financial responsibility, based on eligibility criteria.
- c. The facility's administrator shall contact the center's anesthesia provider and inform them the patient has been approved for Financial Assistance at Harborside and request their participation by providing uncompensated or discounted care for the patient's case.
- d. The facility's administrator shall contact the surgeon and staff and inform them that the patient has been approved for Financial Assistance Program at Harborside and request their participation by providing uncompensated or discounted care for the patient's case.

7. Post Operative Process

- a. The facility's administrator shall email billing and inventory, following the surgical procedure and provide communication and correspondence, including documentation of all supplies used in the surgery.

8. Plan for Achieving Charity Care Goals

- a. Annually, a representative from Harborside will meet with surgeons, practice leaders, nurse coordinators of practice to reinforce the program, policy, and commitment, provide written materials for dissemination to patients and answer questions about patient enrollment.
- b. Annually, Harborside will publish information about its Charity Care and Financial Assistance Policy, in English and Spanish, on its website, post information and place fliers in provider offices and post within waiting rooms.

ATTACHMENT 34

Tables 3 and 4 – Revenues and Expenses
(Revised)

TABLE 3: REVENUES AND EXPENSES - ENTIRE FACILITY (including proposed project)

(INSTRUCTION: ALL EXISTING FACILITY APPLICANTS MUST SUBMIT AUDITED FINANCIAL STATEMENTS)

CY or FY (Circle)	Two Most Recent Years Actual		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	2022	2023	2024	2025	2026	2027	2028
1. Revenue							
a. Inpatient services	0	0	0	0	0	0	0
b. Outpatient services	82,867,820	135,756,360	173,714,825	192,611,848	217,616,111	241,160,779	248,076,963
c. Gross Patient Service Revenue	82,867,820	135,756,360	173,714,825	192,611,848	217,616,111	241,160,779	248,076,963
d. Allowance for Bad Debt	(15,099)	(263,323)	(296,772)	(372,545)	(420,333)	(465,191)	(477,899)
e. Contractual Allowance	69,558,999	114,017,154	145,728,275	161,584,147	182,617,139	202,435,711	208,294,810
f. Charity Care	0	0	(248,030)	(271,443)	(297,545)	(320,324)	(328,181)
g. Net Patient Services Revenue	13,293,722	21,475,883	27,441,748	30,383,713	34,281,094	37,939,642	38,976,073
h. Other Operating Revenues (Specify)	116,512	159,401	203,391	225,518	254,446	281,601	289,294
i. Net Operating Revenue	13,410,235	21,635,284	27,645,139	30,609,231	34,535,540	38,221,243	39,265,367

Table 3 Cont.	Two Most Recent Years Actual		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	2022	2023	2024	2025	2026	2027	2028
2. Expenses							
a. Salaries, Wages, and Professional Fees, (including fringe)	2,705,517	3,942,055	4,595,195	5,216,653	5,734,085	6,023,197	6,198,313

benefits)							
b. Contractual Services	588,960	836,770	1,083,722	1,155,922	1,275,031	1,386,431	1,420,565
c. Interest on Current Debt	71,765	973,779	987,297	884,644	776,320	667,996	559,673
d. Interest on Project Debt	0	0	0	0	0	0	0
e. Current Depreciation	151,344	1,034,315	735,004	735,004	735,004	735,004	735,004
f. Project Depreciation	0	0	0	14,799	14,799	14,779	14,779
g. Current Amortization	4,302,711	7,302,711	4,316,151	4,316,151	4,316,151	4,316,151	4,316,151
h. Project Amortization	0	0	0	0	0	0	0
i. Supplies	4,564,749	8,559,580	11,505,788	13,004,778	15,003,970	16,900,641	17,551,225
j. Other Expenses (Specify)	866,297	1,210,866	1,579,795	1,816,354	1,890,092	1,979,167	2,022,339
k. Total Operating Expenses	13,251,974	20,860,076	24,802,953	27,144,305	29,754,451	3,023,386	32,818,068
3. Income							
a. Income from Operation	158,260	775,208	2,842,186	3,464,926	4,781,089	6,197,857	6,447,299
b. Non-Operating Income	(902,768)	(675,969)	0	0	0	0	0
c. Subtotal	(744,507)	(99,239)	2,842,186	3,464,926	4,781,089	6,197,857	6,447,299
d. Income Taxes	0	0	0	0	0	0	0
e. Net Income (Loss)	(744,507)	99,239	2,842,186	3,464,926	4,781,089	6,197,857	6,447,299
4. Patient Mix:							
A. Percent of Total Revenue							
1. Medicare	11.77%	19.85%	25.24%	25.56%	25.89%	26.04%	26.11%

2. Medi0aid	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
3. Blue Cross	38.32%	36.40%	31.22%	31.32%	31.50%	31.50%	31.45%
4. Commercial Insurance	39.56%	35.97%	37.39%	36.84%	36.45%	36.24%	36.15%
5. Self-Pay	0.23%	0.57%	0.23%	0.20%	0.18%	0.16%	0.16%
6. Other (WC, VA)	10.12%	7.22%	5.92%	6.08%	5.98%	6.06%	6.13%
7. TOTAL	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Note: Totals may not match due to rounding.

Table 3 Cont.	Two Most Recent Years Actual		Current Year Projecte d	Projected Years (ending with first full year at full utilization)			
	2022	2023	2024	2025	2026	2027	2028
B. Percent of Patient Days/Visits/Procedures (as applicable)							
1. Medicare	17.92%	24.38%	31.25%	31.30%	31.76%	32.00%	32.08%
2. Medicaid	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
3. Commercial Insurance	73.47%	66.83%	61.74%	60.69%	60.25%	59.94%	59.82%
4. Self-Pay	0.27%	0.56%	0.08%	1.08%	1.07%	1.06%	1.06%
5. Other (WC, VA)	8.33%	8.23%	6.93%	6.93%	6.92%	7.00%	7.04%
6. TOTAL	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Note: Totals may not match due to rounding

TABLE 4: REVENUES AND EXPENSES - PROPOSED PROJECT

(INSTRUCTION: Each applicant should complete this table for the proposed project only)

CY or FY (Circle)	Projected Years (Ending with first full year at full utilization)			
	2025	2026	2027	2028
1. Revenues				
a. Inpatient Services	0	0	0	0
b. Outpatient Services	17,059,701	39,193,767	59,392,575	65,501,992
c. Gross Patient Services Revenue	17,059,701	39,193,767	59,392,575	65,501,992
d. Allowance for Bad Debt	(32,942)	(75,608)	(114,434)	(124,112)
e. Contractual Allowance	(14,312,085)	(32,901,942)	(49,876,774)	(54,179,989)
f. Charity Care	(27,993)	(49,875)	(68,438)	(75,694)
g. Net Patient Care Service Revenues	2,686,681	6,166,342	9,332,930	10,122,198
h. Total Net Operating Revenue	2,706,622	6,212,111	9,402,202	10,197,328
2. Expenses				
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	621,458	1,138,890	1,428,002	1,603,118
b. Contractual Services	72,200	191,309	302,709	336,843
c. Interest on Current Debt	0	0	0	0
d. Interest on Project Debt	0	0	0	0
e. Current Depreciation	0	0	0	0
f. Project Depreciation	14,799	14,799	14,799	14,799
g. Current Amortization	0	0	0	0
h. Project Amortization	0	0	0	0
i. Supplies	1,854,278	3,323,215	4,698,898	5,172,059

j. Other Expenses (Specify)	236,559	319,296	399,371	442,544
k. Total Operating Expenses	2,799,293	4,987,509	6,843,780	7,569,362

Table 4 Cont. CY or FY (Circle)	Projected Years (Ending with first full year at full utilization)			
	2025	2026	2027	2028
3. Income				
a. Income from Operation	(92,671)	1,224,602	2,558,422	2,627,966
b. Non-Operating Income	0	0	0	0
c. Subtotal	(92,671)	1,224,602	2,558,422	2,627,966
d. Income Taxes	0	0	0	0
e. Net Income (Loss)	(92,671)	1,224,602	2,558,422	2,627,966
4. Patient Mix:				
A. Percent of Total Revenue				
1. Medicare	27.61%	27.87%	28.01%	28.14%
2. Medicaid	0.00%	0.00%	0.00%	0.00%
3. Commercial Insurance	67.94%	67.72%	67.50%	67.31%
4. Self-Pay	0.25%	0.22%	0.20%	0.20%
5. Other (Workers Comp, VA)	4.20%	4.18%	4.29%	4.36%
6. TOTAL	100.00%	100.00%	100.00%	100.00%
B. Percent of Patient Days/Visits/Procedures (as applicable)				
1. Medicare	34.09%	34.64%	34.94%	35.10%
2. Medicaid	0.00%	0.00%	0.00%	0.00%
3. Commercial Insurance	58.35%	57.87%	57.52%	57.33%
4. Self-Pay	1.13%	1.11%	1.10%	1.10%
5. Other (Workers Comp, VA)	6.43%	6.38%	6.43%	6.47%
6. TOTAL	100.00%	100.00%	100.00%	100.00%

Note: Totals may not match due to rounding

ATTACHMENT 35

Letter from Architect re FGI Guidelines

July 23, 2024

Jane Falk, RN MHA
M2 Orthopedics
Senior Vice President
Clinical Operations and Programs



RE: Harborside Procedure Room 235 Upgrade Requirements

Dear Jane,

The design and construction for the third OR will meet the 2022 FGI Guidelines. It is a 524 sq. ft. OR. The clearance around the OR table is 8'-6" on each side, 6' x 8' at the head and 7'-0" at the foot to allow for circulation, the sterile field, anesthesia and movable equipment zones. There is no fixed equipment in required clearances. Documentation is provided by a computer on wheels. An existing viewbox allows for visual information display. A scrub sink is currently provided with visual access near the door to the OR. Smooth scrubbable surfaces are provided on the walls and ceilings and monolithic flooring with an integral base is used in the OR. Med gas is provided per Table 2.1-2. Nurse call devices are provided per Table 2.1-3. At least 36 electrical receptacles are provided, with a minimum of 2 on each wall.

Sincerely,

A handwritten signature in black ink, appearing to read 'Misty Anguiano', with a long horizontal flourish extending to the right.

Misty Anguiano
Boulder Associates, Inc.

5646 Milton Street, Suite 240, Dallas, Texas 75206
O: 214.420.5700

ATTACHMENT 36

Lab Corp Contract

LABORATORY SERVICES AGREEMENT

THIS AGREEMENT made this 26 day of NOVEMBER 2012, by and between Surgcenter at Harborside, LLC, ("CLIENT") and Laboratory Corporation of America Holdings ("LABORATORY").

WHEREAS, LABORATORY is engaged in the business of providing reference clinical laboratory services (the "Services"); and

WHEREAS, CLIENT desires to contract with LABORATORY to provide reference clinical laboratory services for CLIENT, and LABORATORY desires to provide the Services described herein.

IT IS THEREFORE AGREED AS FOLLOWS:

1. TERM AND TERMINATION

This Agreement shall become effective on the date set forth above and shall continue in effect until terminated by either party. This Agreement shall have an initial term of one (1) year ("Initial Term") and shall be automatically renewed for additional periods of one (1) year ("Renewal Term") at the end of the Initial Term or any Renewal Term, unless previously terminated by either party.

This Agreement may be terminated by either party, with or without cause, at any time, by giving the other party thirty (30) days prior written notice to the address set forth in Section 10.

2. TESTING SERVICES

LABORATORY agrees to perform such Services for CLIENT as may be requested by CLIENT, if available, during the term of this Agreement. The Services shall include those tests listed in LABORATORY's current Directory of Services, as the same may be modified from time to time by LABORATORY and such additional services as the parties may agree to in writing.

The service area under this Agreement shall be the state of Maryland ("Service Area").

3. ADDITIONAL SERVICES

A. SPECIMEN PICK UP AND REPORT DELIVERY

LABORATORY will provide a reference specimen pick up and report delivery service to CLIENT on a daily basis Monday through Friday of each week, except on holidays. For the purposes of this Agreement, holidays shall include New Year's Day, Memorial Day, Fourth of July, Labor Day, Thanksgiving Day and Christmas Day. LABORATORY shall make reasonable efforts to deliver or transmit results of a routine nature (general routine chemistries) to CLIENT within 24 hours of the time the specimen is received by LABORATORY's testing facility. LABORATORY shall make reasonable efforts to deliver or transmit results of tests performed on specimens of a special nature (special chemistries, tissues, etc.) to CLIENT within the times set forth in LABORATORY's then current turn-around-time schedule. LABORATORY shall report panic or critical values performed at LABORATORY facilities in a manner consistent with LABORATORY's standard policies and procedures.

B. SUPPLIES

LABORATORY will provide, as part of its charges for the Services, such items, devices or supplies that are used solely to collect, transport, process or store specimens to be submitted to LABORATORY for testing.

C. CONSULTATION

LABORATORY staff shall be available to consult with CLIENT by telephone during normal LABORATORY working hours to discuss LABORATORY's procedures and to provide the status of test results.

4. FEES

CLIENT agrees to pay, to the extent responsible for payment, for the Services provided under this Agreement the fees set forth in Exhibit A. For services sent to another reference laboratory for testing,, CLIENT shall pay the greater of (a) the fees listed in Exhibit A and (b) the charges to LABORATORY for reference testing performed by the laboratory not owned by or affiliated with LABORATORY. After the Initial Term of this Agreement, CLIENT and LABORATORY agree that fees shall either increase on the renewal date hereof or with LABORATORY's general annual fee increase of which CLIENT shall receive thirty (30) days written notice. CLIENT and LABORATORY acknowledge and agree that fees shall not be adjusted more frequently than once a year.

Notwithstanding the foregoing, CLIENT acknowledges that LABORATORY may develop and/or provide new technologies and/or new methodologies during the term of this Agreement. LABORATORY shall notify CLIENT when such technologies and/or methodologies are available and the fee associated with such technologies and/or methodologies. If, during the term of this Agreement, any nationally recognized professional medical association makes recommendations that establish or change a standard of care for testing, the parties will work in good faith to agree on an appropriate rate of payment for testing affected by the new or modified standard of care on a fee for service basis. If the parties cannot reach agreement, LABORATORY shall have the right to terminate this Agreement by giving thirty (30) days written notice to CLIENT.

5. BILLING

CLIENT shall indicate the entity responsible for payment of Services rendered on the requisition submitted to LABORATORY.

If CLIENT indicates that CLIENT is responsible for payment, LABORATORY will submit to CLIENT a monthly itemized statement of Services rendered to CLIENT by LABORATORY for the prior month. Payment for Services is due thirty (30) days after the date of invoice. Failure to remit payment within said time may result, among other remedies available to LABORATORY, in the loss or reduction of CLIENT's discount and/or special prices on future Services or discontinuation of Service. If, as a result of such non-payment, LABORATORY reduces or removes any discount and/or special prices, the terms and prices contained in LABORATORY's current Fee Schedule shall become the Fees payable by CLIENT. LABORATORY may, at its option, reinstate any discount and/or special prices after CLIENT brings its balance current. Nothing in the foregoing shall waive any rights or remedies available to LABORATORY with respect to late payment by CLIENT. If LABORATORY is compelled to bring suit to collect amounts due hereunder, it shall be entitled to recover interest on amounts due, reasonable attorneys' fees and costs incurred in connection with the action.

If CLIENT indicates that a third party is responsible for payment, LABORATORY, in accordance with legal and regulatory requirements, agrees to bill the patient or other responsible party, including Medicare, Medicaid and insurance companies, for Services performed under this Agreement. CLIENT agrees to promptly provide LABORATORY with all necessary information to accomplish the billing and collection of amounts due, including required diagnosis information. If LABORATORY is unable to obtain payment from any third party due to CLIENT's failure to provide the information required by this Agreement, or as a result of CLIENT's failure to follow applicable rules or regulations, CLIENT agrees to pay LABORATORY for all such Services.

6. ACCREDITATION OF TESTING SITES

The Services performed hereunder shall be performed at testing facilities to be selected by LABORATORY. LABORATORY's facilities are and shall remain duly licensed clinical laboratories under applicable federal, state and local law. Reasonable documentation of such credentials shall be provided upon written request.

7. PREVENTION OF FRAUD, WASTE AND ABUSE

The terms of this Agreement are intended to be in compliance with all federal, state and local statutes, regulations and ordinances applicable on the date the Agreement takes effect including but not limited to, the Health Insurance Portability and Accountability Act of 1996, as amended, and its accompanying regulations ("HIPAA"), the Program Fraud Civil Remedies Act of 1986, the Deficit Reduction Act of 2005, the related Federal Civil False Claims Act and State False Claims Acts, and associated whistleblower protections. LABORATORY has written policies and procedures for detecting and preventing fraud, waste, and abuse and

expects that test orders, services, supplies or materials provided to LABORATORY are in accordance with the requirements of the applicable federal and state laws.

8. CHANGE IN LAW OR REGULATION

Should either party reasonably conclude that any portion of this Agreement is or may be in violation of such requirements or any other legal requirements or subsequent modifications by federal, state or local authorities, or if any such change or proposed change would materially alter the amount or method of compensating LABORATORY for Services performed for CLIENT or for any other party under this Agreement, or would materially increase the cost of LABORATORY's performance hereunder, the parties agree to negotiate written modifications to this Agreement as may be necessary to establish compliance with such authorities and/or to reflect applicable changes in compensation necessitated by such legal requirements.

9. NON-ASSIGNABILITY

This Agreement may not be assigned by either party without the written consent of the other party which consent shall not be unreasonably withheld or delayed.

10. NOTICES

Any notice required to be given pursuant to the terms and provisions hereof shall be in writing and shall be sent by certified or registered mail to LABORATORY at:

Laboratory Corporation of America Holdings
430 South Spring Street
Burlington, North Carolina 27215
Attention: Contracts Administrator

with a copy to:

Laboratory Corporation of America Holdings
531 South Spring Street
Burlington, North Carolina 27215
Attention: Law Department

and to CLIENT at:

Surgecenter at Harborside, LLC
125 Potomac Passage, Suite 200
National Harbor, MD 20745
Attention: Ms. Daniela Booton

11. INDEPENDENT RELATIONSHIP

None of the provisions of this Agreement are intended to create, nor shall be deemed or construed to create, any relationship between CLIENT and LABORATORY other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. Neither of the parties hereto, nor any of their respective employees shall be construed to be the agent, employer or representative of the other.

12. FORCE MAJEURE

LABORATORY shall not be liable for any claims or damages and shall be excused for such claims, damages, failures and delays in the performance of its obligations under this Agreement due to any act or cause beyond the reasonable control and without the fault of LABORATORY including, without limitation, acts of God such as fire, flood, tornado, earthquake; acts of government (i.e., civil injunctions or enacted statutes and regulations); or acts or events caused by third parties such as riot, strike, power outage or explosion; or the inability due to any of the aforementioned causes to obtain necessary labor or materials.

13. WARRANTY

- A. CLIENT WARRANTS TO LABORATORY THAT NEITHER CLIENT NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.
- B. LABORATORY WARRANTS TO CLIENT THAT NEITHER LABORATORY NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.
- C. LABORATORY WARRANTS TO CLIENT THAT ALL SERVICES PROVIDED HEREUNDER SHALL BE IN ACCORDANCE WITH ESTABLISHED AND RECOGNIZED CLINICAL LABORATORY TESTING PROCEDURES AND WITH REASONABLE CARE IN ACCORDANCE WITH APPLICABLE FEDERAL, STATE AND LOCAL LAWS.
- D. NO OTHER WARRANTIES ARE MADE BY LABORATORY.
- E. IN NO EVENT SHALL LABORATORY BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR SPECIAL DAMAGES OF CLIENT OR OF ANY THIRD PARTY.

14. BENEFIT

This Agreement is intended to inure only to the benefit of LABORATORY and CLIENT. This Agreement is not intended to create, nor shall be deemed or construed to create, any rights in any third parties.

15. NONDISCRIMINATION

All Services provided by LABORATORY hereunder shall be in compliance with all applicable Federal and State laws, regulations and ordinances prohibiting discrimination on the basis of race, color, religion, sex, national origin, handicap, veteran status or any other protected class.

16. HEADINGS

The headings in this Agreement are for convenience and reference only and are not intended to, and shall not, define or limit the scope of the provisions to which they relate.

17. ENFORCEABILITY/SEVERANCE CLAUSE

The invalidity or unenforceability of any term or provisions of this Agreement in any jurisdiction shall not affect the validity or enforceability of any of the other terms or provisions in that jurisdiction or of the entire Agreement in any other jurisdiction. If any provision is held invalid by a court of competent jurisdiction, such shall be severed and the Agreement shall be interpreted as though the severed provision had not existed.

18. WAIVER

No course of dealing between the parties or any delay on the part of either party in exercising any rights they may have under this Agreement shall operate as a waiver of any of the rights of the other party. No express waiver shall affect any condition, covenant, rule, regulation, right or remedy other than the one specified in such waiver and only for the time and in the manner specifically stated.

19. ACCESS TO BOOKS AND RECORDS

If the Services to be provided by LABORATORY hereunder are subject to the disclosure requirements of 42 U.S.C. 1395x (v) (1) (I), LABORATORY shall until expiration of four (4) years make available, upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly authorized representatives, a copy of this Agreement and the books, documents and records of LABORATORY that are necessary to certify the nature and extent of the costs incurred under this Agreement through a subcontractor with a value or cost of \$10,000.00 or more over a twelve (12) month period. In addition, with respect to any applicable subcontract, such subcontract shall contain a clause to the effect that, should the subcontractor be deemed a related organization, until the expiration of four (4) years after the furnishing of services pursuant to such subcontract, the subcontractor shall make available upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly

authorized representatives, a copy of the subcontract, and the books, documents and records of such third party that are necessary to verify the nature and extent of the costs incurred under this Agreement.

During the term of this Agreement, upon reasonable prior written request and during normal business hours, LABORATORY shall allow CLIENT reasonable access to LABORATORY records concerning the Services provided hereunder. CLIENT warrants and represents that it has obtained any necessary written consent from CLIENT patients for the release of such records. Such consent shall satisfy all applicable laws and regulations including but not limited to the privacy regulations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

20. MODIFICATION

This Agreement may only be modified in a writing signed by authorized representatives of each party.

21. ENTIRE AGREEMENT

This Agreement constitutes the entire understanding between the parties hereto concerning the subject matter herein and is a complete statement of the terms thereof and shall supersede all previous understandings between the parties, whether oral or written with respect to the subject matter herein. The parties shall not be bound by any representation made by either party or agent of either party that is not set forth in this Agreement. Any applicable provisions required by federal, state, or local law are hereby incorporated by reference.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in their names as their official acts by their respective representatives, each of whom is duly authorized to execute the same.

LABORATORY:
Laboratory Corporation of America Holdings

By: _____

Print Name: _____

Date: _____

CLIENT:
Surgcenter at Harborside, LLC

By: 

Print Name: DANIEL BOSTON

Date: 11/26/12

EXHIBIT A

FEES

For the Services ordered by CLIENT and performed by LABORATORY that are not set forth above, CLIENT agrees to pay the fees set forth in LABORATORY's current Professional Fee Schedule, as modified from time to time by LABORATORY.



November 30, 2012

Surgcenter at Harborside, LLC
125 Potomac Passage, Suite 200
National Harbor, MD 20745

Dear Client:

Enclosed is a fully executed original of the Laboratory Services Agreement for your files.

Please feel free to contact your LabCorp Representative, Robert Sutton at (800) 788-8765 x0352, with future questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads 'Jennifer Wall'.

Jennifer Wall
Laboratory Corporation of America Holdings
Contracts Department,

Enclosure

cc: Robert Sutton

ATTACHMENT 37

Attachment 17 (revised) Historical and
Projected Cases, Operating Room,
Procedure Room, and Total

Harborside Surgery Center
Historical and Projected Cases
Operating Room, Procedure Room, and Total

Physician	Operating Room Cases (a)				Procedure Room Cases				Total Cases (b)			
	Historical	Projected			Historical	Projected			Historical	Projected		
	2023	2025	2026	2027	2023	2025	2026	2027	2023	2025	2026	2027
Azer, Nigel	76	120	160	200	2	10	16	20	78	130	176	220
Branche, George	95	75	80	84	160	194	206	218	255	269	286	302
Engl, Charles	40	72	96	120	0	0	0	1	40	72	96	121
Fricka, Kevin	363	484	521	558	0	0	0	0	363	484	521	558
Gallagher, Brian	31	44	46	48	82	162	170	177	113	206	216	225
Gandhi, Rikesh	17	14	15	15	200	288	300	313	217	302	315	328
Gebrelul, Aaron	21	85	102	136	0	0	0	0	21	85	102	136
Hamilton, William	266	386	414	414	0	0	0	0	266	386	414	414
Kittredget, Ben	6	19	19	19	72	65	65	65	77	84	84	84
McAsey, Craig	70	134	179	201	2	8	10	11	72	142	189	212
Nagda, Sameer	136	110	120	140	129	174	175	204	265	284	295	344
Narvaez, Michael	182	83	95	118	0	72	83	104	182	155	178	222
Nathan, Michael	27	159	159	159	21	0	0	0	48	159	159	159
Root, Cassie	43	22	22	22	289	170	170	170	332	192	192	192
Saddler, Stephen	101	85	91	91	54	101	107	107	155	186	198	198
Sershon, Robert	259	404	477	551	2	5	7	7	261	409	484	558
Wallach, Corey	18	10	11	12	104	148	174	179	122	158	185	191
Weinritt, David	59	54	54	54	75	114	114	114	134	168	168	168
Wolff, Andrew	36	15	15	15	0	0	0	0	36	15	15	15
Total	1,845	2,376	2,676	2,959	1,192	1,510	1,597	1,688	3,037	3,885	4,273	4,647

Notes:

(a) Application, Table 11

(b) Application, Table 14 and Attachment 17

ATTACHMENT 38

Affirmations

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and attachments are true and correct to the best of my knowledge, information and belief.

By: Sandra Gateau

Printed Name: Sandra Gateau

Title: Administrators

Date: 7/30/24

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and attachments are true and correct to the best of my knowledge, information and belief.

By: John F. Hill

Printed Name: JOHN F. HILL

Title: Consultant

Date: July 30, 2024

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and attachments are true and correct to the best of my knowledge, information and belief.

By: *m.jane Falk*

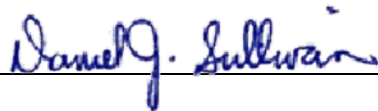
Printed Name: M. Jane Falk RN, BSN, MHA

Title: SVP, Clinical Operations. M2Orthopaedics

Date: 7/25/2024

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and attachments are true and correct to the best of my knowledge, information and belief.

By: 

Printed Name: Daniel J. Sullivan

Title: President

Date: July 30, 2024