

Comments Submitted by Novant Health New Hanover Regional Medical Center, LLC

In Opposition to:

- **Project ID # O-12121-21 Wilmington ASC, LLC**

Pursuant to N. C. Gen. Stat. § 131E-185, Novant Health New Hanover Regional Medical Center, LLC (“NHRMC”) submits these comments in opposition to the application filed by Wilmington ASC, LLC (“WASC” or “the applicant”) to acquire a cardiac catheterization (“cardiac cath”) unit in New Hanover County, in response to the need determination in the 2021 SMFP, Table 17A-4, page 322. As discussed below, WASC’s application is non-conforming with several CON criteria and the performance standard and must be disapproved. NHRMC’s application is conforming with all applicable CON criteria and the performance standard. A comparative analysis also shows that the NHRMC application is the more effective alternative compared to the WASC application. Accordingly, the NHRMC application should be approved and the WASC application should be denied.

Overview

In this application, WASC proposes to change the scope of its previously approved but not yet developed ambulatory surgery center project (Project I.D. No. O-11441-17) by adding cardiac cath services. If it is awarded the CON, WASC states that it will perform both diagnostic and therapeutic¹ cardiac cath procedures in its lab. Only interventional cardiologists perform both diagnostic and therapeutic cardiac cath procedures; diagnostic cardiologists perform only diagnostic cath. A demonstrated track record of performing a substantial number of diagnostic and therapeutic cardiac cath procedures is essential to WASC’s ability to demonstrate that its projections are reasonable and supported. WASC’s application lacks this essential element.

Wilmington Health is the sole member of WASC and the employer of the cardiologists who will use WASC’s proposed cardiac cath lab. Wilmington Health has only one board certified interventional cardiologist on staff, Dr. Andrew Bishop. Dr. Bishop is the *only* Wilmington Health cardiologist who performs therapeutic cardiac cath procedures. If the other Wilmington Health cardiologists who perform cardiac cath procedures determine their patients need an intervention, they call Dr. Bishop. WASC failed to disclose that it has only one interventional cardiologist. Dr. Bishop is not only Wilmington Health’s sole provider of therapeutic cardiac cath procedures; among the Wilmington Health cardiologists, Dr. Bishop’s patients constitute the highest number of patients (between 40% and 47%) receiving diagnostic cardiac cath. Table 1 on the next page shows the number of patients on whom the Wilmington Health cardiologists performed diagnostic cardiac cath from 2018 to July 31, 2021. Table 2 below shows the number of patients on whom Dr. Bishop performed therapeutic cardiac cath from 2018 to July 31, 2021.

¹ Therapeutic cardiac cath are sometimes referred to as interventional cardiac cath or percutaneous coronary interventions (“PCI”).

Both tables show the total for Wilmington Health, and the total for the other cardiologists who perform diagnostic and interventional cardiac cath at NHRMC:

TABLE 1
NUMBER OF PATIENTS WHO RECEIVED DIAGNOSTIC CARDIAC CATHS IN
NHRMC'S CATH LABS
January 1, 2018 to July 31, 2021

| Physician | Number of patients on whom diagnostic cardiac caths were performed in | | | |
|--|---|--------------|--------------|--------------|
| | 2018 | 2019 | 2020 | 2021* |
| Bishop, Andrew H. | 362 | 476 | 385 | 255 |
| Janik, Matthew J. | 216 | 311 | 273 | 136 |
| Payne, Paul A. | 225 | 100 | 0 | 0 |
| Roberts, Gregory J. | 98 | 128 | 111 | 66 |
| Romig, Michael C. | 0 | 0 | 22 | 108 |
| Smith, Carin J. | 0 | 0 | 28 | 57 |
| Total Wilmington Health cardiologists | 901 | 1,015 | 819 | 622 |
| % of Dr. Bishop's patients as % of total Wilmington Health cath patients | 40% | 47% | 47% | 41% |
| Total other cardiologists not associated with Wilmington Health | 3,956 | 4,221 | 3,812 | 2,322 |
| Total all cardiologists | 4,857 | 5,236 | 4,631 | 2,944 |

Source: Internal NHRMC records

* Through 07/31/2021

TABLE 2
NUMBER OF PATIENTS WHO RECEIVED THERAPEUTIC CARDIAC CATHS IN
NHRMC'S CATH LABS
January 1, 2018 to July 31, 2021

| Physician | Number of patients on whom therapeutic cardiac caths were performed in | | | |
|--|--|--------------|--------------|--------------|
| | 2018 | 2019 | 2020 | 2021* |
| Bishop, Andrew H. | 375 | 413 | 336 | 283 |
| Janik, Matthew J. | 0 | 0 | 0 | 0 |
| Payne, Paul A. | 0 | 0 | 0 | 0 |
| Roberts, Gregory J. | 0 | 0 | 0 | 0 |
| Romig, Michael C. | 0 | 0 | 0 | 0 |
| Smith, Carin J. | 0 | 0 | 0 | 0 |
| Total Wilmington Health cardiologists | 375 | 413 | 336 | 283 |
| % of Dr. Bishop's patients as % of total Wilmington Health cath patients | 100% | 100% | 100% | 100% |
| Total other cardiologists not associated with Wilmington Health | 1,906 | 2,138 | 2,093 | 1,340 |
| Total all cardiologists | 2,281 | 2,551 | 2,429 | 1,623 |

Source: Internal NHRMC records

* Through 07/31/2021

As can be readily seen from Tables 1 and 2 above, there is a major difference in the number of cardiac cath patients treated by Dr. Bishop compared to the number of cardiac cath patients treated by other Wilmington Health cardiologists. See Tables 1 and 2 above. There is nothing in the application to indicate that cardiologists who are not part of Wilmington Health will be credentialed to perform cardiac cath procedures at WASC’s proposed new lab. The application provides no information about Wilmington Health or WASC’s plans to recruit additional cardiologists to Wilmington. **Thus, the projections in the application depend mainly on one physician who did not provide support for the project. This calls into question one of the central premises of the application, i.e., that the WASC cardiac cath lab will be used by five different cardiologists to perform diagnostic and interventional cardiac cath. It will not.**

Even if one assumes that Dr. Bishop supports the project and will perform appropriate procedures in the proposed lab, it is entirely unreasonable to build volume projections mainly on the performance of one physician, especially with regard to therapeutic cardiac cath. Therapeutic cath volumes are integral to WASC’s ability to meet the performance standards. If Dr. Bishop takes vacation, becomes ill, moves away, or even has fewer patients in a given year whose procedures can be safely performed at WASC, this casts serious doubt on the projections, especially with respect to therapeutic cardiac cath since Dr. Bishop is the only Wilmington Health physician who can perform therapeutic cardiac cath. In fact, if Dr. Bishop performs just seven fewer interventions at WASC than are projected in the fourth quarter of Project Year 3, the applicant will not meet the 60% performance standard in 10A N.C.A.C. 1603(a)(1). Table 3 uses the same information reported on page 66 of the application but simply reduces the number of interventions Dr. Bishop is projected to perform at WASC in the fourth quarter of Year 3 from 42 to 35.

TABLE 3

WASC’s VOLUMES ADJUSTED FOR SEVEN FEWER INTERVENTIONS

| | 4th Quarter of Project Year 3 (as shown on page 66 of the application) |
|----------------------------------|--|
| Diagnostic | 161 |
| Therapeutic (interventional) | 35 |
| Total Procedures | 196 |
| Diagnostic Equivalent Procedures | 222 |
| # of units | 1 |
| Capacity | 375 |
| % Utilization | 59% |

Source: Page 66 of WASC Application

A seven procedure difference in one quarter is not much; it equates to fewer than 2 procedures per week over a four week period. Applying the same seven procedure difference per quarter over the course of four quarters (28 fewer interventions performed at WASC over the course of a year) produces the same result; utilization falls below 60%.

TABLE 4

WASC’S VOLUMES ADJUSTED FOR 28 FEWER INTERVENTIONS PERFORMED OVER A YEAR

| | Project Year 1 (as shown on page 7 of Form C) | Project Year 2 (as shown on page 7 of Form C) | Project Year 3 (as shown on page 7 of Form C) |
|---|--|--|--|
| Diagnostic | 627 | 635 | 643 |
| Intervention | 137 | 139 | 141 |
| Total Procedures | 764 | 774 | 784 |
| Diagnostic Equivalent Procedures | 867 | 878 | 890 |
| # of units | 1 | 1 | 1 |
| Capacity | 1,500 | 1,500 | 1,500 |
| % Utilization | 58% | 59% | 59% |

Source: Page 7, Form C of WASC Application

Thus, there is practically no room for any differences in WASC’s numbers, which illustrates why it is unreasonable to base projections mainly on the performance of one physician. Even a slight shift in Dr. Bishop’s numbers whether due to patient needs or other reasons, such as vacation or sick days, has a dramatic effect.

It is equally unreasonable to assume that Wilmington Health’s four diagnostic cardiologists will begin to perform therapeutic cardiac cath procedures.

Without reasonable and supported assumptions for the volume projections, the application fails to demonstrate conformity with multiple CON criteria, including Criteria (1), (3), (4), (5), (6) and (18a), as well as the performance standard, 10A N.C.A.C. 14C.1603².

Another issue that makes the WASC volume projections unreliable is the inherent limitation that exists in freestanding cardiac cath labs. They cannot treat all patients. As WASC forthrightly declares: “WASC is not proposing to support emergent PCI as the proposed project involves the development of cardiac cath equipment in a freestanding ASF to perform diagnostic and elective interventional cardiac cath procedures for appropriate patients only.” Application, p. 33. WASC also states that it “will perform only the diagnostic and elective interventional cardiac cath procedures that are included in CMS’s list of Medicare-covered ASF procedures for patients that are appropriate for a freestanding setting.” Application, p. 34. WASC must necessarily limit its

² WASC asserts that freestanding cath labs save time versus procedures performed in hospitals. Application, p. 53. This is highly doubtful in the case of WASC, where a single physician will perform interventions. Dr. Bishop can only perform one case at a time, so there is no efficiency associated with him performing cases at WASC compared to performing cases at NHRMC. Moreover, as WASC acknowledges, not all procedures are appropriate for its facility. It is not reasonable to assume that Dr. Bishop will stop performing any cases at the hospital and will instead perform 100% of his cases, including his interventions, at WASC, so Dr. Bishop will continue to perform some cardiac cath at the hospital. This means instead of being efficient, Dr. Bishop will likely be going back and forth to the hospital. The same could be true for the other cardiologists; not all of their diagnostic procedures may be appropriate for WASC.

patient population to lower-risk patients which will, in turn, limit its usefulness as a community resource and as a place to which physicians, including those associated with Wilmington Health, will want to refer their cardiac cath cases.³ Attached as Exhibit 1 is a list of cardiac cath CPT codes performed in the NHRMC cath labs, separated by inpatient and outpatient procedures performed between 2017 and 2021. The yellow highlighting represents the procedures WASC will do. NHRMC will perform *all* the procedures in the yellow highlighting *and* all the procedures that are not highlighted. The difference is substantial. Wilmington Health will perform 13 cardiac cath CPT codes on an outpatient basis. NHRMC will perform 46 outpatient cardiac cath CPT codes *and* all inpatient CPT codes. Expressed as a percentage, the WASC cardiac cath lab will perform approximately 28% of the types of outpatient procedures that the NHRMC lab will perform.⁴ The limited utility of WASC's proposed project is further evidenced by the fact WASC only proposes to operate the cardiac catheterization unit at 62.6% (939 / 1,500) of capacity. See Application, p. 67; Form C page 7. As previously discussed, that level of utilization is questionable because it leaves no room for time off for any diminution in Dr. Bishop's volume, for any reason. Thus, when evaluating where to place limited resources that are intended to serve the community's needs for decades, the Agency must carefully consider which provider will offer the most services for the most patients.⁵ The answer is clearly NHRMC.

In addition to performing comparatively few procedures, as a freestanding facility, WASC faces the inevitable problem of addressing patient complications that cannot be handled at WASC's facility. Despite the most rigorous patient screening process, which is intended to limit the patient population WASC will serve, it is impossible to forecast if an otherwise healthy cardiac cath patient will develop complications requiring hospitalization. Even patients who present as "ideal" candidates for cardiac cath in an ASF can develop complications. Complications may include hematoma/retroperitoneal bleeding⁶. As discussed later in these comments regarding Criterion (18a), a recent study shows that patients who have therapeutic cardiac cath procedures in freestanding ASCs have a higher risk of bleeding complications than patients who had their procedures performed in hospital outpatient departments ("HOPD"). Regardless of whether WASC considers complications such as bleeding to be a relatively rare occurrence, complications do occur, and there must be a plan for addressing them. WASC's application hardly addresses this issue, simply stating that its location is "proximate to New Hanover Regional Medical Center (NHRMC) in the event of an emergency." Application, p. 29. Left unanswered are questions such as how a transfer from WASC to NHRMC might impact continuity of patient care and the cost to

³ Although not expressly stated in the application, it also appears that the WASC facility will be for the patients of Wilmington Health providers. All of the provider letters of support included in the WASC application are from Wilmington Health providers. No providers who are not affiliated with Wilmington Health provided a letter of support in the application.

⁴ $13/46 \times 100 = 28\%$.

⁵ WASC asserts that its proposal will result in increased capacity at the hospital for procedures that must be performed at the hospital. Application, p. 53. Not true. Given the limited utility of WASC's project, the WASC cath lab will not reduce capacity constraints at NHRMC. On the contrary, it will have the opposite effect. NHRMC will continue to do everything it does today to serve a growing and aging population, plus handle complications and emergencies that are transferred from WASC.

⁶ See *Cardiac Catheterization Risks and Complications*, located at <https://www.ncbi.nlm.nih.gov/books/NBK531461>. (July 26, 2021).

the patient and their payor source.⁷ Adding to this uncertainty is WASC's lack of experience. It has never operated an ASC or a cardiac cath lab. In fact, as WASC notes, its proposed ASC will be the first of its kind in North Carolina.⁸ Application, p. 30⁹.

In addition to these issues, the WASC application suffers from a variety of other deficiencies that render the application unapprovable. For example, the staffing falls far short of what is necessary. WASC proposes to have one LPN covering a seven-bay prep/recovery area. See Application, p. 37; Form H Staffing. This is not only insufficient in terms of numbers of people, as one LPN cannot provide the "close monitoring" for seven patients as WASC describes, see Application, p. 37, but also insufficient in terms of qualifications. An LPN is a limited scope of practice that must be directed and supervised by an RN, physician, or other person authorized by state law. See Exhibit 2. Conscious sedation (also known as moderate sedation) is regularly used during cardiac cath procedures.¹⁰ In North Carolina, conscious sedation requires an RN level of care. The North Carolina Board of Nursing does not permit LPNs to administer conscious sedation. See Exhibit 3 (NC Board of Nursing Position Statement on Procedural Sedation/Analgesia, stating that administration of sedation/analgesia is outside the LPN scope of practice). An RN may administer moderate sedation, but the nurse may not assume other responsibilities which would leave the patient unattended, thereby jeopardizing patient safety. See Exhibit 3. Note also that according to Form H, there will be only one RN. The sole RN cannot be assisting with cath procedures, supervising the sole LPN, *and* closely monitoring pre and post procedure patients all at the same time. WASC's minimal staffing plan not only raises concerns about patient safety but also presents the obvious question whether the staffing costs have been purposely understated to make WASC appear a less expensive alternative to NHRMC.

WASC has also understated its capital costs. Cardiac cath was not part of the original WASC ASC application. As a new provider of cardiac cath services, it should have included amounts for startup and initial working capital. WASC also materially understated its capital costs by omitting the cost of the cardiac cath equipment itself. WASC contends that because it plans to lease the equipment, it was not required to include it as a capital cost, which is incorrect. But even if one assumes that WASC properly accounted for all costs, WASC has not adequately demonstrated the availability and commitment of funds for the project as well as the project proposed in its pending linear accelerator application (Project I.D. No. O-012121-21). According to the cardiac cath and linear accelerator applications, Wilmington Health intends to fund both projects with

⁷ NHRMC estimates that the cost of an Advanced Life Support (ALS) emergency transfer from WASC to NHRMC would cost approximately \$1,300.

⁸ There was a freestanding cardiac cath lab in Greensboro in the early 2000s. This lab, called Greensboro Heart Center, began performing procedures in 2003 and first appeared in the 2005 SMFP. Greensboro Heart Center used a cardiac cath unit owned and operated by MedCath (now known as DLP Cardiac Partners). See 2005 SMFP, Table 9W, p. 130. Greensboro Heart Center closed in 2010. See 2012 SMFP, Table 9Q, p. 197.

⁹ To be clear, it is not NHRMC's view that cardiac cath cannot be performed in an ASC; clearly, it can be, but there are limitations, and in the case of WASC, a complete lack of experience running an ASC or a cath lab. As described in these comments, the WASC proposal is not a carefully planned and well thought out approach by an experienced operator.

¹⁰ <https://scai.org/moderate-sedation-practices-adult-patients-cardiac-catheterization-laboratorycccl>.

accumulated reserves. WASC claims that its accumulated reserves are found in its “cash and cash equivalents,” which is questionable, since there is nothing in the financial statements to indicate that the cash and cash equivalents have been reserved for a particular purpose. More concerning, however, is the fact that when current liabilities are netted against the cash and cash equivalents, most of Wilmington Health’s cash would be eliminated, thereby making it impossible for Wilmington Health to pay for either the cardiac cath project or the linear accelerator project.

Conversely, NHRMC is not a new provider of cardiac catheterization services. NHRMC has been providing cardiac catheterization services in southeast North Carolina for over 20 years. NHRMC will treat all patients regardless of their ability to pay. NHRMC has seven interventionalists besides Dr. Bishop on staff.¹¹ NHRMC’s experience in serving cardiac and cardiovascular patients at its Heart Center continues to bring innovative cardiac and cardiovascular treatments to the service area including structural heart procedures. Several interventional cardiologists perform cardiac catheterizations at NHRMC. NHRMC has the acute care services to support cardiac catheterizations including open heart surgery and more complex interventional procedures. Cardiac catheterization patients who are not suited for the ASC or who develop complications at Wilmington ASC will be transferred to NHRMC. NHRMC will be hiring 6.75 FTEs to cover the new cardiac catheterization lab; 3.75 FTE registered nurses and 3.0 FTE Cardiovascular Tech-C. NHRMC projects to operate at 87.2 percent of capacity in Year 3, so the additional lab will be fully utilized well above the performance standard in 10A N.C.A.C. .1603(c)(2).

The following sections review the WASC application in relation to each of the applicable CON criteria and performance standards. Finally, NHRMC will demonstrate that it is the comparatively superior applicant in this review.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms or home health offices that may be approved.**

The WASC application conforms to the need determination in the 2021 SMFP for one additional cardiac cath lab in New Hanover County but it fails to conform to Policy GEN-3, which requires the applicant to demonstrate:

... how the project will promote safety and quality in the delivery of health care services will promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to

¹¹ They are Dr. Barber, Dr. Buchanan, Dr. Iyer, Dr. Lewis, Dr. Meine, Dr. Pflum, and Dr. Wiegman (all with Cape Fear Heart Associates).

services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the service area.

The WASC application does not meet the requirements of Policy GEN-3 for several reasons. First, the cardiac cath services proposed by WASC will only be available to certain patients whose procedures qualify for reimbursement by CMS for cardiac cath in an ASF. Only scheduled, lower-risk patients will be served by WASC's cardiac cath lab. This means many other patients will not be served by WASC, such as emergent patients. For example, patients experiencing heart attack will still need to be treated at NHRMC. Patients who have multiple comorbidities will not be served by the WASC cardiac cath lab. As shown in Exhibit 1, WASC's lab will perform approximately 28% of the outpatient cardiac cath procedures that the NHRMC lab will perform. By its very nature, WASC's proposed cardiac cath lab will *not* address "the needs of *all* residents in the service area." (emphasis added).

Second, the project proposed in the WASC application will not be accessible to patients with limited financial resources. WASC declines to provide a percentage of charity care patients in its Section L, stating that this information is not included in its internal data. Application, p. 109. In its Form F.2, WASC provides dollar amounts for charity care but it is unclear how WASC arrived at these amounts. WASC's financial assistance policy, included as an Exhibit to the application, does not explain how the decision is made to offer charity care, other than stating charity care is "available for patients who meet charitable guidelines as determined by the U.S. Department of Health & Human Services Annual Poverty Guidelines." These Guidelines, however, do not compel WASC to offer charity care, nor do they provide suggested amounts of charity care. The decision is left entirely to WASC's discretion, and it is unknown what factors WASC will use to determine the amount of charity care. The policy states: "If a patient is deemed as qualified, a Financial Hardship Adjustment will be made on the patient's account for the approved percentage." The Agency cannot tell what that percentage may be for any cardiac cath case performed at WASC. There is also no way for the Agency to know if the percentages will be applied uniformly to all similarly situated patients. The percentage adjustment may vary from case to case. Wilmington Health's audited financial statements provide no insight into the amount of charity care, if any, Wilmington Health has provided for any service it offers, including physician services for the performance of cardiac cath procedures. Although WASC, as a new facility, was not required to provide historical information about its charity care, as the sole member of WASC, Wilmington Health's information would have been important to validate the projected amounts WASC provided. Due to the lack of information in the application, there is no way for the Agency to know how the charity care amounts were derived. The Agency should not just take WASC's word for it that it will provide the amounts of charity care stated in Form F.2 when there is no way for the Agency to verify this information.

Third, the project does not maximize healthcare value for resources expended. As discussed in the Overview above and below with respect to Criterion (3), the projections WASC provided are not reasonably achievable. As discussed in the Overview above and below with respect to Criterion (7), the staffing WASC proposes is inadequate, especially with respect to the LPN coverage. Additionally, since the WASC cardiac cath lab will only treat certain patients and will not be able to handle emergent situations, like bleeding, the patient will need to be transferred to NHRMC. The costs of a transfer to the hospital increase the cost to patients and payors. NHRMC estimates that the ambulance charge to transfer a patient from WASC to NHRMC is approximately \$1,300.

This is the first time in more than a decade that there has been a need for an additional cath lab in New Hanover County. An applicant with no experience proposes to spend almost \$4 million on a new venture to serve a limited subset of cardiac cath patients. Any patient whose procedure is deemed not appropriate for the ASC, any patient for whom Medicare will not pay for the procedure, any emergent patient and any patient who develops complications will be sent to the hospital. This does not demonstrate maximum value for resources expended. Accordingly, the WASC application should be found nonconforming with Criterion (1).

- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

The WASC Form C Assumptions and Methodology are neither reasonable nor adequately supported. Starting at the beginning of its cardiac cath methodology, WASC states:

It does, however, have data from Wilmington Health regarding the number of procedures referred and performed by its physicians. Wilmington Health currently includes 11 cardiology providers, five of whom are physicians, as well as more than 60 adult primary care providers who refer to cardiologists.¹²

WASC Application, Form C Assumptions and Methodology, p. 1.

WASC fails to state that only one Wilmington Health physician is an interventional cardiologist, Dr. Andrew Bishop. Without knowing this, the Agency might incorrectly assume that all five

¹² Some of the letters of support purporting to be from cardiologists are actually from nurse practitioners. See, e.g., letters from Katie Monroe, Pamela Adler, Steven Snyder, and Dina Sarro. See <https://www.wilmingtonhealth.com/find-a-doctor/cardiology>.

cardiologists are qualified to perform and in fact perform both diagnostic and interventional cardiac catheterizations. They are not. Drs. Smith, Roberts, Janik and Romig do not perform interventions; they only perform diagnostic cardiac cath procedures. If any of their patients requires an interventional procedure, they call Dr. Bishop to perform the intervention. As the discussion in the Overview section demonstrates, even a slight reduction in the number of interventions WASC projects to perform causes the projections to fall the 60% utilization standard.

WASC continues:

Other specialists may also refer to cardiologists. Given the experience of its physician practice, in order to project utilization of the proposed unit of cardiac cath equipment at Wilmington ASC, WASC first analyzed the historical number of diagnostic and interventional cardiac cath procedures either performed or referred by Wilmington Health providers from 2018 to 2021, as shown in the table below.

WASC Application, Form C Assumptions and Methodology, p. 1.

The number of cardiac cath procedures “referred” to Wilmington Health’s cardiologists is meaningless. A referral does not mean the patient actually had a cardiac cath procedure, as the cardiologist may determine the patient does not need cardiac cath. The patient may also decline to have the procedure if the physician recommended it. It cannot be assumed that all referrals turned into an actual cardiac cath procedure. The chart WASC provides does not distinguish between cases that were actually performed compared to referrals that did not generate actual procedures, so the addition of the referrals artificially increases the volumes in WASC’s chart. While Wilmington Health and WASC do not own or operate their own cardiac cath lab, Wilmington Health certainly has records that reveal the actual number of therapeutic and diagnostic cardiac cath procedures each of its physicians performed between CY 18 and CY 21. Wilmington Health chose not to provide the information.

WASC then states:

The total number of cardiac cath procedures performed or referred by Wilmington Health increased 21.3 and 3.1 percent annually from 2018 to 2019 and from 2018 to seasonalized 2021, respectively. Further, the total number of diagnostic equivalent cardiac cath procedures performed or referred by Wilmington Health increased 20.7 and 4.3 percent annually from 2018 to 2019 and from 2018 to seasonalized 2021, respectively.

WASC Application, Form C Assumptions and Methodology, p. 2.

Again, rather than provide actual numbers of cases performed, WASC provides percentages that have no basis for comparison due to the total number performed and referred cardiac catheterizations being combined. The Agency does not know if the 21.3 percent increase is on 100 cardiac catheterization or 1,000 cardiac catheterizations. This is important for the Agency to understand the reasonableness of the assumptions, but WASC combined the performed and referred cardiac catheterizations, presumably to make the volumes appear larger.

WASC then reduces the potential cardiac catheterizations by eliminating those procedures not included in the CMS List of Medicare-covered ASF procedures and those assumed to be performed on an inpatient basis. In support of these assumptions WASC states:

For example, based on research performed by Bain and Company, a top management consulting firm, in 2018, approximately 10 percent of all cardiovascular procedures were performed in an ASF, and it is expected that this number will increase to between 30 and 35 percent by the mid-2020s for an annual growth of approximately 20 percent.

WASC Application, Form C Assumptions and Methodology, p. 3.

WASC links to a Bain & Company brief dated September 23, 2019, entitled *Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?* The Bain & Company brief does not support the point WASC attempts to make. The Bain & Company brief refers to “cardio surgeries” and “cardiology procedures” increasing between 30 and 35 percent. Cardiac cath is not a surgical procedure. The brief does not state cardiac cath procedures make up the 10 percent or that cardiac catheterizations will increase between 30 and 35 percent. Notably, the brief does not address North Carolina at all, and it should not be assumed that experience in other states or nationally will be applicable in North Carolina because, as WASC notes, its project is the first of its kind in North Carolina. A copy of the Bain & Company brief is attached to these comments as Exhibit 4.

WASC continues:

Please note that if the proposed project is approved, it will be one of six cardiac cath units in New Hanover County, meaning that it would be expected to provide approximately one-sixth, or 16.7 percent, of cardiac cath procedures in the service area. Given the expectation that these procedures may grow to 30 to 35 percent in an ASF setting nationwide, this assumption is conservative.

WASC Application, Form C Assumptions and Methodology, p. 3.

WASC’s assumption that its cath lab would provide 16.7 percent of cardiac catheterization procedures in New Hanover County is unreasonable. First, while it is correct that the cardiac cath

unit available in the 2021 SMFP would be 1/6th of the total cardiac cath lab inventory in New Hanover County, it is incorrect to assume that procedures are evenly distributed across the inventory. Some units may be more highly utilized than others, and some units may be less highly utilized. Since the WASC cardiac cath lab will only be used for a limited patient population, one would not expect the WASC lab to perform 1/6th of the total number of cardiac cath procedures. Second, considering WASC only has one interventional cardiologist and does not include any discussion in its application about recruiting any additional interventional cardiologists, it is unreasonable to assume that a WASC cardiac cath lab would have the same utilization as an NHRMC cath lab.

On page 4 of Form C, WASC identifies the percentage of outpatient diagnostic and interventional cardiac catheterizations performed by “Wilmington Health cardiologists.” Note the usage of the plural “cardiologists,” implying that all Wilmington Health cardiologists perform both interventional and diagnostic cardiac cath procedures, which is not the case. Only Dr. Bishop performs both interventions and diagnostic cardiac cath procedures. The other four Wilmington Health cardiologists who perform cardiac cath procedures perform only diagnostic cardiac cath procedures. No information is contained in the application to show that WASC has a plan for recruiting more interventional cardiologists, or even a back for when Dr. Bishop takes a day off for any reason. Accordingly, when Dr. Bishop is not available for any reason, there will be no interventions performed in the WASC lab. As previously discussed, even a slight reduction in Dr. Bishop’s projected interventions at WASC has a dramatic, negative effect on the projections.

WASC states:

As shown above, in partial year 2021, 55.6 and 34.4 percent of Wilmington ASC potential diagnostic and interventional cardiac cath procedures, respectively, performed by Wilmington Health cardiologists were outpatient. As demonstrated in the table above, WASC assumes partial year 2021 percentages will remain constant through the end of 2021.

WASC Application, Form C Assumptions and Methodology, p. 4.

WASC utilizes the percentage of cardiac catheterization performed on an outpatient basis but does not provide any basis that this assumption is reasonable. As previously discussed, the Agency does not know if the single, WASC interventional cardiologist performed 100 cardiac catheterizations or 1,000 cardiac catheterizations or even the number of diagnostic versus interventional cardiac catheterizations performed by the sole WASC interventional cardiologist.

Interestingly, WASC assumes that 34.4 percent of its “potential” interventional cardiac catheterizations would be outpatient and eligible to be performed at WASC. On July 30, 2020, NHRMC instituted a “Same Day PCI Discharge” program and since that time (over a year), only seven Wilmington Health cardiac catheterization patients have been discharged home on the same day as their interventional cardiac catheterization procedures. This is dramatically different from assuming that 34.4 percent of “potential” interventional cardiac catheterizations would be

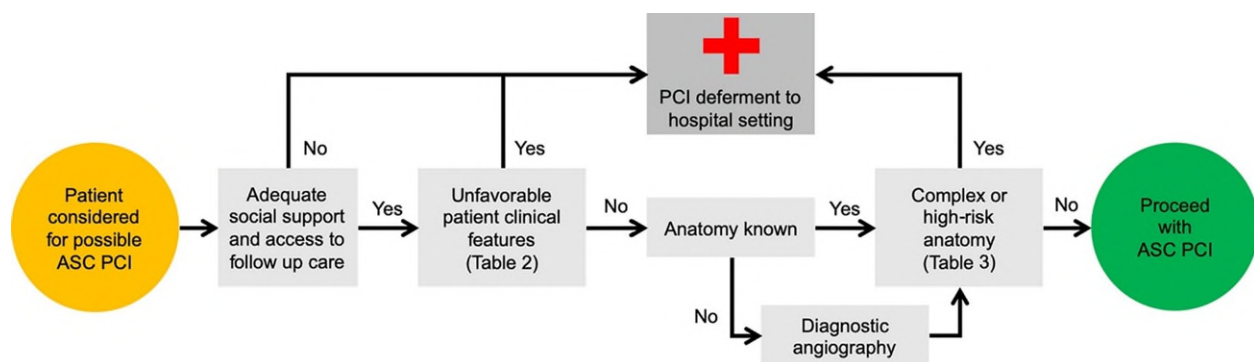
outpatient and discharged on the same day as their interventional cardiac catheterization. WASC then states:

WASC projects 1,091 Wilmington ASC potential outpatient cardiac cath procedures to be performed in 2026. Of note, while all of the outpatient cardiac cath procedures shown above are appropriate for an ASF based on coverage by CMS, WASC recognizes that some patients will nonetheless not meet the patient selection criteria for the ASF. To determine what portion of these patients would be better served in a hospital-based setting, WASC discussed the criteria with the Wilmington Health cardiologists who will perform these cases. The cardiologists indicated that it is reasonable to assume that no more than 25 percent of outpatients will require a hospital-based setting for their cardiac cath procedure.

WASC Application, Form C Assumptions and Methodology, p. 6. WASC therefore assumes that 75% of its cases will be suitable for its lab.

Again, WASC refers to “Wilmington Health cardiologists who will perform these cases,” inviting the Agency to assume more than one interventional cardiologist is on staff at Wilmington Health. There is no basis for the 75 percent outpatient assumption. As previously discussed, over the course of a year, only seven Wilmington Health cardiac catheterization patients have been discharged home on the same day as their interventional cardiac catheterization.

Additionally, on page 52 of the application, WASC identifies an article on the Wiley Online Library titled, SCAI position statement on the performance of percutaneous coronary intervention in ambulatory surgical centers, which includes the following flow chart and tables:



ASC=Ambulatory Surgical Center; PCI=percutaneous coronary intervention; Table 2. Unfavorable Patient Conditions Warranting PCI Deferment to the Hospital Setting; Table 3. Complex or High-Risk Lesion Characteristics Warranting PCI Deferment to the Hospital Setting

TABLE 2. Unfavorable patient conditions warranting PCI deferment to the hospital setting

1. Decompensated CHF (NYHA class 3–4)

2. Recent TIA/stroke (<8 weeks)
3. Left ventricular ejection fraction <30%
4. Chronic kidney disease with an estimated glomerular filtration rate < 45 ml/min/1.73 m²
5. Anemia (Hgb < 9 g/dl) or coagulopathy (eg, INR >1.5 or platelet count <100 K)
6. Acute coronary syndrome
7. Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen)
8. Unprotected left main stenosis or three-vessel CAD
9. Any cardiac or noncardiac signs of clinical instability
10. Significant PAD limiting femoral and radial access
11. Severe aortic stenosis
12. Severe contrast allergy
13. Operator judgment on other condition(s)

TABLE 3. Complex or high-risk lesion characteristics warranting PCI deferment to the hospital setting

1. Bifurcation lesions with significant side branch involvement
2. Severe lesion calcification
3. Extremely angulated segment or excessive proximal tortuosity
4. Bypass graft lesions
5. Chronic total occlusions
6. Other vessel characteristics that the operator judges would impede stent deployment
7. Thrombus in target vessel or lesion
8. Unprotected left main lesions
9. Last remaining conduit
10. Possible need for upfront mechanical circulatory support

On page 6 of Form C, WASC states that “WASC discussed the criteria with the Wilmington Health cardiologists who will perform these cases.” It is not reasonable, credible, or supported to then assume 75 percent of cardiac catheterization patients have:

1. adequate social support and access to follow-up care,
2. none of the 13 unfavorable patient clinical features, and
3. none of the 10 complex or high-risk lesion characteristics.

In fact, based on Wilmington Health’s own same-day interventional cardiac catheterization discharges of only seven patients over more than a year, it is an exaggeration to assume 75 percent outpatient. A rate of 75 percent of interventional cardiac catheterization patients being low-risk and appropriate for same day discharge is a rate not experienced anywhere in the county, let alone in a single, interventional cardiologist’s patient load. In addition, any patients who undergo cardiac catheterizations at WASC and are then found to have one of the high-risk/complex lesions, those patients will be required to undergo a second procedure at NHRMC, thereby increasing patient risk and patient cost, as well as cardiac catheterization lab inefficiency.

Without any reasonable support to make an assumption as to how many cardiac catheterization patients would be eligible for a procedure on an outpatient basis other than “WASC discussed the criteria with the Wilmington Health cardiologists who will perform these cases” the projected

cardiac catheterizations are baseless, as the entire assumption of providing cardiac catheterizations at an ASF is solely based on the ability of the cardiac catheterization to be performed on an outpatient basis.

Additionally, WASC identifies two different cardiac catheterization projections as shown in the following three tables from the Form C Assumptions and Methodology:

Form C Assumptions and Methodology, Page 6:

Projected Wilmington ASC Fixed Cardiac Cath Utilization

| | CY23* | CY24 | CY25 | CY26 |
|--|--------------|-------------|-------------|-------------|
| Total Wilmington ASC Potential Cardiac Cath Procedures – Outpatient Only | 612 | 1,063 | 1,077 | 1,091 |
| Percent of Cardiac Cath Procedures to Shift to Wilmington ASC | 75.0% | 75.0% | 75.0% | 75.0% |
| Total Wilmington ASC Potential Cardiac Cath Procedures – Outpatient Only to Shift | 459 | 797 | 808 | 818 |
| Diagnostic Cardiac Cath Procedures to Shift** | 364 | 631 | 640 | 648 |
| Interventional Cardiac Cath Procedures to Shift^ | 96 | 166 | 168 | 170 |
| Total Cardiac Cath Procedures to Shift | 459 | 797 | 808 | 818 |
| Total Diagnostic Equivalent Cath Procedures to Shift | 531 | 922 | 934 | 946 |

*Adjusted to reflect operational start date of June 1, 2023.

**Diagnostic Cardiac Cath Procedures to SHIFT = Total Wilmington ASC Potential Cardiac Cath Procedures – Outpatient Only to SHIFT x (1 – 0.208).

^Interventional Cardiac Cath Procedures to SHIFT = Total Wilmington ASC Potential Cardiac Cath Procedures – Outpatient Only to SHIFT x 0.208.

Form C Assumptions and Methodology, Page 8:

Projected Wilmington ASC Fixed Cardiac Catheterization Utilization

| | PY1 | PY2 | PY3 |
|---|--------------|--------------|--------------|
| Diagnostic Procedures | 627 | 635 | 643 |
| Interventional Procedures | 165 | 167 | 169 |
| Total Procedures | 791 | 802 | 812 |
| Diagnostic Equivalent Procedures | 915 | 927 | 939 |
| # of Units | 1 | 1 | 1 |
| Total Capacity* | 1,500 | 1,500 | 1,500 |
| % Utilization^ | 61.0% | 61.8% | 62.6% |

*Total Capacity = Number of units x 1,500 procedure capacity per CON rules definition.

^Percent Utilization = Diagnostic Equivalent Procedures ÷ Total Capacity.

Form C.2b:

| Form C.2b Projected Medical Equipment Utilization upon Project Completion ^ Wilmington ASC | Partial FY | 1st Full FY | 2nd Full FY | 3rd Full FY |
|---|---------------|---------------|---------------|---------------|
| | F: 06/01/2023 | F: 01/01/2024 | F: 01/01/2025 | F: 01/01/2026 |
| | T: 12/31/2023 | T: 12/31/2024 | T: 12/31/2025 | T: 12/31/2026 |
| Cardiac Cath Equipment (see Tab C) | | | | |
| # of Units | 1 | 1 | 1 | 1 |
| # of Diagnostic Procedures | 364 | 631 | 640 | 648 |
| # of Therapeutic Procedures | 96 | 166 | 168 | 170 |
| # of Diagnostic Equivalent Procedures | 531 | 922 | 934 | 946 |

As can be readily seen, page 6 of Form C matches Form C.2b, but page 8 does not match. The Agency cannot assume which volume projections are correct and which are incorrect.

WASC failed to provide a reasonable methodology to project the number of cardiac catheterizations to be performed at WASC because WASC did not provide a methodology that reasonably determines how many diagnostic or interventional cardiac catheterizations could be performed on an outpatient basis.

WASC provides payor mix for the entire ASF and for the cardiac catheterization procedures in the following tables:

WASC Application, p. 109:

**Projected Payor Mix during the 3rd Full FY
01/01/2026 to 12/31/2026**

| <Wilmington ASC> | |
|---|-------------------------------------|
| Payor Source | Percentage of Total Patients Served |
| Self-Pay | 4.7% |
| Charity Care [^] | |
| Medicare * | 46.6% |
| Medicaid * | 4.7% |
| Insurance * | 39.2% |
| Workers Compensation ^{^^} | |
| TRICARE ^{^^} | |
| Other (Military and Other Government) ^{^^} | 4.7% |
| Total | 100.0% |

* Including any managed care plans.

[^] WASC's internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

^{^^} TRICARE and Workers Compensation included in the Other payor category.

WASC Application, p. 110:

| <Cardiac Cath> | |
|---|--|
| Payor Source | Percentage of Total Patients Served |
| Self-Pay | 4.5% |
| Charity Care [^] | |
| Medicare * | 65.0% |
| Medicaid * | 2.4% |
| Insurance * | 25.0% |
| Workers Compensation ^{^^} | |
| TRICARE ^{^^} | |
| Other (Other Government) ^{^^} | 3.1% |
| Total | 100.0% |

* Including any managed care plans.

[^] WASC's internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

^{^^} TRICARE and Workers Compensation included in the Other payor category.

However, WASC fails to explain how it will achieve these payor mixes when Wilmington Health's actual, practice-wide payor mix is included in Exhibit F.2-3, page 13:

A summary of net patient service revenue for the years ended December 31, 2020 and 2019 is as follows:

| | 2020 | | 2019 | |
|------------------------------------|----------------------|-------------|----------------------|-------------|
| Blue Cross and Blue Shield | \$ 6,680,861 | 34% | \$ 7,326,228 | 41% |
| Other third-party payors | 5,814,503 | 29% | 5,597,267 | 32% |
| Self-pay | 4,698,429 | 24% | 1,286,813 | 7% |
| Medicare | 2,384,583 | 12% | 3,330,613 | 19% |
| Medicaid | 15,287 | 1% | 201,878 | 1% |
| Net patient service revenue | \$ 19,593,663 | 100% | \$ 17,742,799 | 100% |

In all of Wilmington Health's services, it only provided 1% Medicaid and 19% Medicare in 2019 with the percentage of Medicare decreasing in 2020 to 12%. Yet WASC projects 2.4 percent cardiac catheterization utilization and 65.0 percent Medicare for cardiac catheterization utilization. WASC does not explain these inconsistent numbers. Wilmington Health could have reviewed the payor mix for the physician services related to cardiac cath procedures it has historically performed in the NHRMC cardiac cath labs, but there is no indication that it did so. WASC fails to provide a reasonable basis for its projected payor mix.

Finally, the minimal staffing WASC proposes for its cath lab (discussed above) and in Criterion (7) below naturally limits its ability to handle the patient volumes it forecasts. The physician component, discussed elsewhere, is highly questionable because the volumes depend mainly on one physician, Dr. Bishop. In addition, there are issues with the non-physician staffing. There

will be only one RN and one LPN to care for patients before, during and after their procedures¹³. This is not sufficient, and as explained elsewhere in these comments, the LPN's scope of practice is limited. The LPN cannot, for example, administer conscious sedation. See Exhibit 3.

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (3) and must be disapproved.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

An applicant whose utilization projections are not reasonable and supported does not propose the least costly or most effective alternative. As discussed above, the WASC application's utilization projections are riddled with unsupported assumptions. In addition, the proposed WASC lab will only be used by a specific subset of patients who need cardiac cath, *i.e.*, those Wilmington Health patients who are low risk and non-emergent. By definition, this is not the least costly or most effective alternative. This is evidenced by the fact WASC only proposes to operate the cardiac catheterization unit at 62.6% (939 / 1,500) utilization. While the Agency does not compare applications to determine whether any application is conforming with Criterion (4), it is worth noting that NHRMC proposes to operate its six cardiac catheterization units at 87.2% (7,847 / (1,500 x 6)) utilization. Any WASC patient who suffers from a complication (*e.g.*, bleeding) must be transferred to the hospital for care, thereby increasing cost and inefficiency.

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (4) and must be disapproved.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

As discussed in Criterion (3), WASC fails to demonstrate that its projected cardiac catheterization volumes are reasonable, credible, or supported. Thus, the application must also be found non-conforming with Criterion (5) because the project will not be financially feasible.

As also discussed in Criterion (3), WASC provides two different projected cardiac catheterization volumes, calling into question the financial feasibility of the project.

¹³ Form H also reflects one radiologist technician and one cardiovascular invasive specialist. These professionals will be needed during the actual performance of the procedure.

In response to Section F.3.a., WASC indicated that it will not incur any start-up expenses. WASC states:

The proposed project involves the development of a unit of fixed cardiac cath equipment at Wilmington ASC, a previously approved ASF that is currently under development. Wilmington ASC will be operational prior to the start of the project proposed in this application. Therefore, the proposed project will not result in any start-up expenses.

However, nowhere in the previously approved ASF CON application (Project I.D. No. O-11441-17) does WASC indicate that it will be hiring a registered radiologist technician, a registered cardiovascular invasive specialist, a registered nurse, and an LPN to work in a future cardiac catheterization lab. None of these employees will be on staff when the ASF becomes operational, making the staff hiring and training a start-up expense. WASC will also not have cardiac catheterization supplies on-hand when the ASF becomes operational, making supplies a start-up expense. Furthermore, unless WASC intends to have the cardiac catheterization unit installed *after* the date of operation, the cardiac catheterization unit will have to be installed prior to operation, making a lease payment or at least a partial lease payment prior to operation, thus incurring a start-up expense.

Additionally, WASC failed to include the cost of the cardiac catheterization unit in its total capital cost. See Form F.1b Assumptions, note f. WASC asserts that if a piece of medical equipment is leased, then it does not need be included as a capital cost. This is incorrect. The lease is only how WASC funds the acquisition of the cardiac catheterization unit. The use of a lease to fund the cardiac catheterization unit would be identified in Section F.2.d. Other Forms of Financing.

For purposes of the CON Law, a lease of cardiac cath equipment is an acquisition, and is treated no differently than a purchase. See N.C. Gen. Stat. § 131E-176(16)f1.3. If WASC's assumption that the cost of the cardiac catheterization unit is not required to be identified as a project capital cost, then the Agency will have to agree that there is no dollar threshold for major medical equipment requiring CON approval if the major medical equipment is leased. It is the cost of the major medical equipment, not the means of financing, that generates the need for CON approval. By not identifying the cost of the cardiac catheterization unit, WASC underreported the project capital costs and failed to submit the accurate CON filing fee.

Wilmington Health's ability to fund this project as well as its currently pending linear accelerator project (approximately \$4.9 million), is also questionable. Wilmington Health, the sole member of WASC, states that it will fund the project through accumulated reserves, specifically the Line Item "Cash and cash equivalents." There are several problems with this. First, "Cash and cash equivalents" is not the same as "accumulated reserves." Accumulated reserves are usually included in the Balance Sheet with Current Assets labeled "Assets limited as to use" because they are not meant to be used to fund ongoing operations or pay expenses. No such line item appears on the Wilmington Health balance sheet, though Wilmington Health's auditors clearly understand this principle because they separated Wilmington Health's investment in SCA-Wilmington, recognizing that investment is not meant to be used to fund ongoing operations.

Second, in 2019, Wilmington Health had only \$49,125 in “Cash and cash equivalents” but that amount increased to over \$21.0 million in 2020. Superficially, it appears that Wilmington Health has the necessary funds for the project, but the additional \$21.0 million appears to be merely a timing issue at the end of the year because Wilmington Health also experienced a \$17.3 million increase in current liabilities as compared to 2019. $(34,365,495 - 17,007,991 = 17,359,504)$. Payment of those liabilities would deplete most of the cash and cash equivalents $(21,030,821 - 17,359,504 = 3,671,317)$. This makes it impossible for WASC to fund the cath lab project (\$3.8 million, which amount is understated as discussed previously), not to mention the linear accelerator project (\$4.9 million) out of “accumulated reserves.” While the ASC project (which is where the cath lab is proposed to be located) is being funded by a loan, see page 56 of the findings for Project I.D. No. O-11441-17, depletion or elimination of Wilmington Health’s cash could jeopardize Wilmington Health’s loan covenants, as most lenders would require a borrower to maintain a certain cash position. WASC relies entirely on its so-called “accumulated reserves” as the means by which it will fund the cardiac cath and linear accelerator projects, so it would not be appropriate for the Agency to assume that Wilmington Health might be able to obtain other financing for the cardiac cath lab project or the linear accelerator project.

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (5) and must be disapproved.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

WASC fails to adequately demonstrate the need for its proposed project. See Criterion (3) for discussion. Consequently, the applicant did not adequately demonstrate that its proposal will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Please refer to the discussion under Criteria (1), (3) and (4).

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (6) and must be disapproved.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

WASC refers several times to the Wilmington Health cardiologists on staff at NHRMC, stressing the experience of Wilmington Health cardiologists in performing cardiac catheterizations. As previously discussed, Wilmington Health has only one interventional cardiologist, Dr. Andrew Bishop. One hundred percent of Wilmington Health’s interventional cardiac cath procedures are performed by Dr. Bishop. Compared to his colleagues, Dr. Bishop also treats the vast majority (between 40% and 47%) of Wilmington Health’s diagnostic cardiac cath patients. If one of the other Wilmington Health cardiologists determines during a diagnostic cardiac cath procedure that the patient also requires an intervention, he or she will call Dr. Bishop to perform the intervention. If Dr. Bishop goes on vacation or is out sick, or his patient acuity changes even slightly because the patients need to have their procedures performed in a hospital, WASC’s volume projections will decline precipitously.

The following table identifies the Wilmington Health cardiologists and their board certifications:

| Cardiologist | Board Certifications | |
|--------------------------------|---|---|
| Andrew Bishop, MD, FACC | Internal Medicine Cardiovascular Disease | Interventional Cardiology |
| Matt Janik, MD, FACC | Internal Medicine Cardiovascular Disease Nuclear Cardiology | Cardiovascular MRI Cardiovascular CT |
| Craig McCotter, MD, FACC, FHRS | Internal Medicine Cardiovascular Disease | Cardiac Electrophysiology |
| Gregory Roberts, MD, FACC | Internal Medicine Cardiovascular Disease | Nuclear Cardiology |
| Michael Romig, DO, FACC | Cardiology Echocardiography | Internal Medicine Nuclear Cardiology |
| Carin Smith, MD, FACC | Internal Medicine Cardiovascular Disease Echocardiography | Cardiovascular CT Nuclear Cardiology |

Source: Wilmington Health website, www.wilmingtonhealth.com, <https://www.wilmingtonhealth.com/find-a-doctor/cardiology> (visited 9/23/21).

In the Form C Assumptions and Methodology, WASC refers to “11 cardiology providers, five of whom are physicians.” While literally true, this statement does not tell the Agency that only one of these physicians can perform interventional cardiac cath procedures or that same physician performs most of the diagnostic cardiac cath procedures, as compared to his partners.¹⁴ Regarding Dr. Bishop, while a letter of support from Dr. Bishop was not required, given the volumes in the application are

¹⁴ The sixth cardiologist listed on Wilmington Health’s website, Dr. McCotter, does not perform any type of cardiac cath procedures; he is an electrophysiologist.

premised mainly on Dr. Bishop, it is curious that the application lacks a letter of support from Dr. Bishop. The Agency should not be misled into assuming that each of Wilmington Health's cardiologists is able to perform both diagnostic and interventional cardiac cath, and that procedures are dispersed relatively evenly across the group. They are not. Historical volumes are disproportionately weighted toward Dr. Bishop, and with no recruitment plan discussed or provided in the application, it is unreasonable to assume that situation will change. See discussion above regarding Criterion (3).

It should be noted that when WASC's only interventional cardiologist is performing procedures at WASC, he is unavailable to cover required STEMI/emergency call at the hospital or provide WHA emergency call 8AM-5PM every day. The NHRMC medical staff bylaws require members to take unassigned call. As part of unassigned call, the expectation is providers should be able to care for patients in a timely manner. For STEMI, timely manner means treatment within treatment with 60 minutes.

Furthermore, to keep operational costs down, WASC proposes to hire only a single LPN to cover a seven-bay prep/recovery area. NHRMC always has two registered nurses working prep/recovery. A single LPN is simply not enough coverage to safely care for up to seven cardiac cath patients. Additionally, caring for patients who are preparing for or recovering from cardiac cath, which requires sedation, is not within an LPN's scope of practice. In North Carolina, an LPN may not administer conscious sedation or monitor patients recovering from conscious sedation. See Exhibit 4. This means the lone RN must care for these patients, leaving no room for even a momentary break, as the patients cannot be left unattended for any period of time. Thus, the staffing WASC proposes is highly questionable.

The working assumption of the WASC application seems to be that all of its cardiac cath patients will recover quickly and be discharged within the facility's normal operating hours. Such an assumption is faulty, as different patients will recover at different rates. With only one RN and one LPN, it is unclear how WASC will care for any patient who require a longer period of recovery. Will the one RN and one LPN remain late into the night? Who will relieve them? These questions are not addressed in the WASC application.

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (7) and must be disapproved.

(13)c. The applicant shall demonstrate . . . [t]hat the elderly and medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services

The WASC application does not meet the requirements of Criterion (13)c. The payor mix tables in the application do not provide any amounts for charity care. See application, p. 109. As discussed above, the Financial Assistance Policy contains no specific information about how the policy will be applied or any discounts that may be offered to patients who qualify for financial

assistance. Noticeably absent from the application is any discussion about any historical amounts of charity care the Wilmington Health physicians may have provided for the physician component of the cardiac cath services they have performed. Wilmington Health has this information; it simply chose not to provide it, so there is no way the Agency can verify WASC's representations. In addition, as previously discussed, the projected Medicare utilization of the cardiac cath service is entirely inconsistent with the Wilmington Health experience.

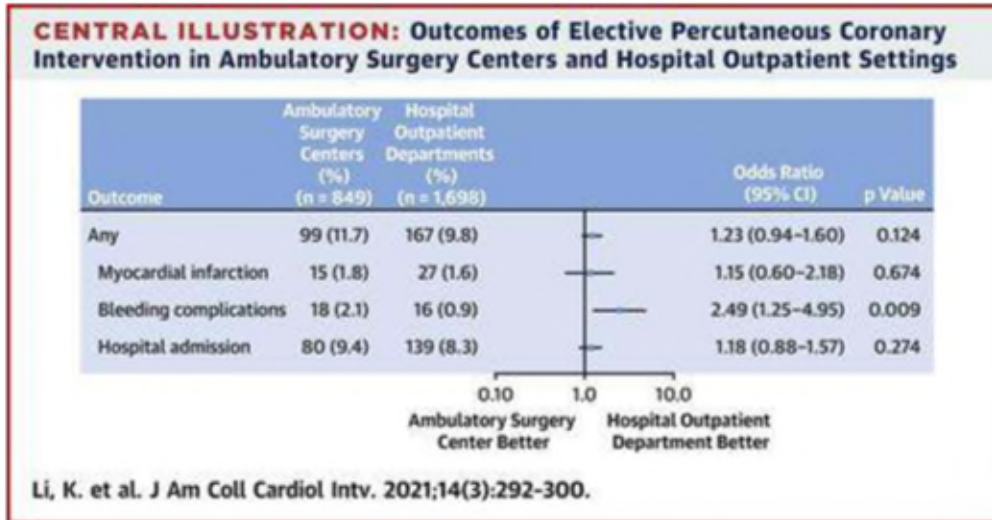
All information provided in a CON application needs to be reasonable and adequately supported. The Agency cannot just take the applicant's word for it, especially where something as critical as access for medically underserved populations is concerned. For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (13)c. and must be disapproved.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

WASC failed to adequately demonstrate that its proposal will have a positive impact upon the cost effectiveness, access, and quality of the proposed services. *See also* Criteria (1), (3), (4), (5), (6), and (7) for discussion. While it would be easy to assume that as a new provider of cardiac cath services, WASC would provide beneficial competition and choice, the analysis is far more nuanced than simply being a new entrant. Regardless of whether an applicant is a new entrant or an established provider, the applicant must demonstrate the need for its project, and WASC has not done so. WASC is proposing a *limited* service for a *limited* subset of patients, *i.e.*, scheduled, lower-risk patients who are already patients of Wilmington Health physicians. This does not enhance cost effectiveness, quality, or access for most patients.

Quality is also a relevant consideration under Criterion (18a). With no experience running an ASC or a cath lab, WASC's quality as a startup is simply unknown.

Additionally, a recent study in the Journal of American College of Cardiology, [J Am Coll Cardiol Intv. 2021 Feb, 14 \(3\) 292–300](#), reports the following results about the outcomes of PCI in ASC as compared to hospital outpatient departments ("HOPD"):



Abstract

Objectives

The aim of this study was to explore characteristics and outcomes of patients undergoing elective percutaneous coronary intervention (PCI) in ambulatory surgery centers (ASCs).

Background

Little is known about patients who underwent ASC PCI before Medicare reimbursement was instituted in 2020.

Methods

Using commercial insurance claims from MarketScan, adults who underwent hospital outpatient department (HOPD) or ASC PCI for stable ischemic heart disease from 2007 to 2016 were studied. Propensity score analysis was used to measure the association between treatment setting and the primary composite outcome of 30-day myocardial infarction, bleeding complications, and hospital admission.

Results

The unmatched sample consisted of 95,492 HOPD and 849 ASC PCIs. Patients who underwent ASC PCI were more likely to be younger than 65 years, to live in the southern United States, and to have managed or consumer-driven health insurance. ASC PCI was also associated with decreased fractional flow reserve utilization (odds ratio [OR]: 0.31; 95% confidence interval [CI]: 0.20 to 0.48; $p < 0.001$). In unmatched, multivariate analysis, ASC PCI was associated with increased odds of the primary outcome (OR: 1.25; 95% CI: 1.01 to 1.56; $p = 0.039$) and bleeding complications (OR: 1.80; 95% CI: 1.11 to 2.90; $p = 0.016$). In propensity-matched analysis, ASC PCI was not associated with the primary outcome (OR: 1.23; 95% CI: 0.94 to 1.60; $p = 0.124$) but was significantly associated with increased bleeding complications (OR: 2.49; 95% CI: 1.25 to 4.95; $p = 0.009$).

Conclusions

Commercially insured patients undergoing ASC PCI were less likely to undergo fractional flow reserve testing and had higher odds of bleeding complications than HOPD-treated patients. Further study is warranted as Medicare ASC PCI volume increases.

A copy of the study is attached as Exhibit 5.

The Medicare reimbursement of cardiac catheterizations performed at ambulatory surgical facilities is relatively new, less than two years old, with nearly all that time affected by the global pandemic. As the previously mentioned study indicates, cardiac catheterization patients treated in an ambulatory surgery center setting were more likely to be under 65 and have consumer-driven health insurance, which mirrors Wilmington Health's payor mix in its Consolidated Financial Statements found in Exhibit F.2-3. Additionally, cardiac catheterization patients treated in an ambulatory surgery center setting were more likely associated with increased bleeding complications with 9.4 percent requiring hospitalization. If a patient experiences a bleeding complication at WASC's facility, the patient will be transferred to the hospital, at an additional cost.

While WASC's proximity to NHRMC is important, WASC avoids discussing the cost, time, and inconvenience of transferring a patient from WASC to the hospital, in addition to the disruptions in continuity of care. The research shows that a not insignificant number of patients will develop complications, not all of which will warrant open heart surgery. The application is entirely unclear about how these situations will be handled, or what the resulting cost to the patient will be.

For the reasons stated in these comments as well as any other reasons the Agency may discern, the WASC application is non-conforming with Criterion (18a) and must be disapproved.

Performance Standards 10A N.C.A.C. .1603

The WASC application does not meet the applicable performance standards for the following reasons:

(a)(1): As discussed above, the utilization projections are not based on reasonable and adequately supported assumptions. The applicant also failed to disclose that it only has one interventional cardiologist who does all of Wilmington Health's interventions and, compared to his partners, the vast majority of its diagnostic cardiac cath. See discussion above in the Overview and Criterion (3).

(a)(2): As discussed above, the utilization projections are not based on reasonable and adequately supported assumptions. The applicant also failed to disclose that it only has one interventional cardiologist who does all of Wilmington Health's interventions and, compared to his partners, the vast majority of its diagnostic cardiac cath. See discussion above in the Overview and Criterion (3).

(a)(3): As discussed above, the utilization projections are not based on reasonable and adequately supported assumptions. The applicant also failed to disclose that it only has one

interventional cardiologist who does all of Wilmington Health's interventions and, compared to his partners, the vast majority of its diagnostic cardiac cath. See discussion above in the Overview and Criterion (3).

COMPARATIVE ANALYSIS¹⁵

Pursuant to G.S. 131E-183(a)(1) and the 2021 SMFP, no more than one cardiac catheterization unit may be approved for New Hanover County in this review. Because each application proposes to acquire a cardiac catheterization unit in New Hanover County, both applications cannot be approved. For the reasons set forth below, the application submitted by NHRMC should be approved and the other application should be disapproved.

Conformity with Applicable Statutory and Regulatory Review Criteria

Only an application that is conforming to all statutory and regulatory review criteria can be found comparatively superior. As discussed in these comments, the WASC application is non-conforming with multiple CON review criteria and the performance standards. The NHRMC application is conforming with all applicable review criteria and the performance standards. Therefore, the NHRMC application is the more effective alternative with respect to this comparative factor.

Geographic Accessibility

Both applicants propose to operate the cardiac catheterization unit in New Hanover County. Therefore, both applications are equally effective with respect to this comparative factor.

Patient Access to a Variety of Cardiac Cath Procedures

WASC will perform only the diagnostic and elective interventional cardiac cath procedures that are included in CMS's list of Medicare-covered ASF procedures for patients that are appropriate for a freestanding setting. NHRMC will perform diagnostic and interventional cardiac cath procedures on all patients who require such procedures, regardless of whether Medicare reimburses for the procedure. Wilmington Health has only one interventional cardiologist, whereas NHRMC has seven. Therefore, NHRMC is the more effective alternative with respect to this comparative factor.

¹⁵ It has been many years since there has been a competitive cardiac cath review anywhere in North Carolina. Aside from the current review, NHRMC is not aware of any other competitive cardiac cath reviews in North Carolina between 2010 and 2021. The factors discussed in these comments are often found in a variety of recent competitive CON reviews and are relevant to this review.

Projected Access by Medicare Recipients

The following table compares a) the number of Medicare patients in Project Year 3; and b) Medicare patients as a percentage of total patients. Generally, the application projecting the highest number or percentage is the most effective alternative regarding these comparative factors. The applications are listed in the table below in decreasing order of effectiveness.

| Rank | Applicant | Project Year 3 | |
|------|-----------|-------------------|------------------------|
| | | Medicare Patients | % of Medicare Patients |
| 1 | NHRMC | 3,727 | 64.9% |
| 2 | WASC | 532 | 65.0% |

As shown in the table, in Project Year 3, NHRMC projects to serve the highest number of Medicare patients and essentially the same percentage of Medicare patients. Because it proposes to serve a much higher number of Medicare patients, the NHRMC application is the more effective alternative with respect to this comparative factor.

Projected Access by Medicaid Recipients

The following table compares a) the number of Medicaid patients in Project Year 3; and b) Medicaid patients as a percentage of total patients. Generally, the application projecting the highest number or percentage is the most effective alternative regarding these comparative factors. The applications are listed in the table below in decreasing order of effectiveness.

| Rank | Applicant | Project Year 3 | |
|------|-----------|-------------------|------------------------|
| | | Medicaid Patients | % of Medicaid Patients |
| 1 | NHRMC | 258 | 4.5% |
| 2 | WASC | 20 | 2.4% |

As shown in the table, in Project Year 3, NHRMC projects to serve the highest number of Medicaid patients and the highest percentage of Medicaid patients. NHRMC is the more effective alternative with respect to this comparative factor.

Access to Support Services

The following table looks at the support services at each facility should a complication arise during the cardiac catheterization.

| Rank | Applicant | Open Heart Surgery | Acute Cardiology Care |
|------|-----------|--------------------|-----------------------|
| 1 | NHRMC | Yes | Yes |
| 2 | WASC | No | No |

As shown in the table, only NHRMC has the necessary services available if a complication occurs during the cardiac catheterization. As previously discussed, in a recent study 9.4 percent of ASF cardiac catheterization patients required hospitalization after the procedure. NHRMC is the more effective alternative with respect to this comparative factor.

Revenues, Operating Costs, and Net Income

These three factors cannot be adequately evaluated as WASC only proposes to perform outpatient cardiac catheterizations and NHRMC performs both inpatient and outpatient procedures. Inpatient cardiac catheterization procedures are billed globally and includes all revenue and operating costs from the inpatient stay. Therefore, the Agency should decline to use these comparative factors.

Competition

Although WASC would be a new cardiac cath provider in the service area, its effectiveness as a competitor is limited. WASC proposes to treat only a subset of patients, *i.e.*, scheduled, non-emergent Wilmington Health patients whose procedures are reimbursed by Medicare. NHRMC will treat *all* patients regardless of payor source who require cardiac cath. NHRMC is equipped to handle all emergencies and complications that might arise. As NHRMC's application demonstrates, it has the bench strength of physicians, and a proven track record of providing quality care to its cardiac cath patients, which distinguishes NHRMC from a startup such as WASC. WASC is the less effective alternative with respect to this comparative factor.

Utilization

NHRMC projects to utilize the cardiac catheterization lab at 87.2 percent while WASC only proposes to utilize the proposed cardiac catheterization lab at 62.6 percent. As discussed previously in these comments, even the slightest reduction in the number of interventions performed at WASC causes WASC to fall below the 60% utilization standard. NHRMC is the more effective alternative with respect to this comparative factor.

SUMMARY

The following is a summary of the reasons the proposal submitted by NHRMC should be determined to be the most effective alternative in this review:

- NHRMC is conforming with all applicable statutory and regulatory review criteria.
- NHRMC projects the highest number of Medicare patients and nearly the same percentage of Medicare patients in Project Year 3.
- NHRMC projects the highest number of Medicaid patients and the highest percentage of Medicaid patients in Project Year 3.
- NHRMC is the only applicant to offer a variety of cardiac cath procedures.
- NHRMC is the only applicant with immediate access to acute care services should a complication arise during the cardiac catheterization.
- NHRMC projects higher utilization at 87.2 percent.

CONCLUSION

The WASC application is non-conforming with multiple CON criteria and the performance standards and must be disapproved. The NHRMC application is conforming with all applicable CON criteria and the performance standards. A comparative analysis shows that the NHRMC application is comparatively superior in this review. The NHRMC application should be approved, and the WASC application should be denied.



LPN SCOPE OF PRACTICE - CLARIFICATION

POSITION STATEMENT
for LPN Practice

A Position Statement does not carry the force and effect of law and rules but is adopted by the Board as a means of providing direction to licensees who seek to engage in safe nursing practice. Board Position Statements address issues of concern to the Board relevant to protection of the public and are reviewed regularly for relevance and accuracy to current practice, the Nursing Practice Act, and Board Administrative Code Rules.

INTRODUCTION

The [Nursing Practice Act, G.S. 90-171.20\(8\)](#) and North Carolina Administrative Code, [21 NCAC 36.0225](#) (LPN rules) govern Licensed Practical Nurse (LPN) practice in North Carolina. Reading this Position Statement and the LPN rules together serves to clarify the LPN Scope of Practice/Components of Practice for LPNs, RNs, employers, consumers, and others. Comparison with [21 NCAC 36.0224](#) (RN Rules) provides distinction from RN scope of practice.

LPN Scope of Practice in all steps of the nursing process is limited and focused because, by law, it is a dependent and directed scope of practice. LPN practice requires assignment or delegation by and performance under the supervision, orders, or directions of a registered nurse (RN), physician, dentist, or other person authorized by State law to provide the supervision. LPNs implement health care plans developed by the RN and/or by any person authorized by State law to prescribe such a plan.

Note: The practice of nursing is constantly evolving as new and changing technology and therapies are introduced. The North Carolina Board of Nursing defines and interprets scopes of practice for all levels of providers of nursing care. Each agency/employer is responsible for developing policies/procedures/standards of practice and ensuring competency of the nursing staff. An agency/employer, including a registered nurse or physician employer, may restrict the nurse's practice but never expand the practice beyond the legal scope as defined. LPN practice is not defined by specific activities or tasks, but rather as a process consisting of a set of legally defined Components of Practice using the steps of the nursing process as outlined in the LPN rules, 21 NCAC 36.0225.

For specific questions, the [NCBON Scope of Practice Decision Tree for the RN and LPN](#) is available at www.ncbon.com – select Nursing Practice on the top banner – select Position Statements and Decision Trees – select Scope of Practice Decision Tree. NCBON Practice Consultants can also be reached for clarification at 919-782-3211.

Critical Thinking: Critical thinking is used throughout all components of the nursing process. Critical thinking is purposeful and reflective judgment in response to events, observations, experiences, and verbal or written expressions. It involves determining the meaning and significance of what is observed or expressed to determine need for action. Nurses (RNs and LPNs) use critical thinking in clinical problem-solving and decision-making processes relative to scope of practice, knowledge, competency, and experience.

Co-signature of LPN Documentation:

North Carolina nursing law and rules do not require LPN documentation to be co-signed by the RN. All nurses are responsible and accountable for their own actions and documentation. Agencies may, however, establish policies requiring RN co-signature of LPN documentation. Agency policy should define what the RN co-signature means. (For example, the co-signature might indicate “review”, “agreement”, or that every element has been checked by the RN depending upon the policy requirements.)

ACCEPTING AN ASSIGNMENT

The first decision required by the LPN is whether or not to accept the assignment given by the registered nurse, physician or other person authorized to make the assignment. The LPN shall accept only those assigned nursing activities and responsibilities, as defined in Paragraphs (b) through (j) of the LPN rules. Paragraph (a) of the LPN rules lists the variables in each practice setting which the LPN must consider in making this decision. Please see Position Statement, [Accepting an Assignment](#), for additional guidance on this important topic at www.ncbon.com – select Nursing Practice on the top banner – select Position Statements – select Accepting an Assignment.

COMPONENTS OF LPN PRACTICE

ASSESSMENT, the first step of the nursing process and an essential component of nursing practice, is an ongoing process. Beginning with the initial encounter and continuing throughout the episode(s) of care, assessment is the basis for nursing judgments, decisions, and interventions. Nursing assessment is the gathering of information about a patient's physiological/biological, psychological, sociological, and spiritual status.

Both registered nurses and licensed practical nurses assess clients. Some elements of assessment are identical for both the RN and LPN. These include:

- The collection of data for a nursing history, psychological, spiritual, and social history, and physical examination (including vital signs, head to toe and/or targeted physical assessment, and other physiological/biological data);
- Comparison of the data collected to normal values and findings;
- Ongoing determination of client status for changes in condition, positive and negative.

For the LPN, nursing assessment is a focused appraisal of an individual's status and situation at hand, contributing to assessment, analysis, and development of a comprehensive plan of care by the RN. The LPN supports ongoing data collection and decides who to inform of the information and when to inform them. The LPN identifies the need for immediate assessment (beyond that specified in the plan of care) in response to current client status and condition. (National Council of State Boards of Nursing, Model Law and Rules, 2008)

The LPN participates in both initial and ongoing nursing assessments of the client's health status, including reaction to illness and treatment regimens while the RN retains overall responsibility for verifying data collected, interpreting data, and formulating nursing diagnoses.

“Participating in” means to have a part in or contribute to the elements of the nursing process.

Participation of the LPN in assessment is limited to:

- Collection of data according to structured written guidelines, policies and forms;
- Recognition of existing relationships between data gathered and the client's current health status;
- Determination of the need for immediate nursing interventions.

LPN Participation in “Initial”, “Admission”, or “Event-focused” Assessment:

These terms used by health care agencies to describe different types of assessments are not defined in nursing law and rules. The components of “initial”, “admission”, “event-focused” (e.g., post patient fall, pre-transfer, etc.), or other specifically-named assessment processes are defined by agency policy based on the laws and regulations, standards of care, accreditation standards, and reimbursement requirements applicable to specific practice settings. (For example, if federal Medicare regulations require that an RN perform the initial assessment, then the LPN cannot perform this assessment by proxy for the RN.) The LPN within scope of practice participates in any assessment process, if permitted by agency policy, using structured written guidelines, policies, and forms that outline the data to be obtained.

PLANNING is the second step of the nursing process. For the LPN, planning includes participation in the identification of the client's needs related to the findings of the nursing assessment. Elements of planning are listed in the LPN rules in Paragraph (c) and include:

- Identification of nursing interventions and goals for review by the RN;
- Participation in decision-making regarding the implementation of nursing and medical interventions utilizing assessment data;
- Participation in multidisciplinary planning by providing resource data

Therefore, the LPN provides important input in the planning process while the RN has the responsibility for developing the nursing plan of care and modifying the plan as indicated by ongoing assessment and evaluation.

IMPLEMENTATION is the third step of the nursing process and consists of delivering nursing care according to an established health care plan and as assigned by the RN or other person(s) authorized by law. Elements of implementation for the LPN are listed in the LPN rules in Paragraph (d)(1) and include the following:

- Procuring resources needed to implement the care plan;
- Implementing nursing interventions and medical orders consistent with nursing rules and within an environment conducive to client safety;
- Prioritizing performance of nursing interventions within assignment;
- Recognizing responses to nursing interventions;
- Modifying immediate nursing interventions based on changes in a client's status;
- Delegating specific nursing tasks as outlined in the plan of care and consistent with nursing rules.

The degree of supervision by an RN or other authorized person required for the performance of any assigned or delegated nursing activity by the LPN when implementing nursing care is determined by the variables listed in Paragraph (d)(3) of the LPN rules.

The LPN also participates in implementing the health care plan by assigning nursing care activities to other licensed practical nurses and delegating nursing care activities to unlicensed assistive personnel (UAP) qualified and competent to perform such activities providing certain essential criteria are met. These criteria are listed in the LPN rules in Paragraph (d)(2) and include:

- Assuring that competencies of personnel to whom nursing activities may be assigned or delegated have been validated by an RN;
- Continuous availability of a registered nurse for supervision;
- Participation by the LPN in on-going observations of clients and evaluation of client's responses to nursing actions;
- Accountability is maintained by the LPN for responsibilities accepted, including care provided by self and by all other personnel to whom care is assigned or delegated;
- Supervision provided by the LPN is limited to assuring that tasks have been performed as assigned or delegated and according to established standards of practice.

The appropriate and effective LPN delegation of nursing activities to UAP is an essential element in assuring safe client care. The [NCBON Decision Tree for Delegation to UAP](#) and the Position Statement on [Delegation and Assignment of Nursing Activities](#) (both available at www.ncbon.com) provide guidance for LPN practice.

It is beyond LPN scope of practice to assign nursing responsibilities to RNs.

Please note: Managing the Delivery of Nursing Care and Administering Nursing Services are not components within LPN Scope of Practice. Supervision by LPNs is limited to the assuring that tasks have been performed as assigned or delegated and according to established standards of practice as stated in Paragraph (d)(2)(E) of the LPN rules.

Therefore, it is beyond LPN scope of practice to be responsible for the following activities: nursing unit management, nursing administration, performance appraisal, orientation and teaching of nursing staff, validation of competence, or nursing staff development.

Please see Position Statements describing the limited role of the LPN in supervision within environments providing care for clients with relatively stable status (such as Skilled Nursing/Long Term Care Facilities) and the LPN role in staff development at www.ncbon.com – select Practice in left side column – select Position Statements – select:

- [Nurse in Charge Assignment to LPN](#)
- [Staff Development](#)

EVALUATION is the fourth step of the nursing process and consists of LPN participation in determining the extent to which desired outcomes of nursing care are met and in planning for subsequent care. Elements of evaluation by the LPN are listed in Paragraph (e) of the LPN rules and include:

- Collecting evaluative data from relevant sources according to written guidelines, policies, and forms;
- Recognizing the effectiveness of nursing interventions;
- Proposing modifications to the plan of care for review by the registered nurse or other person(s) authorized by law to prescribe such a plan.

REPORTING and RECORDING are those communications, written and verbal, required in providing the nursing care for which the LPN has been assigned responsibility. Reporting is the verbal communication of information to other persons responsible for or involved in the care of the client. Recording is the written or electronic documentation of information on the appropriate client record, nursing care plan or other documents. This documentation must reflect the verbal communication of information to other persons, and accurately describe the nursing care provided by the LPN. Both reporting and recording must be completed within a time period consistent with the client's need for care and according to agency policies and procedures. See LPN rules, Paragraph (f), for more information on the required elements of reporting and recording.

COLLABORATING involves communicating and working cooperatively in implementing the health care plan with individuals whose services may have a direct or indirect effect on the client's health care. As assigned by the RN or other person(s) authorized by law, the LPN participates in collaborating in client care. Elements of collaboration by the LPN are listed in the LPN rules in Paragraph (g) and include:

- Implementing nursing or multidisciplinary approaches for the client's care;
- Seeking and utilizing appropriate resources in the referral process;
- Safeguarding confidentiality.

TEACHING and COUNSELING of clients and their families may be implemented by the LPN utilizing an established teaching plan/protocol as assigned by the registered nurse, physician or other qualified professional licensed to practice in North Carolina. The LPN participates in teaching and counseling as listed in the LPN rules in Paragraph (h) by:

- Providing accurate and consistent information, demonstrations, and guidance to clients, their families or significant others regarding the client's health status and health care in order to
 - increase knowledge
 - assist the client to reach an optimum level of health functioning and participation in self care
 - promote the client's ability to make informed decisions;
- Collecting evaluative data and reporting this to the RN or other authorized person.

Teaching nursing activities to health care personnel is beyond the scope of practice of the LPN.

ACCEPTING RESPONSIBILITY for self for individual nursing action, competence and behavior is a component of practice shared by LPNs and RNs. The elements within this component of practice are listed in the LPN rules in Paragraph (j).

Please reference the LPN rules and the [RN and LPN Scope of Practice Comparison Chart](#)

References:

Nursing Practice Act, G.S. 90-171.20(8)

21 NCAC 36.0221 – License Required

21 NCAC 36.0224 – Rules for the Registered Nurse

21 NCAC 36.0225 – Rules for the Licensed Practical Nurse

NCBON Decision Tree for Delegation to UAP

NCBON Position Statement - Delegation and Assignment of Nursing Activities

NCBON Scope of Practice Decision Tree for the RN and LPN

NCBON Position Statement – Nurse in Charge Assignment to LPN

NCBON Position Statement – Staff Development

NCBON Position Statement – RN and LPN Scope of Practice Comparison Chart

Origin: 1/2010

Reviewed: 2/2013, 9/2017

Revised 1/2014



Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

As outpatient surgery centers perform a growing share of procedures, medtech leaders are rethinking their commercial strategies.

By Tim van Biesen and Todd Johnson

Tim van Biesen leads Bain & Company's Global Healthcare practice, and Todd Johnson is a partner with Bain's Healthcare practice. Both are based in the firm's New York office.

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

At a Glance

- ▶ The volume of procedures at ambulatory surgery centers is forecast to grow by 6% to 7% a year through 2021.
 - ▶ Orthopedic, spine and cardio procedures will increase the fastest through the mid-2020s.
 - ▶ Medtech companies' traditional commercial model is too costly and complex for ambulatory surgery centers.
 - ▶ Surgeons at ambulatory surgery centers have a greater propensity than those in hospitals to switch to a competing device manufacturer if offered a discount.
-

Ambulatory surgery centers (ASCs) are transforming healthcare delivery as well as the market for medical devices and equipment. By focusing on routine, lower-risk procedures in a more convenient setting, ASCs can offer surgical procedures at rates 35% to 50% lower than hospitals. That's saving the US healthcare system an estimated \$40 billion a year and fueling ASC growth. In 2018, 5,700 ASCs operating in the US performed 23 million procedures and generated \$35 billion in revenue.

The steady growth of ASCs creates new challenges and opportunities for medtech companies. Most leadership teams have been focused on acute care hospitals as their primary customers given their historical dominance of most surgical procedures; as a result, they have not devoted much strategic energy and attention to ASCs as an important customer channel.

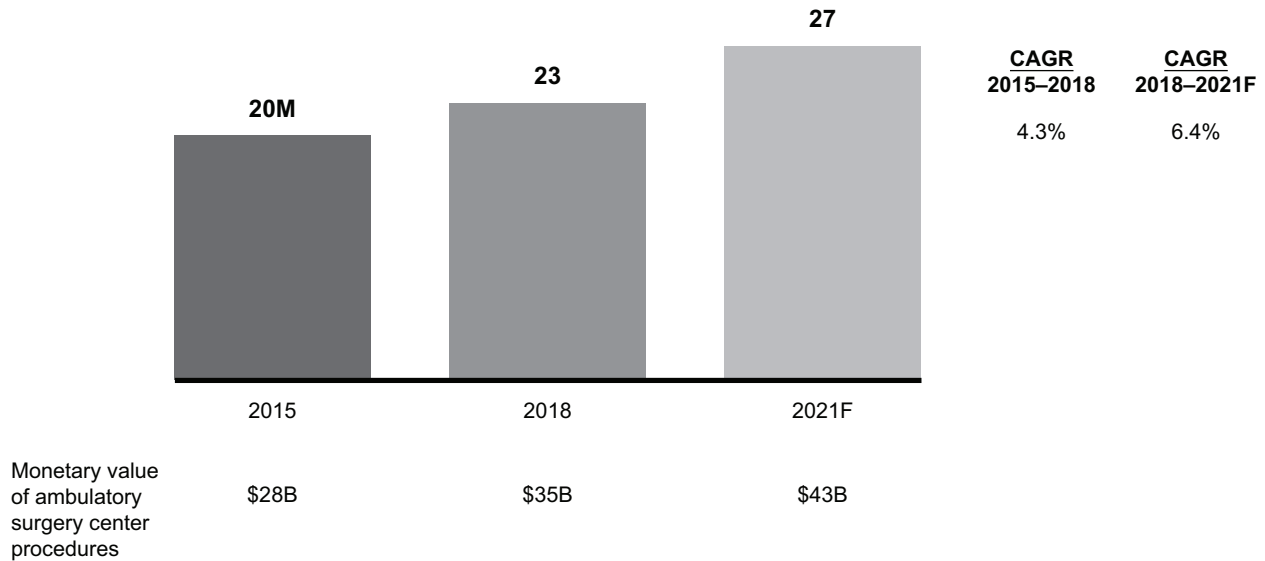
Now it's becoming urgent. ASCs performed more than half of all outpatient surgeries in 2017, up from 32% in 2005, and their influence is set to increase. Bain research shows procedures performed at ASCs will grow by an average 6% to 7% a year through 2021, up from 4% to 5% over the past three years (see *Figure 1*). Orthopedic, spine and cardio procedures will grow the fastest. That shift will increase price pressure on medical devices and products because ASCs have lower reimbursement rates and ASC-based physicians are more price sensitive than their hospital-based peers are. Selling to ASCs, which are smaller, lower volume and more geographically dispersed, drives up the costs of sales and distribution and adds complexity to medtech companies' business models.

A handful of medtech leadership teams are forging strategies to capture that new business. To compete effectively for a share of the outpatient surgery market, the leaders in this fast-growing sector are turning necessity into a virtue by developing lower-cost service models and simplifying their product offerings. They also are providing ASCs with a wider range of customized services and offering partnerships that address ASC needs. Such services include support for administration, scheduling, operating room utilization and staffing.

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

Figure 1: Ambulatory surgery centers are handling a growing volume of procedures

Total ambulatory surgery center procedures (2015–2021F)



Sources: VMG; Definitive Healthcare; Ambulatory Surgery Center Association; MedPac; MarketWatch; Advisory Board; Bain & Company Medtech Physician Survey, 2019 (n=360)

The growing volume of procedures handled by ASCs affects the broader healthcare industry as well. Hospitals and payers are rethinking their business models as highly profitable surgical procedures shift to outpatient centers. Many hospital networks are responding to this trend by acquiring ASCs to recapture a slice of the lost business—around 25% of ASCs now have hospitals as shareholders—while others are acquiring physician groups to control referral patterns. Payers continue to support the shift to lower-cost healthcare settings, and some are becoming ASC operators. In 2017, Optum acquired Surgical Care Affiliates, significantly expanding its own ambulatory surgery business.

Accelerated growth

Broad industry trends are fueling the growth of ASCs, the first of which was founded in 1970. A steady rise in healthcare spending has put fierce pressure on costs and margins throughout the industry, encouraging the shift to outpatient care. Payers are helping steer procedures to ASCs by lowering provider reimbursements for hospitals and reducing patient copayment for procedures performed at outpatient centers.

ASCs hold strong allure for physicians as well. A recent Bain survey showed that nearly 60% of physicians who are not affiliated with an ASC are interested in practicing at one. As advantages, they cite the potential to own equity in the center, the increased control over their own surgery schedules and the reduced bureaucracy when compared with traditional hospitals.

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

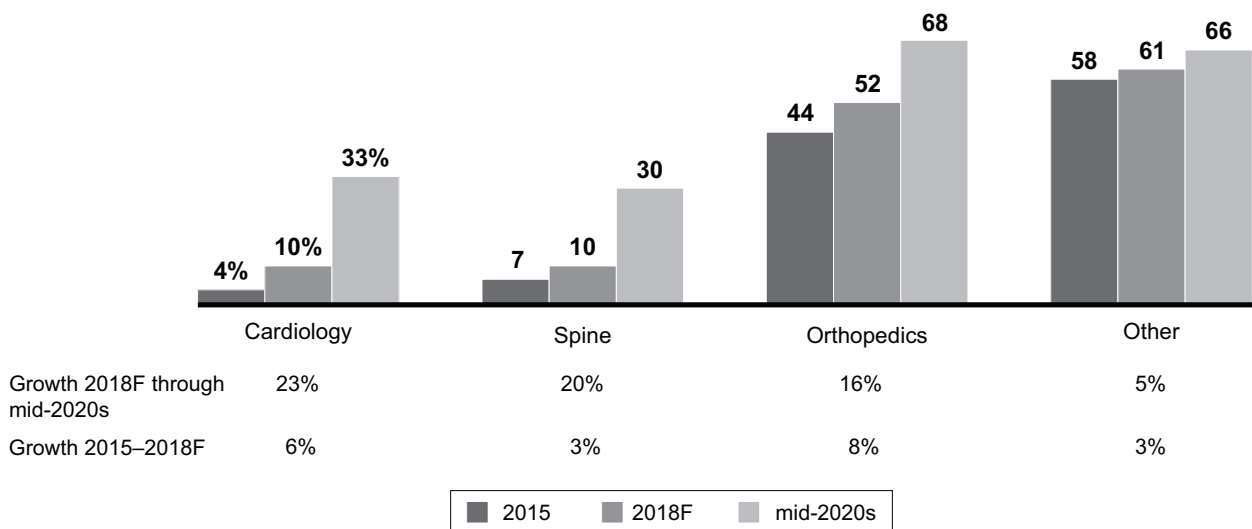
Over the next three years, growth in the volume of procedures performed in ASCs will accelerate, propelled by cost pressure, Medicare approval to reimburse a growing number of procedures for ASCs, the rise of results-based care models, and physician and patient preference for outpatient surgery centers.

Our analysis shows single-specialty centers focused on orthopedics, cardiology and spinal surgery will see the fastest growth in volume of procedures through the mid-2020s. These centers also are likely to have a higher average reimbursement per procedure. Let’s take a closer look at the ASC growth dynamic in each of these specialties (see Figure 2).

Orthopedics. Commercial payers recently began reimbursing total joint replacements in ASCs, where they typically cost 30% to 35% less than the same procedure in a hospital. That shift has led to an eightfold increase in the number of ASCs offering total joint replacements over the past four years, to a total of 250 in 2018. Medicare is now following suit: In 2018, it removed total knee arthroplasty from the Medicare inpatient-only list, and many expect other orthopedic procedures to follow. The decision to reimburse knee and joint procedures at ASCs will have a significant effect on ASC volumes: Total joint replacements are one of Medicare’s most common inpatient procedures, accounting for more than \$7 billion in annual spending. Bain research indicates the share of hip replacements performed in ASCs will grow from slightly more than 9% today to nearly 25% by the mid-2020s, while knee replacements performed in ASCs will rise from 10% today to nearly 30%.

Figure 2: Cardiology, spine and orthopedic procedures will fuel rapid growth of ambulatory surgery centers through the mid-2020s

Percentage of procedures performed in ambulatory surgery centers



Notes: Other includes ophthalmology, gastroenterology, pain management, dermatology, urology, podiatry, ENT (respiratory), OB/GYN, neurology, general surgery, plastic surgery, oral surgery; pain management reflects nonspinal pain management procedures only
 Sources: VMG; Definitive Healthcare; Ambulatory Surgery Center Association; MedPac; Bain & Company Medtech Physician Survey, 2019 (n=360)

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Spine. ASCs performed slightly more than 10% of all spinal surgeries in 2018, but based on our survey findings, we expect that figure to rise to around 30% by the mid-2020s. Physicians still perform the majority of outpatient spinal surgeries in hospital outpatient departments rather than ASCs. The number of ASCs specializing in spinal surgery rose in 2019, however, to 145, up from 35 in 2013, and physicians are increasingly willing to shift these procedures to ASCs. For instance, 86% of spine surgeons expect lumbar discectomies to move to ASCs at accelerating rates over the next three years, while 74% anticipate the same change for cervical-lumbar decompressions. Medicare approval for procedures performed in ASCs will contribute to the shift—the Centers for Medicare & Medicaid Services (CMS) approved two cervical spine procedures in 2018. In addition, spine procedures are among the most profitable for ASCs. That creates an incentive for spine surgeons to shift spinal surgeries to ASCs.

Cardiology. Cardio surgeries also are growing rapidly from a small base. ASCs handled an estimated 10% of all cardio procedures in 2018, but based on our survey findings, we expect ASCs will be performing between 30% and 35% by the mid-2020s, for an annual growth rate of approximately 20%. Diagnostic cardiology procedures began shifting to outpatient settings in 2005 with Medicare's approval of outpatient arterial endovascular interventions. That approval led to the rapid spread of office-based laboratories across the US, with the total recently surpassing 500. Today, cardiologists and regulators are becoming increasingly comfortable performing procedures such as angiograms and angioplasties in ASCs. Over the first half of 2019, CMS added 12 cardiac catheterization procedures to its ASC-covered list.

A different kind of customer

The business model at most medtech companies is designed for large hospitals and provider systems, which have high patient volumes, a broad range of procedural complexity and well-established buying behaviors. For ASCs, which are smaller, more nimble and have simpler needs, that commercial model is often too costly and overly complex.

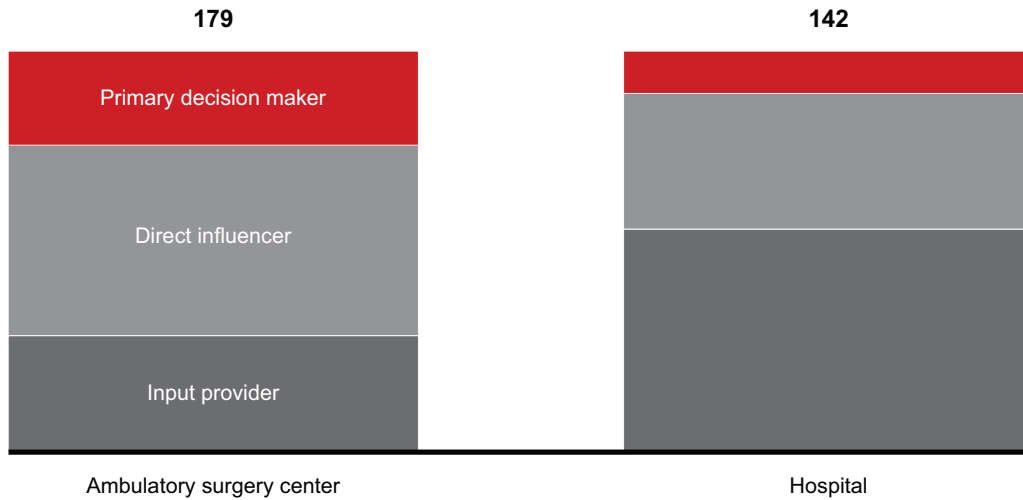
Importantly, surgeons at ASCs have greater direct influence over purchasing decisions for medical devices and equipment compared with surgeons working in hospitals, where procurement departments have a role. At ASCs, 70% of physicians are the primary decision maker or have direct influence on the decision to purchase medical devices or equipment compared with slightly less than 45% at hospitals, Bain research shows (see Figure 3).

Since payers reimburse ASCs less for the same procedure carried out in a hospital, ASCs are under constant pressure to reduce costs and improve efficiency. The risk to manufacturers is that ASCs will have a greater propensity than hospitals to switch to another manufacturer. Our research shows that ASC physicians are more price sensitive when purchasing medtech devices and expect lower prices than hospitals pay for the same equipment, especially in orthopedics. Sixty percent of ASC physicians said they would purchase a similar device from a different manufacturer if it were offered at a 15% discount (see Figure 4). Physicians in ASCs also are more likely to use innovative purchasing models

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

Figure 3: In ambulatory surgery centers, physicians are more likely to be the primary decision maker when purchasing medical equipment

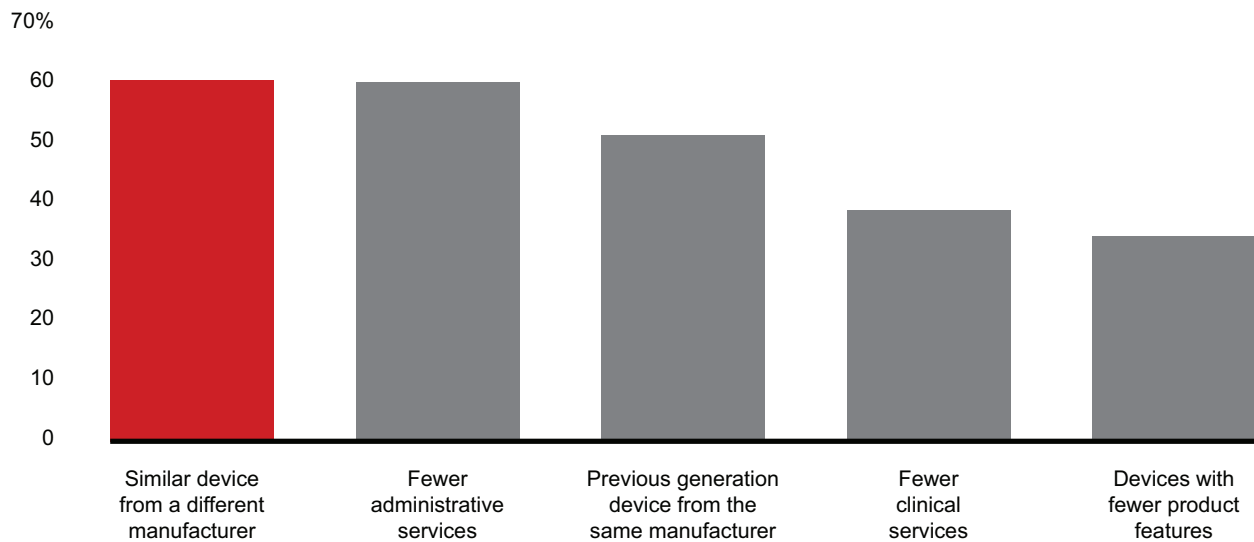
Percentage of total respondents



Note: Participants were asked what best describes the primary setting of care in which they perform the majority of their procedures/surgeries as well as their level of involvement in the purchasing process for medical devices/equipment at their organization or practice
 Sources: Bain & Company Medtech Physician Survey, 2019 (n=360); Bain Front Line of Healthcare Study, US 2017

Figure 4: Physicians at ambulatory surgery centers are likely to switch device makers if offered a discount

Relative likelihood to accept option in exchange for a 15% price discount



Note: Participants were asked which option they would be most likely to accept for a price discount of 15% on medical devices and which option they would be least likely to accept for a price discount of 15% on medical devices
 Source: Bain & Company Medtech Physician Survey, 2019 (n=360)

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and are willing to experiment with nontraditional services, such as 24-hour remote service instead of full-time onsite technicians, in exchange for a break on prices. Manufacturers will need to determine how to meet these price expectations without compromising their more comprehensive offerings in the acute care environment.

Bain research shows that ASCs differ from hospitals in the services they value most from medtech companies. ASCs rank technical support first, while hospitals say operating room coverage is most important. ASCs also rank information on payer reimbursement as a top service, while hospital physicians include information on product upgrades in their top three choices. It is important to note that ASCs are less willing to compromise on the products themselves; they may be willing to switch to a different device manufacturer to reduce costs, but they are less inclined to use previous generation products or those with fewer features. Similarly, they expect the same high quality of technical and clinical support that medtech companies provide to hospitals, but tailored to their needs.

ASCs have significantly different supply chain needs than hospitals, requiring medtech companies to be more flexible.

For medtech sales and distribution teams, serving ASCs efficiently is a challenge. Outpatient centers are more dispersed geographically than hospitals, and they perform a lower volume of procedures than hospitals. They have less space for stocking inventory and don't have sophisticated inventory management systems. As a result, ASCs have significantly different supply chain needs than hospitals, requiring medtech companies to be more flexible.

Winning in the ASC market

As outpatient surgery centers take an ever-larger slice of profitable business from hospitals, leading medtech companies are rethinking their sales and marketing models, particularly for ASCs specializing in orthopedic, spine and cardiology procedures. To succeed in this fast-growing market, medtech companies are taking four bold steps to target ASCs' needs.

Developing lower-cost service models. Medtech companies need to adjust their sales and service models to efficiently deliver the services that ASCs value most. One example: virtual

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

operating room representatives. They also are training in-person operating room reps to cover multiple products instead of one, increasing their versatility. In addition, winning medtech companies are adjusting their logistics and distribution models, leaning more heavily on third-party logistics suppliers, for instance, to efficiently deliver and service products in ASCs.

Simplifying products. Medtech devices that reduce customer-holding costs by minimizing required inventory or increasing single-use offerings can help address ASC needs. Medtech companies can also create streamlined procedure-in-a-box kits that are designed for lower-acuity ASC procedures, are less expensive and are easier to manage logistically.

Addressing a broader spectrum of ASC needs. New products and services may help address a wider spectrum of ASC needs to offset pricing pressure. For example, some medtech companies are offering IT services and inventory management as well as innovative partnerships to help ASCs focus on their core business and maintain a streamlined business model.

Considering new business models. As healthcare delivery models change, with payers moving into the provider space and hospitals seeking to expand their networks, medical device companies may see new and innovative opportunities to collaborate with ASCs. For example, some may become equity owners of ASCs, providing cash or capital equipment to help bring the latest technologies to these centers. Others may provide perioperative consulting or marketing services to help ASCs grow faster and improve efficiency. These new models are still experimental, but we expect leading medtech companies to carve out new paths to create value by addressing ASCs' needs.

ASCs already are transforming the healthcare market. As they capture a growing volume of surgical procedures, outpatient centers will force down prices on medtech devices and trigger changes for payers and providers. Despite these challenges, medtech companies that pivot quickly can take advantage of ASC growth. For leadership teams keen to win their business, the market is wide open—no one has staked a major claim to this fast-moving sector. Those that lead in developing new business models for ASCs will help shape a changing market.

Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

Shared Ambition, True Results

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PROCEDURAL SEDATION/ANALGESIA

POSITION STATEMENT for RN Practice

A Position does not carry the force and effect of law and rules but is adopted by the Board as a means of providing direction to licensees who seek to engage in safe nursing practice. Board Position Statements address issues of concern to the Board relevant to protection of the public and are reviewed regularly for relevance and accuracy to current practice, the Nursing Practice Act, and Board Administrative Code Rules.

Issue: Administration of sedative, analgesic, and anesthetic pharmacological agents, for the purpose of Moderate or Deep Procedural Sedation/Analgesia, to non-intubated clients undergoing therapeutic, diagnostic, and surgical procedures, is within the non-anesthetist Registered Nurse (RN) scope of practice.

Administration of pharmacologic agents for Moderate and/or Deep Procedural Sedation/Analgesia by an RN (who is not a licensed/certified anesthesia provider) **requires all of the following:**

- Policies and procedures of employing agency authorize RN-administered Moderate and/or Deep Procedural Sedation/Analgesia;
- The RN possesses specific knowledge and validated competencies as described in this Position Statement;
- The RN responsible for sedation/analgesia administration and monitoring of a client receiving moderate or deep sedation/analgesia does NOT assume other responsibilities which would leave the client unattended, thereby jeopardizing the safety of the client;
- The physician, certified registered nurse anesthetist (CRNA), nurse practitioner (NP), or physician assistant (PA) ordering RN-administered Moderate Procedural Sedation/Analgesia is physically present in the procedure area and immediately available during the time moderate procedural sedation/analgesia is administered; and,
- The Physician, CRNA, NP, or PA ordering RN-administered Deep Procedural Sedation/Analgesia is physically present at the bedside throughout the time deep sedation/analgesia is administered.

The intended level of sedation/analgesia may quickly change to a deeper level due to the unique characteristics of the pharmacological agents used, as well as the physical status and drug sensitivities of the individual client. The administration of these pharmacologic agents requires ongoing assessment and monitoring of the client and the ability to respond immediately to deviations from the norm.

Given the level of independent assessment, decision-making, and evaluation required for safe care, nursing care of these clients exceeds Licensed Practical Nurse (LPN) scope of practice.

Exclusions from NCBON Procedural Sedation/Analgesia Position Statement:

1. Advanced Practice Registered Nurse - Certified Registered Nurse Anesthetists (APRN-CRNAs) are professional anesthesia providers qualified by education, certification, licensure, registration, and experience to administer anesthesia and all levels of procedural sedation. CRNA scope of practice exceeds and is not limited by the constraints of this Position Statement.

Administration of general anesthesia, including the use of inhalation anesthetics, is limited solely to anesthesia providers, including CRNAs. (Note: Nitrous oxide, used as a procedural sedative/analgesic

agent, is the ONLY agent that can be administered by non-anesthetist RNs via the inhalation route.)

2. Administration of sedation/analgesia for the purpose of intubation, including Rapid-Sequence Intubation (RSI), is within RN scope of practice with specific education, competence, and policies and procedures as detailed in the [NCBON RSI Position Statement](#).
3. Administration of medications for moderate to deep sedation/analgesia of already-intubated, critically ill clients is within RN scope of practice and is not limited by the constraints of this Position Statement.
4. The following are within scope of practice for both RNs and LPNs and are not limited by the constraints of this Position Statement:
 - Administration of Analgesia for pain control without sedatives,
 - Administration of Minimal Sedation/Analgesia (Anxiolysis),
 - Administration of Topical/Local Anesthesia, and,
 - Administration of Sedation/Analgesia solely for the purpose of managing altered mental status.

Definitions:

American Society of Anesthesiologists (ASA) Physical Status Classification –

- a. Class I – normally healthy client
- b. Class II – client with mild systemic disease
- c. Class III – client with severe systemic disease
- d. Class IV – client with severe systemic disease that is constant threat to life
- e. Class V – a moribund client who is not expected to survive 24 hours with or without the procedure.

Anesthetic Agents – medications that, when administered, cause partial or complete loss of sensation, with or without loss of consciousness

Computer-assisted personalized sedation/analgesia devices - integrated drug infusion pump and physiological client monitoring system that administers medication (i.e., propofol) intravenously for initiation and maintenance of minimal to moderate procedural sedation/analgesia. The device continually monitors client physiological parameters and responsiveness, detects signs associated with over-sedation/analgesia, and adjusts the medication delivery rate to limit the depth of sedation/analgesia.

Deep Sedation/Analgesia – drug-induced depression of consciousness during which clients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The client's ability to independently maintain ventilatory function may be impaired. Clients may require assistance to maintain a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia – drug-induced loss of consciousness during which clients are not arousable, even by painful stimulation. The client's ability to independently maintain ventilatory function is often impaired. Clients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Immediately available – present on site in the unit of care and not otherwise engaged in any other uninterrupted procedure or task.

Minimal Sedation/Analgesia (Anxiolysis) – drug-induced state during which clients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Administration of medications appropriate for this purpose include benzodiazepines and opioids, but not anesthesia agents, and is within the scope of practice for both RNs and LPNs.

Moderate (Conscious) Sedation/Analgesia – drug-induced depression of consciousness during which the client responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required for the client to maintain a patent airway and adequate spontaneous ventilation. Cardiovascular function is usually maintained.

Monitored Anesthesia Care (MAC) – anesthesia care that includes the monitoring of the client by a practitioner who is qualified to administer anesthesia. Indications for MAC depend on the nature of the procedure, the client's clinical condition, and/or the potential need to convert to a general or regional anesthetic.

Procedural Sedation/Analgesia – technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows the client to tolerate unpleasant procedures while maintaining cardiovascular and respiratory function.

Rapid-Sequence Intubation (RSI) – airway management technique in which potent sedative or induction agent is administered simultaneously with a paralyzing dose of a neuromuscular blocking agent to facilitate rapid tracheal intubation. The technique includes specific protection against aspiration of gastric contents, provides excellent access to the airway for intubation, and permits pharmacologic control of adverse responses to illness, injury, and the intubation itself.

(For details see [NCBON RSI Position Statement](#).)

Regional Anesthesia – delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required.

Rescue Capacity – requires the competency to manage a compromised airway, provide adequate oxygenation and ventilation, and administer emergency medications and/or reversal agents to clients whose level of sedation becomes deeper than intended.

Sedating Agent – medication that produces calmness, relaxation, reduced anxiety, and sleepiness when administered.

Topical or Local Anesthesia – application or injection of a medication or combination of medications to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which are also not anesthesia, despite the name.

RN Education and Competency Requirements for Procedural Sedation/Analgesia:

Education, training, experience, and validation of initial and ongoing competencies appropriate to RN responsibilities, procedures performed, and the client/population must be documented and maintained. (Note: Employing agency determines frequency with which ongoing competencies are re-validated.)

A. The RN administering moderate and/or deep procedural sedation/analgesia must possess in-depth knowledge of and validated competency to apply the following in practice:

1. Anatomy & physiology, including principles of oxygen delivery, transport and uptake, cardiac dysrhythmia recognition and interventions, and complications related to moderate and deep procedural sedation/analgesia;
2. Pharmacology of sedation, analgesia, and anesthetic agent(s) administered singly or in combination, including appropriate administration routes, drug actions, drug interactions, side effects, contraindications, reversal agents (as applicable), and untoward effects;
3. Airway management skills required to rescue a patient from sedation/analgesia level deeper than intended and to manage a compromised airway or hypoventilation (i.e., establish an open airway, head-tilt, chin lift, use of bag-valve mask, and oral and nasal airways); and,
4. Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) certification including dysrhythmia recognition, cardioversion/defibrillation, and emergency resuscitation appropriate to the status of the client/population.

B. In addition, the RN administering moderate and/or deep procedural sedation/analgesia must possess validated practice competencies needed to:

5. Assess total client care needs before and during the administration of moderate or deep procedural sedation/analgesia and throughout the recovery phase, including implementing nursing care strategies appropriate to the client's ASA Physical Status Classification as determined by Physician, CRNA, NP, or PA;
6. Perform appropriate physiologic measurements and evaluation of respiratory rate; oxygen saturation; carbon dioxide level; blood pressure; cardiac rate and rhythm; and level of consciousness;
7. Assess, identify, and differentiate the levels of sedation/analgesia and provide monitoring appropriate to the client's desired and actual level of sedation/analgesia;
8. Identify and implement appropriate nursing interventions in the event of sedation/analgesia complications, untoward outcomes, and emergencies; and,
9. Assess sedation/analgesia recovery including the use of a standardized discharge scoring system.

Agency Responsibilities in Procedural Sedation/Analgesia:

Based on client care needs, facility regulations, accreditation requirements, applicable standards, personnel, equipment, and other resources, each employing agency determines IF the administration of moderate and/or deep procedural sedation/analgesia by non-anesthetist RNs is authorized in their setting. If administration of moderate and/or deep procedural sedation/analgesia by non-anesthetist RNs IS permitted, the Director of Nursing or lead RN in the employing agency, in collaboration with anesthesia providers and other appropriate agency personnel, is responsible for assuring that written policies and procedures, including but not limited to the following, are in place to address:

1. Credentialing requirements for non-anesthesiologist Physicians, NPs, and PAs approved to perform moderate and/or deep procedural sedation/analgesia;

2. Required documentation of initial and ongoing RN education and competency validation in the manner and at the frequency specified by agency policy;
3. Physician, CRNA, NP, or PA (not the non-anesthetist RN) responsibility for pre-procedure assessment of the client, including assessment and determination of ASA Physical Status Classification score;
4. Number and qualifications of personnel to be present in the room during RN administration of moderate and/or deep procedural sedation/analgesia and requirement that designated personnel are competent to rescue the client should the airway or hemodynamic status be compromised;
5. Requirement that the Physician, CRNA, NP, or PA ordering RN-administered moderate procedural sedation/analgesia be physically present in the procedure area and immediately available during the time moderate procedural sedation/analgesia is administered in order to respond and implement emergency protocols in the event level of sedation deepens or another emergency occurs;
6. Requirement that the Physician, CRNA, NP, or PA ordering RN-administered deep procedural sedation/analgesia be physically present at the bedside throughout the time deep sedation/analgesia is administered in order to respond in the event of an emergency;
7. Requirement that the RN responsible for sedation/analgesia administration and monitoring of a client receiving moderate or deep sedation/analgesia will NOT assume other responsibilities which would leave the client unattended, thereby jeopardizing the safety of the client;
8. Specification of nursing care responsibilities for client assessment, monitoring, medication administration, potential complications, and documentation during moderate and/or deep procedural sedation/analgesia;
9. Specification of medications approved to be ordered and administered by RNs for moderate and/or deep procedural sedation/analgesia, including dosage limits as appropriate;
10. Specification of emergency protocol(s) including immediate on-site availability of resuscitative equipment, medications, and personnel; and
11. Requirement that age and size-appropriate procedural equipment, emergency resuscitation equipment, and medications, as well as personnel qualified to provide necessary emergency measures, such as intubation and airway management, be readily available during moderate and/or deep procedural sedation/analgesia. Age and size-appropriate equipment includes, but is not limited to:
 - blood pressure cuff and stethoscope - cardiac monitor and defibrillator
 - oxygen and suction devices - pulse oximetry and capnography
 - positive pressure ventilation equipment - intravenous administration devices & fluids
 - basic and advanced airway management devices
 - medications including sedatives, analgesics, reversal agents for opioids or benzodiazepines, and resuscitation drugs

Note: RNs retain responsibility and accountability for direct client assessment, intervention, and evaluation throughout the administration of moderate or deep procedural sedation/analgesia. Mechanical monitoring and medication administration devices (e.g., cardiac monitors, infusion pumps, and computer-assisted personalized sedation/analgesia devices) do not replace, but rather support, the RN's assessment and evaluation of client status.

Note: Pulse oximetry measures oxygenation, not ventilation. In the presence of supplemental oxygen, arterial oxygen desaturation as measured by pulse oximetry may represent a delayed sign of hypoventilation. For this reason, monitoring pulse oximetry is not a substitute for direct observation of patient ventilatory function. Capnography may be able to detect hypoventilation before pulse oximetry indicates oxygen desaturation and has been shown to be a more sensitive gauge of hypoventilation than visual observation.

RN Role in Moderate and Deep Procedural Sedation/Analgesia:

1. The administration and monitoring of sedating and anesthetic agents to produce moderate or deep procedural sedation/analgesia for non-intubated adult and pediatric clients undergoing therapeutic, diagnostic, or surgical procedures is within the non-anesthetist RN scope of practice.
2. The RN must be educationally prepared; clinically competent; permitted to administer moderate and/or deep procedural sedation/analgesia by agency written policies and procedures; and not prohibited from doing so by facility-focused laws, rules, standards, and policies.
3. A qualified anesthesia provider (anesthesiologist or CRNA) or appropriately credentialed attending Physician, NP, or PA must assess client, determine ASA Physical Status Classification, select, and order the sedative/anesthetic agents to be administered; intended level of sedation/analgesia must be clearly communicated.
4. The RN is accountable for ensuring that moderate and/or deep procedural sedation/analgesia orders implemented are consistent with the current standards of practice and agency policies and procedures.
5. The RN accepts the assignment to administer ordered moderate or deep procedural sedation/analgesia only if competent and the practice setting has provided the age and size-appropriate equipment, medications, personnel, and related resources needed to assure client safety.
6. The RN administers moderate procedural sedation/analgesia to adult and pediatric clients only if a Physician, CRNA, NP, or PA credentialed by the facility in moderate procedural sedation/analgesia, and competent in airway management, is physically present in the procedure area and immediately available in order to respond and implement emergency protocols in the event level of sedation deepens or another emergency occurs.
7. The RN administers deep procedural sedation/analgesia to adult and pediatric clients only if a Physician, CRNA, NP, or PA credentialed by the facility in deep procedural sedation/analgesia, and competent in intubation and airway management, is present at the bedside in order to respond to any emergency.
8. The RN role in moderate and deep procedural sedation/analgesia is dedicated to the continuous and uninterrupted monitoring of the client's physiologic parameters and administration of medications ordered.
9. The administration of all medications via any appropriate route (including Nitrous Oxide via inhalation) for the purpose of moderate or deep procedural sedation/analgesia is within RN scope of practice. Medications, including *Etomidate, Propofol, Ketamine, Fentanyl, and Midazolam*, administered for moderate and/or deep procedural sedation/analgesia purposes, if ordered by Physician, CRNA, NP, PA, or other _____

credentialed health care practitioner, and allowed by agency policy, is not prohibited provided the appropriate indications and precautions are in place.

LPN Role in Moderate and Deep Procedural Sedation/Analgesia: Given the level of independent nursing assessment, decision-making, and evaluation required for the safe care and management of clients undergoing therapeutic, diagnostic, and surgical procedures, the administration of sedation/anesthetic agents for the purposes of moderate or deep procedural sedation/analgesia is **beyond** LPN scope of practice.

RN and LPN Role in Regional Anesthesia: Regional anesthesia requires anesthetic agent delivery at a specific level of the spinal cord and/or to peripheral nerves, including epidurals, spinals, and other central neuraxial nerve blocks, when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. In these situations the positioning and stabilization of the client receiving regional anesthesia is sometimes challenging and the provider performing the procedure may need mechanical assistance from the nurse (RN or LPN) to attach and/or push the medication syringe plunger while personally maintaining appropriate positioning of the medication delivery device.

In such situations, the nurse may provide the needed manual support by functioning as the “third hand” of the provider. When acting as the provider’s “third hand”, the nurse is **not** accepting responsibility for administration of regional anesthesia, which is **beyond** both RN and LPN scope of practice. Instead, the provider retains full responsibility for the appropriate medication administration and accountability for outcomes.

Note:

1) This “third hand” specification does **not** include the administration of anesthetic agents by the non-anesthetist nurse in any other situation. It is **not** permissible for the RN or LPN to function as the “third hand” of, or to provide only manual support or mechanical assistance to, a provider in the administration of moderate or deep procedural sedation/analgesia. To do so leaves the provider with responsibility for both performing the procedure and monitoring the patient. Moderate and/or deep procedural sedation/analgesia requires careful monitoring by a dedicated person. Therefore, the RN who administers moderate or deep sedation (this is beyond LPN scope of practice) is providing a nursing intervention and retains full accountability and responsibility for his/her actions. The RN functioning in this capacity must meet the Moderate/Deep Procedural Sedation education and competence requirements as delineated in this Position Statement.

2) It is within RN scope of practice to administer ordered **additional or subsequent** medication doses through a pre-established, indwelling epidural/caudal device per provider order. This constitutes RN medication administration for which the RN retains full responsibility and accountability. This is **not** within LPN scope of practice and is **not** considered manual or “third hand” assistance.

References:

[21 NCAC 36.0224 Components of Practice for the Registered Nurse](#)

[21 NCAC 36.0225 Components of Practice for the Licensed Practical Nurse](#)

American Association of Nurse Anesthetists (AANA) – www.aana.com– Resources section provides specific policy considerations for Registered Nurses Engaged in the Administration of Sedation/Analgesia

American Association of Moderate Sedation Nurses (AAMSN) – www.aamsn.org – Resources section provides information on Certified Sedation Registered Nurses (CSRN).

Origin: 1/2015

Revised: 4/2015, 9/2018

Sum of Units Of Service
 Patient Type - IO Rollup
 Inpatient

| Billed CPT - CPT | Service Date - Calendar Year | | | | | Grand Total |
|--|------------------------------|-------------|-------------|-------------|-------------|--------------|
| | 2017 | 2018 | 2019 | 2020 | 2021 | |
| 0 - Not Specified | | | | 2 | | 2 |
| 02387 - TRULUM PERIPHERAL ATHERECTOMY ILIAC ARTERY EA | | | 1 | 2 | | 3 |
| 33340 - PERQ CLSR TCAT L ATR APNDG W-ENDOCARDIAL IMPLNT | | | | | 5 | 5 |
| 33990 - INSI PERQ VAD W-RSANDI L HRT ARTERIAL ACCESS ONLY | 11 | 21 | 61 | 48 | 22 | 163 |
| 36200 - INTRODUCTION CATHETER AORTA | | | 2 | 2 | | 4 |
| 92920 - PRQ TRULUM CORONARY ANGIOPLASTY ONE ART-BRANCH | 107 | 82 | 68 | 59 | 55 | 371 |
| 92921 - PRQ TRULUM CORONARY ANGIOPLASTY ADDL BRANCH | 54 | 65 | 34 | 40 | 25 | 218 |
| 92924 - PRQ TRULUM CORONARY ANGIO-ATHERECT ONE ART-BRANCH | 2 | | 4 | 5 | 2 | 13 |
| 92925 - PRQ TRULUM CORONARY ANGIO-ATHERECT ADDL ART-BRANCH | | | | | 1 | 1 |
| 92928 - PRQ TRULUM CORONARY STENT W-ANGIO ONE ART-BRANCH | 65 | 25 | 8 | 5 | 2 | 105 |
| 92929 - PRQ TRULUM CORONARY STENT W-ANGIO ADDL ART-BRANCH | 1 | 3 | | | | 4 |
| 92933 - PRQ TRULUM CORONARY STENT-ATH-ANGIO ONE ART-BRANCH | | | | 1 | | 1 |
| 92937 - PRQ TRULUM CORONARY BYP GRFT REVASC ONE VESSEL | 7 | 5 | 2 | 2 | | 16 |
| 92941 - PRQ TRULUM CORONARY TOT OCCLUS REVASC MI ONE VSL | 45 | 41 | 32 | 26 | 14 | 158 |
| 92943 - PRQ TRULUM CORONARY CHRONIC OCCLUS REVASC ONE VSL | 2 | 4 | 4 | | | 10 |
| 92973 - PRQ TRANSLUMINAL CORONARY MECHANICAL THROMBECTOMY | 8 | 6 | 45 | 51 | 37 | 147 |
| 92978 - ENDOLUMINAL CORONARY IVUS OCT IANDR INITIAL VESSEL | 90 | 59 | 66 | 107 | 120 | 442 |
| 92979 - ENDOLUMINAL CORONARY IVUS OCT IANDR ADDL VESSEL | 6 | 3 | 4 | 10 | 18 | 41 |
| 92986 - PRQ BALLOON VALVULOPLASTY AORTIC VALVE | 11 | 9 | 5 | 10 | 6 | 41 |
| 93451 - RIGHT HEART CATH O2 SATURATION AND CARDIAC OUTPUT | 41 | 59 | 64 | 60 | 34 | 258 |
| 93453 - R AND L HRT CATH W-NIX L VENTRICULOG IMG SANDI | | 1 | 4 | | 4 | 9 |
| 93454 - CATH PLACEMENT AND NIX CORONARY ART ANGIO IMG SANDI | 226 | 207 | 230 | 163 | 93 | 919 |
| 93455 - CATH PLMT AND NIX CORONARY ART GRFT ANGIO IMG SANDI | 80 | 63 | 61 | 44 | 26 | 274 |
| 93456 - CATH PLMT R HRT AND ARTS W-NIX AND ANGIO IMG SANDI | 15 | 19 | 30 | 21 | 17 | 102 |
| 93457 - CATH PLMT R HRT-ARTS-GRFTS W-NIX AND ANGIO IMG SANDI | 8 | 1 | 5 | 4 | 1 | 19 |
| 93458 - CATH PLMT L HRT AND ARTS W-NIX AND ANGIO IMG SANDI | 1505 | 1472 | 1494 | 1327 | 908 | 6706 |
| 93459 - CATH PLMT L HRT-ARTS-GRFTS WNIX AND ANGIO IMG SANDI | 251 | 221 | 216 | 194 | 106 | 988 |
| 93460 - R AND L HRT CATH WINIX HRT ARTAND L VENTR IMG | 140 | 148 | 210 | 213 | 148 | 859 |
| 93461 - RAND L HRT CATH W-INIEC HRT ART-GRFTAND L VENT I | 24 | 27 | 23 | 37 | 24 | 135 |
| 93503 - INSERTION FLOW DIRECTED CATHETER FOR MONITORING | 2 | 8 | 8 | 7 | 8 | 33 |
| 93505 - ENDOMYOCARDIAL BIOPSY | | | | 5 | | 5 |
| 93567 - NIX SUPRAVALV AORTOG HRT CATH W-SANDI | 18 | 12 | 11 | 5 | 6 | 52 |
| C9600 - PERC DRUG-EL COR STENT SING | 856 | 861 | 1033 | 929 | 646 | 4325 |
| C9601 - PERC DRUG-EL COR STENT BRAN | 36 | 54 | 58 | 50 | 47 | 245 |
| C9602 - PERC D-E COR STENT ATHER S | 8 | 8 | 25 | 35 | 26 | 102 |
| C9604 - PERC D-E COR REVASC T CABG S | 96 | 79 | 63 | 83 | 49 | 370 |
| C9605 - PERC D-E COR REVASC T CABG B | 2 | 2 | 1 | | | 6 |
| C9606 - PERC D-E COR REVASC W AMI S | 219 | 249 | 270 | 276 | 193 | 1207 |
| C9607 - PERC D-E COR REVASC CHRO SIN | 3 | 5 | 2 | 2 | 3 | 15 |
| C9764 - REVASC INTRAVASC LITHOTRIPSY | | | | | 1 | 1 |
| Inpatient Total | 3939 | 3819 | 4145 | 3824 | 2648 | 18375 |
| Outpatient | | | | | | |
| 02387 - TRULUM PERIPHERAL ATHERECTOMY ILIAC ARTERY EA | | | 1 | 1 | | 2 |
| 33289 - TCAT IMPL WRLS P-ART PRS SNR L-T HEMODYN MNTR | | | 4 | 6 | 5 | 15 |
| 33990 - INSI PERQ VAD W-RSANDI L HRT ARTERIAL ACCESS ONLY | | | 1 | 1 | 3 | 5 |
| 36200 - INTRODUCTION CATHETER AORTA | 2 | 7 | 6 | 1 | 1 | 17 |
| 36245 - SCLTV CATHI EA 1ST ORD ABDL PEL-LXTR ART BRNCH | | 1 | | | | 1 |
| 92920 - PRQ TRULUM CORONARY ANGIOPLASTY ONE ART-BRANCH | 41 | 46 | 34 | 48 | 29 | 198 |
| 92921 - PRQ TRULUM CORONARY ANGIOPLASTY ADDL BRANCH | 40 | 31 | 20 | 24 | 19 | 134 |
| 92924 - PRQ TRULUM CORONARY ANGIO-ATHERECT ONE ART-BRANCH | | 1 | 1 | 3 | 2 | 7 |
| 92925 - PRQ TRULUM CORONARY ANGIO-ATHERECT ADDL ART-BRANCH | | 2 | | | | 2 |
| 92928 - PRQ TRULUM CORONARY STENT W-ANGIO ONE ART-BRANCH | 30 | 11 | 2 | 2 | 4 | 49 |
| 92929 - PRQ TRULUM CORONARY STENT W-ANGIO ADDL ART-BRANCH | 3 | 1 | 1 | 2 | | 7 |
| 92933 - PRQ TRULUM CORONARY STENT-ATH-ANGIO ONE ART-BRANCH | | | | 5 | 1 | 6 |
| 92937 - PRQ TRULUM CORONARY BYP GRFT REVASC ONE VESSEL | 4 | 6 | 3 | 2 | 3 | 18 |
| 92943 - PRQ TRULUM CORONARY CHRONIC OCCLUS REVASC ONE VSL | 2 | 2 | 2 | 2 | | 8 |
| 92973 - PRQ TRANSLUMINAL CORONARY MECHANICAL THROMBECTOMY | | | 1 | 2 | 1 | 4 |
| 92978 - ENDOLUMINAL CORONARY IVUS OCT IANDR INITIAL VESSEL | 77 | 69 | 70 | 116 | 147 | 479 |
| 92979 - ENDOLUMINAL CORONARY IVUS OCT IANDR ADDL VESSEL | 6 | 13 | 11 | 18 | 23 | 71 |
| 92986 - PRQ BALLOON VALVULOPLASTY AORTIC VALVE | 5 | 4 | 5 | | 2 | 16 |
| 93451 - RIGHT HEART CATH O2 SATURATION AND CARDIAC OUTPUT | 42 | 28 | 28 | 12 | 22 | 132 |
| 93452 - L HRT CATH W-NIX L VENTRICULOGRAPHY IMG SANDI | | | 1 | 1 | | 2 |
| 93453 - R AND L HRT CATH W-NIX L VENTRICULOG IMG SANDI | | | 1 | | | 1 |
| 93454 - CATH PLACEMENT AND NIX CORONARY ART ANGIO IMG SANDI | 104 | 125 | 115 | 69 | 42 | 455 |
| 93455 - CATH PLMT AND NIX CORONARY ART GRFT ANGIO IMG SANDI | 36 | 41 | 52 | 31 | 25 | 185 |
| 93456 - CATH PLMT R HRT AND ARTS W-NIX AND ANGIO IMG SANDI | 41 | 43 | 48 | 44 | 41 | 217 |
| 93457 - CATH PLMT R HRT-ARTS-GRFTS W-NIX AND ANGIO IMG SANDI | 14 | 7 | 9 | 7 | 5 | 42 |
| 93458 - CATH PLMT L HRT AND ARTS W-NIX AND ANGIO IMG SANDI | 1660 | 1778 | 1954 | 1824 | 1340 | 8556 |
| 93459 - CATH PLMT L HRT-ARTS-GRFTS WNIX AND ANGIO IMG SANDI | 261 | 272 | 302 | 267 | 220 | 1322 |
| 93460 - R AND L HRT CATH WINIX HRT ARTAND L VENTR IMG | 324 | 306 | 320 | 266 | 292 | 1508 |
| 93461 - RAND L HRT CATH W-INIEC HRT ART-GRFTAND L VENT I | 47 | 52 | 60 | 43 | 38 | 240 |
| 93463 - MEDICATION ADMIN AND HEMODYNAMIC MEASUREMENT | | 1 | 2 | | | 3 |
| 93505 - ENDOMYOCARDIAL BIOPSY | 1 | | 4 | 5 | 5 | 15 |
| 93567 - NIX SUPRAVALV AORTOG HRT CATH W-SANDI | 24 | 8 | 10 | 11 | 7 | 60 |
| 93571 - IV DDP VELAND-OR PRESS C-FLO RSRV MEAS 1ST VSL | | | 1 | | | 1 |
| 93580 - PRQ TCAT CLSR CGEN INTRATRAL COMUNICAI W-IMPLT | | 5 | 6 | 14 | 9 | 34 |
| 93582 - PERCUTAN TRANSCATH CLOSURE PAT DUCT ARTERIOSUS | | | | | 2 | 2 |
| 93654 - EPHYS EVAL W-ABLATION VENTRICULAR TACHYCARDIA | | | | | 1 | 1 |
| 93657 - ABLATE L-R ATRIAL FIBRIL W-ISOLATED PULM VEIN | | | 1 | 2 | 1 | 4 |
| C9600 - PERC DRUG-EL COR STENT SING | 739 | 873 | 916 | 903 | 747 | 4178 |
| C9601 - PERC DRUG-EL COR STENT BRAN | 27 | 33 | 39 | 46 | 37 | 182 |
| C9602 - PERC D-E COR STENT ATHER S | 8 | 9 | 18 | 18 | 24 | 77 |
| C9604 - PERC D-E COR REVASC T CABG S | 68 | 54 | 83 | 65 | 48 | 318 |
| C9605 - PERC D-E COR REVASC T CABG B | | 1 | 2 | | | 3 |
| C9606 - PERC D-E COR REVASC W AMI S | | 1 | 5 | 1 | | 7 |
| C9607 - PERC D-E COR REVASC CHRO SIN | 6 | 14 | 22 | 10 | 9 | 61 |
| C9608 - PERC D-E COR REVASC CHRO ADD | | | | | 1 | 1 |
| C9741 - IMPL PRESSURE SENSOR W-ANGIO | 12 | 7 | 1 | | | 20 |
| Outpatient Total | 3624 | 3854 | 4161 | 3872 | 3155 | 18666 |
| Grand Total | 7563 | 7673 | 8306 | 7696 | 5803 | 37041 |

Elective Percutaneous Coronary Intervention in Ambulatory Surgery Centers



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ABSTRACT

OBJECTIVES The aim of this study was to explore characteristics and outcomes of patients undergoing elective percutaneous coronary intervention (PCI) in ambulatory surgery centers (ASCs).

BACKGROUND Little is known about patients who underwent ASC PCI before Medicare reimbursement was instituted in 2020.

METHODS Using commercial insurance claims from MarketScan, adults who underwent hospital outpatient department (HOPD) or ASC PCI for stable ischemic heart disease from 2007 to 2016 were studied. Propensity score analysis was used to measure the association between treatment setting and the primary composite outcome of 30-day myocardial infarction, bleeding complications, and hospital admission.

RESULTS The unmatched sample consisted of 95,492 HOPD and 849 ASC PCIs. Patients who underwent ASC PCI were more likely to be younger than 65 years, to live in the southern United States, and to have managed or consumer-driven health insurance. ASC PCI was also associated with decreased fractional flow reserve utilization (odds ratio [OR]: 0.31; 95% confidence interval [CI]: 0.20 to 0.48; $p < 0.001$). In unmatched, multivariate analysis, ASC PCI was associated with increased odds of the primary outcome (OR: 1.25; 95% CI: 1.01 to 1.56; $p = 0.039$) and bleeding complications (OR: 1.80; 95% CI: 1.11 to 2.90; $p = 0.016$). In propensity-matched analysis, ASC PCI was not associated with the primary outcome (OR: 1.23; 95% CI: 0.94 to 1.60; $p = 0.124$) but was significantly associated with increased bleeding complications (OR: 2.49; 95% CI: 1.25 to 4.95; $p = 0.009$).

CONCLUSIONS Commercially insured patients undergoing ASC PCI were less likely to undergo fractional flow reserve testing and had higher odds of bleeding complications than HOPD-treated patients. Further study is warranted as Medicare ASC PCI volume increases. (J Am Coll Cardiol Intv 2021;14:292-300) Published by Elsevier on behalf of the American College of Cardiology Foundation

In November 2019, the Centers for Medicare and Medicaid Services (CMS) finalized a rule that added percutaneous transluminal coronary angioplasty and transcatheter placement of intracoronary stents to the list of procedures reimbursed in ambulatory surgery centers (ASCs), effective January 1, 2020 (1). The previous year, the agency had also deemed diagnostic catheterization and angiography as reimbursable in ASCs (2). CMS changed these

policies in light of evidence that supports the safety of same-day discharge following elective percutaneous coronary intervention (PCI) (3,4) and of PCI performed without on-site cardiothoracic surgical support (5,6). Same-day discharge has been associated with cost savings compared with overnight observation (7), and studies suggest that this practice has become more common within recent years (4,8,9) as a greater percentage of elective PCI cases are

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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performed under outpatient rather than inpatient admission status (10). However, little is known about commercially insured patients who underwent ASC PCI prior to this CMS rule change (11).

In this study, we used an administrative claims database of commercially insured patients to characterize a sample of adults who underwent outpatient elective PCI for stable ischemic heart disease in either a hospital outpatient department (HOPD) or ASC during the study period. We additionally used propensity score matching to assess the relationship between ASC treatment setting and adverse outcomes following PCI.

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METHODS

DATA SOURCE. We conducted a retrospective, observational analysis of administrative claims data from the IBM MarketScan Commercial and Medicare Supplemental Databases. These claims reflect inpatient and outpatient services and outpatient pharmacy claims for persons in the United States covered by private and Medicare Supplement insurance. Procedures were identified using Current Procedural Terminology, Healthcare Common Procedure Coding System, and International Classification of Disease (ICD)-9th Revision and ICD-10th Revision procedure codes. Diagnoses were identified using ICD diagnosis codes. This study was deemed exempt from human studies review by the Institutional Review Board at Stanford University. Data were used as part of a pre-specified data-use agreement and are not publicly accessible.

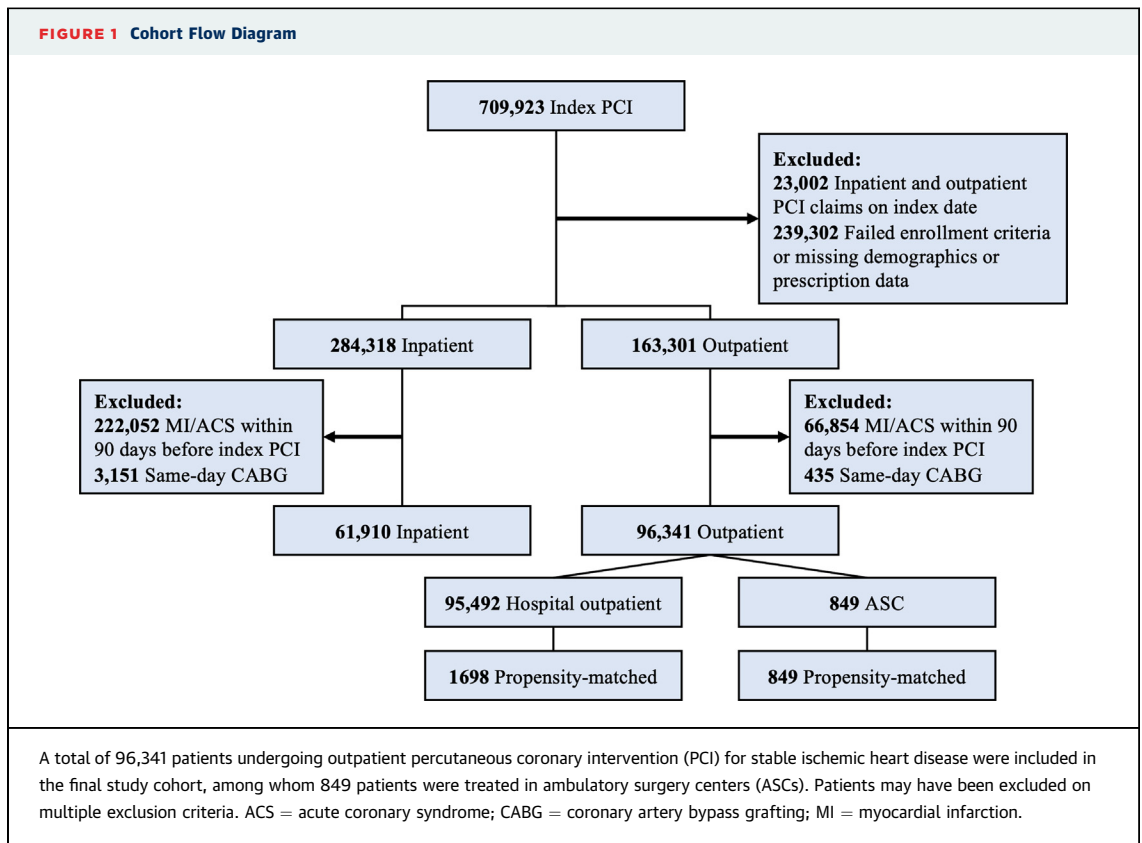
STUDY COHORT. We identified patients 18 years of age or older undergoing outpatient percutaneous transluminal coronary angioplasty with or without stenting between April 1, 2007, and December 1, 2016 (Supplemental Table 1). The first instance of PCI for each patient was designated as the index procedure. Patients with PCI billed in both inpatient and outpatient settings on the index date were excluded to ensure proper attribution of treatment setting (Figure 1). Patients were required to have at least 90 days of continuous insurance enrollment prior to and 30 days of continuous enrollment after the index date. Patients were excluded if demographic information or prescription drug use were not captured. To ensure that cases reflected stable ischemic heart disease, patients were excluded if they had diagnoses of myocardial infarction (MI) or acute coronary syndrome in the 90 days before the index date.

We also excluded patients who underwent same-day coronary artery bypass grafting (CABG) to exclude the possibility of planned hybrid revascularization, which was outside the scope of this study. We note that same-day CABG may also arise because of PCI complications, especially following PCI performed in the freestanding setting, in which planned hybrid procedures are unlikely. However, we were not able to determine from the data whether same-day CABG was planned or arose because of a PCI complication. After applying all other criteria, there was no statistically significant difference in same-day CABG between HOPD PCI and ASC PCI ($p = 0.376$, Fisher exact test), with incidence in both groups $\leq 0.1\%$.

EXPLANATORY VARIABLES. Our primary exposure of interest was the outpatient practice setting in which PCI was performed. Among PCI billed as outpatient procedures, we used CMS place-of-service codes 11 (office) and 24 (ASC) cross-referenced with CMS type-of-bill codes to distinguish those performed in freestanding ASCs from those performed in an HOPD on an ambulatory basis (11,12). Patients were characterized by age, sex, year of treatment, geography of residence, insurance plan type, comorbidities, procedural characteristics, and peri-procedural medication use. Geography was captured at the level of U.S. region, state, and metropolitan statistical area if applicable. Urban areas were defined as those associated with metropolitan statistical areas. Insurance plan groupings were defined by the nature of patient cost sharing and included comprehensive, managed (exclusive provider organization, health maintenance organization, preferred provider organization, point of service with or without capitation), and consumer-driven or high-deductible health plans. Comorbidities were assessed from the beginning of data collection (April 1, 2007) to the index date and included conditions previously found to be associated with PCI complications (13-15) such as heart failure, history of cardiogenic shock, diabetes, chronic obstructive pulmonary disease, chronic kidney disease, peripheral vascular disease, and malignancy (Supplemental Table 1). Other measured comorbidities included a history of MI or acute coronary syndrome diagnosed at least 90 days prior to the index date, previous CABG, and history of stroke, dyslipidemia, hypertension, obesity, and tobacco use. Procedural characteristics included multi-vessel PCI, stent implantation, use of glycoprotein IIb/IIIa inhibitors (GPIs), and performance of

ABBREVIATIONS AND ACRONYMS

| | |
|-------------|--|
| ASC | = ambulatory surgery center |
| CABG | = coronary artery bypass grafting |
| CI | = confidence interval |
| CMS | = Centers for Medicare and Medicaid Services |
| FFR | = fractional flow reserve |
| GPI | = glycoprotein IIb/IIIa inhibitor |
| HOPD | = hospital outpatient department |
| ICD | = International Classification of Diseases |
| MI | = myocardial infarction |
| OCT | = optical coherence tomography |
| OR | = odds ratio |
| PCI | = percutaneous coronary intervention |



fractional flow reserve (FFR), intravascular ultrasound, or optical coherence tomography (OCT). We also assessed whether patients filled outpatient prescriptions for nonsalicylate antiplatelet or anticoagulant medications within the 30 days before or after the index date.

OUTCOME VARIABLES. Our primary outcome was a composite of MI, bleeding or vascular complications (post-procedural hemorrhage, hematoma, or puncture; hemopericardium; cardiac tamponade; or hemoperitoneum including retroperitoneal hemorrhage), and hospital admission in the 30 days following and inclusive of the index date (Supplemental Table 1). Outcomes were also assessed individually. An event was identified if an outcome-related diagnosis was added in the follow-up period and was also not present in the 90 days prior to the index date. Mortality data were not available, and therefore death was not included as an outcome. Repeat PCI was also not included as an outcome, because of the inability to differentiate between planned staged and unplanned revascularization in the dataset. We note that codes corresponding to post-procedural hemorrhage, hematoma, or puncture were not specific to procedure type in ICD-9th Revision and

were made specific to circulatory system structures and procedures only in ICD-10th Revision.

STATISTICAL ANALYSIS. Baseline characteristics were compared between the HOPD and ASC PCI groups, with differences in categorical and continuous variables assessed using chi-square and Student's *t*-tests, respectively. Associations of ASC treatment setting with demographic, comorbidity, and pre-procedural medication variables were assessed using multivariate logistic regression. Propensity score analysis was then used to compare outcomes after HOPD and ASC PCI (16). We matched patients who underwent ASC PCI with those treated in HOPDs using the nearest-neighbor method in order of descending propensity score. Propensity scores were calculated using age group, sex, year of treatment, geography (state and urban status) of residence, insurance plan type, comorbidities, and pre-procedural medication use. To match, a patient treated in an HOPD was required to have the logit of the propensity score be within 0.2 SDs of that of the index ASC patient (17). A 1-to-2 ASC-to-HOPD matching ratio was used to minimize sampling variability (18,19). Balance of variables between HOPD and ASC PCI groups before

and after propensity score matching was assessed using a standardized mean difference threshold of 0.1 (20).

Associations between outpatient treatment setting and outcomes were first estimated using multivariate logistic regression of unmatched cohorts, adjusting for age group, sex, treatment year, state of residence, urban status, insurance plan type, multivessel PCI, GPI use, peri-procedural medication use, and measured comorbidities. In propensity-matched analysis, effect size was estimated using multivariate logistic regression adjusting for multivessel PCI, GPI use, and post-procedural medication use, variables that were not used for matching. Effect size was represented as an odds ratio (OR) with a 95% confidence interval (CI). Statistical significance was assessed at $p < 0.05$. Analysis was conducted using R version 4.0.0 (R Foundation for Statistical Computing, Vienna, Austria) with propensity score analysis performed using the MatchIt (21) R package version 3.0.2.

RESULTS

COHORT CHARACTERISTICS. We identified 96,341 patients (Figure 1) undergoing outpatient elective PCI for stable ischemic heart disease. Among this cohort, 95,492 patients (99.1%) underwent HOPD PCI compared with 849 patients (0.9%) who underwent ASC PCI (Table 1). From 2007 to 2016, the HOPD share of total (inpatient and outpatient) elective PCI increased from 32.0% to 80.6% (Supplemental Figure 1), while the ASC share remained <1% throughout the study period. The majority of patients resided in urban areas and in the South and North Central regions of the United States. ASC utilization as a percentage of outpatient elective PCI varied among states and was highest in Alaska (3.7%), Texas (3.1%), Kentucky (2.8%), Indiana (2.1%), and Kansas (1.3%) (Supplemental Figure 2).

BASELINE CHARACTERISTICS ASSOCIATED WITH ASC PCI. Among the sample of outpatient elective PCI, patients treated in ASCs compared with HOPDs (Table 2) were more likely to be younger than 65 years of age (OR: 1.75; 95% CI: 1.46 to 2.10), to live in the southern U.S. (reference group), and to be covered by managed (OR: 2.25; 95% CI: 1.69 to 3.00) or consumer-driven or high-deductible (OR: 2.09; 95% CI: 1.41 to 3.10) health plans compared with comprehensive health plans. Patients undergoing ASC PCI were also more likely to have histories of dyslipidemia (OR: 1.20; 95% CI: 1.01 to 1.42) and less likely to have histories of stroke (OR: 0.44; 95% CI: 0.27 to 0.70). Sex, urban status, and other measured comorbidities were

TABLE 1 Cohort Characteristics

| | HOPD* (n = 95,492) | ASC* (n = 849) | p Value |
|--|-----------------------|-------------------|---------|
| Demographics | | | |
| Age, yrs | 64.0 ± 10.7 | 59.8 ± 9.7 | <0.001 |
| Female | 26,523 (27.8) | 223 (26.3) | 0.348 |
| Region | | | <0.001 |
| Northeast | 12,037 (12.6) | 64 (7.5) | |
| North Central | 28,152 (29.5) | 178 (21.0) | |
| South | 45,226 (47.4) | 531 (62.5) | |
| West | 10,077 (10.6) | 76 (9.0) | |
| Urban | 75,457 (79.0) | 654 (77.0) | 0.17 |
| Plan type | | | <0.001 |
| Comprehensive | 19,377 (20.3) | 58 (6.8) | |
| Managed | 71,201 (74.6) | 737 (86.8) | |
| CDHP/HDHP | 4,914 (5.1) | 54 (6.4) | |
| Comorbidities | | | |
| Prior myocardial infarction | 2,965 (3.1) | 25 (2.9) | 0.866 |
| Prior acute coronary syndrome | 4,805 (5.0) | 34 (4.0) | 0.199 |
| Heart failure | 14,251 (14.9) | 109 (12.8) | 0.099 |
| History of cardiogenic shock | 182 (0.2) | — | 1.00 |
| Prior coronary artery bypass graft | 2,666 (2.8) | 24 (2.8) | 1.00 |
| Diabetes | 39,405 (41.3) | 324 (38.2) | 0.073 |
| Dyslipidemia | 71,461 (74.8) | 665 (78.3) | 0.022 |
| Hypertension | 74,975 (78.5) | 643 (75.7) | 0.055 |
| Chronic obstructive pulmonary disease | 15,364 (16.1) | 103 (12.1) | 0.002 |
| Chronic kidney disease | 8,237 (8.6) | 62 (7.3) | 0.191 |
| Prior stroke | 5,646 (5.9) | 18 (2.1) | <0.001 |
| Peripheral vascular disease | 13,147 (13.8) | 103 (12.1) | 0.184 |
| Malignancy | 14,012 (14.7) | 83 (9.8) | <0.001 |
| Obesity | 11,622 (12.2) | 99 (11.7) | 0.689 |
| Current tobacco use | 11,210 (11.7) | 104 (12.2) | 0.684 |
| Pre-procedural outpatient prescriptions | | | |
| Antiplatelet, nonsalicylate | 16,073 (16.8) | 138 (16.3) | 0.688 |
| Anticoagulation | 3,612 (3.8) | 17 (2.0) | 0.009 |
| Procedural | | | |
| Multivessel | 11,240 (11.8) | 99 (11.7) | 0.964 |
| Stent | 90,524 (94.8) | 784 (92.3) | 0.002 |
| Glycoprotein IIb/IIIa inhibitor use | 6,964 (7.3) | 34 (4.0) | <0.001 |
| Intravascular imaging/physiology | 17,494 (18.3) | 106 (12.5) | <0.001 |
| Intravascular imaging | 11,219 (11.7) | 87 (10.2) | 0.194 |
| Fractional flow reserve | 7,241 (7.6) | 21 (2.5) | <0.001 |

Values are mean ± SD or n (%). *Cell sizes <12 are hidden for reporting purposes.
 ASC = ambulatory surgery center; CDHP = consumer-driven health plan; HDHP = high-deductible health plan; HOPD = hospital outpatient department.

not associated with treatment in the ASC setting in multivariate regression.

In the 30 days before PCI, 16.8% and 16.3% of HOPD- and ASC-treated patients, respectively, filled prescriptions for nonsalicylate antiplatelet medications (Table 1). Pre-procedural outpatient anticoagulant prescriptions were filled by 3.8% and 2.0% of HOPD and ASC patients, respectively, a difference that was statistically significant ($p = 0.009$) in univariate analysis. However, neither pre-operative antiplatelet nor pre-operative anticoagulant use was significantly associated with the ASC setting in multivariate regression.

PROCEDURAL CHARACTERISTICS. The proportion of multivessel procedures was not significantly

TABLE 2 Multivariable Analysis of Pre-Procedural Factors Associated With the Ambulatory Surgery Center Setting Among Outpatient Elective Percutaneous Coronary Intervention

| | OR | 95% CI | p Value |
|--|-----------|-------------|---------|
| Demographics | | | |
| Age, yrs | | | |
| <65 | 1.75 | (1.46-2.10) | <0.001 |
| ≥65 | Reference | | |
| Female | 1.02 | (0.87-1.19) | 0.785 |
| Region | | | |
| Northeast | 0.51 | (0.39-0.66) | <0.001 |
| North Central | 0.62 | (0.52-0.74) | <0.001 |
| South | Reference | | |
| West | 0.68 | (0.54-0.87) | 0.002 |
| Urban | 0.94 | (0.8-1.10) | 0.443 |
| Plan type | | | |
| Comprehensive | Reference | | |
| Managed | 2.25 | (1.69-3.00) | <0.001 |
| CDHP/HDHP | 2.09 | (1.41-3.10) | <0.001 |
| Comorbidities | | | |
| Prior myocardial infarction | 1.11 | (0.73-1.70) | 0.617 |
| Prior acute coronary syndrome | 0.86 | (0.60-1.25) | 0.440 |
| Heart failure | 1.17 | (0.94-1.45) | 0.163 |
| History of cardiogenic shock | 1.32 | (0.32-5.45) | 0.702 |
| Prior coronary artery bypass graft | 1.06 | (0.68-1.66) | 0.790 |
| Diabetes | 0.91 | (0.79-1.05) | 0.215 |
| Dyslipidemia | 1.20 | (1.01-1.42) | 0.036 |
| Hypertension | 0.90 | (0.76-1.07) | 0.228 |
| Chronic obstructive pulmonary disease | 0.91 | (0.73-1.13) | 0.411 |
| Chronic kidney disease | 1.07 | (0.82-1.41) | 0.611 |
| Prior stroke | 0.44 | (0.27-0.70) | <0.001 |
| Peripheral vascular disease | 1.15 | (0.92-1.42) | 0.220 |
| Malignancy | 0.83 | (0.66-1.05) | 0.127 |
| Obesity | 0.91 | (0.73-1.13) | 0.389 |
| Current tobacco use | 0.96 | (0.77-1.18) | 0.679 |
| Pre-procedural outpatient prescriptions | | | |
| Antiplatelet, nonsalicylate | 0.97 | (0.80-1.16) | 0.726 |
| Anticoagulation | 0.68 | (0.42-1.10) | 0.114 |

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

different between HOPD (11.8%) and ASC (11.7%) PCI in univariate analysis, while the proportion of PCI involving stent placement was higher in HOPDs (94.8%) compared with ASCs (92.3%; $p = 0.002$). GPI use was more common in HOPD PCI (7.3%) than in ASC PCI (4.0%; $p < 0.001$).

Notably, FFR and intravascular ultrasound or OCT were used more frequently in HOPD (18.3%) than in ASC (12.5%) PCI ($p < 0.001$). When adjusted for age group, sex, region, urban status, plan type, comorbidities, and pre-procedural medication use in multivariate logistic regression, the association between ASC setting and decreased use of either FFR or intravascular ultrasound or OCT was statistically significant (OR: 0.62; 95% CI: 0.51 to 0.76; $p < 0.001$). When modalities were considered individually, ASC setting was significantly associated with decreased FFR use (OR: 0.31; 95% CI: 0.20 to 0.48; $p < 0.001$) but not with intravascular ultrasound or OCT use (OR: 0.82; 95% CI: 0.66 to 1.03; $p = 0.086$).

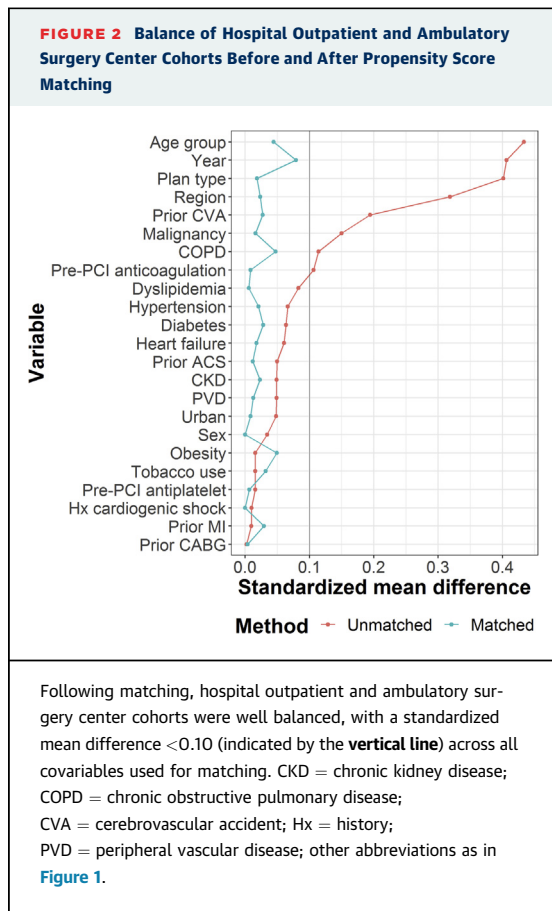
ASC PCI OUTCOMES. In unmatched, multivariate analysis, ASC PCI was associated with increased odds of the primary composite outcome (OR: 1.25; 95% CI: 1.01 to 1.56; $p = 0.039$) and of bleeding complications (OR: 1.80; 95% CI: 1.11 to 2.90; $p = 0.016$) compared with HOPD PCI. The associations of ASC setting with MI (OR: 1.16; 95% CI: 0.69 to 1.95; $p = 0.577$) and with hospital admission (OR: 1.21; 95% CI: 0.95 to 1.53; $p = 0.119$) were not statistically significant.

Propensity scores were used to match the 849 ASC-treated patients with 1,698 HOPD-treated patients. Both groups were well balanced, with a standardized mean difference <0.10 across all variables used in matching (Figure 2). Among the propensity-matched sample, the incidence of the primary composite outcome was 11.7% in ASC PCI and 9.8% in HOPD PCI (Central Illustration). The association between the ASC setting and the primary composite outcome was not statistically significant (OR: 1.23; 95% CI: 0.94 to 1.60; $p = 0.124$) after adjusting for multivessel PCI, GPI use, and post-procedural antiplatelet and anticoagulant use. Bleeding complications were more common in the ASC PCI group (2.1%) compared with the matched HOPD PCI group (0.9%), an association that was statistically significant (OR: 2.49; 95% CI: 1.25 to 4.95; $p = 0.009$) after adjustment. Hospital admission was the most common outcome in matched ASC (9.4%) and HOPD (8.2%) PCI groups. However, ASC PCI was not significantly associated with either hospital admission (OR: 1.18; 95% CI: 0.88 to 1.57; $p = 0.274$) or MI (OR: 1.15; 95% CI: 0.60 to 2.18; $p = 0.674$).

DISCUSSION

Although outpatient elective ASC PCI is now reimbursable under Medicare, there have been limited data on the outcomes of procedures previously performed in this setting. This is the first study to our knowledge to characterize patients treated in free-standing ASCs and their short-term outcomes.

In our sample of commercially insured patients, we did not observe a difference between propensity-matched ASC and HOPD PCI in the primary composite outcome of MI, bleeding complications, or hospital admission. However, we did find increased odds of post-procedural bleeding complications in the ASC-treated group when assessed as an individual outcome after controlling for covariables including GPI use, which was less common in ASC PCI. This may suggest increased risk associated with procedures performed in ASCs due to facility- or operator-level variation across factors such as vascular access site (22), use of vascular closure devices (23), and operator volume. In particular, the overall growth of radial



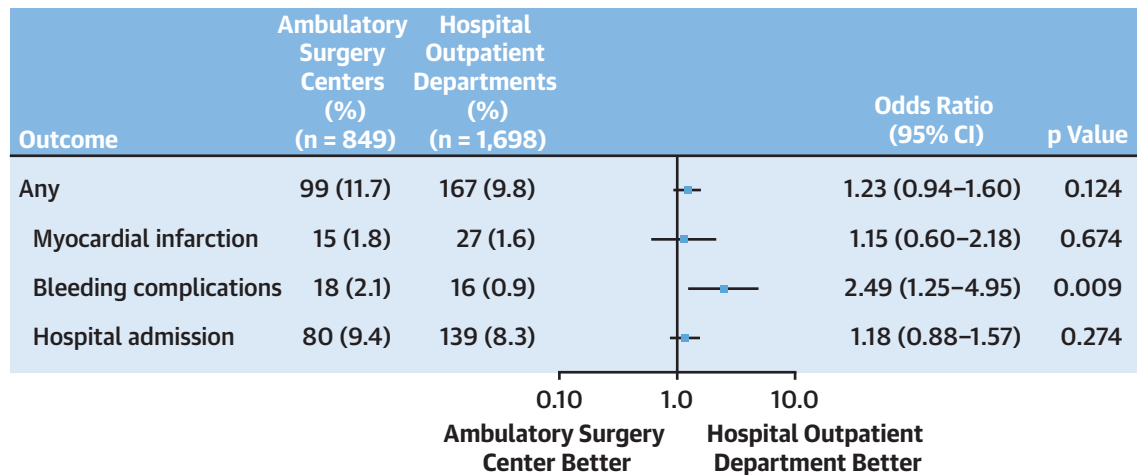
relative to femoral access during the study period may not have been fully realized in the ASC setting, a possible explanation for increased vascular complication rates in these facilities (24). The available data did not allow us to ascertain the severity of bleeding or definitively attribute complications to the index procedure, which limits our ability to judge the clinical significance of the observed difference. The absence of a statistically significant difference in hospital admissions between HOPD and ASC PCI may also suggest that complications arising in the ASC setting were not severe enough to warrant inpatient care. Nevertheless, our findings underscore the need for further study of post-procedural outcomes in the freestanding setting, especially as ASCs may not always be staffed to manage problems like early hematoma formation that could otherwise be observed overnight under outpatient status in a hospital.

We also observed geographic variation in the relative use of ASCs for outpatient elective PCI. This variation is likely multifactorial and may involve financial incentives as well as local practice patterns and provider supply (25). Physician ownership stakes in ASCs may encourage providers to

preferentially perform elective cases in these facilities, a dynamic that has been associated with recent increases in office-based peripheral vascular intervention volume under Medicare (26,27). Patients may also be incentivized to undergo interventional procedures in ASCs through their health insurance plans. We found that patients undergoing ASC PCI were more likely to have managed or consumer-driven health plans than patients undergoing HOPD PCI. Compared with comprehensive policies, these plans may steer care toward lower cost settings through incentives such as reduced out-of-pocket payments. In the California Public Employees Retirement System, for example, ASC use increased after patients were required to pay the difference between a fixed employer contribution and the facility price, which tended to be higher in HOPDs than in ASCs (28).

With ASC PCI poised to grow under Medicare, the Society for Cardiovascular Angiography and Interventions has recommended that patients with unfavorable clinical features or high-risk lesions be treated in hospitals (29). The degree to which such patient selection practices were implemented in this sample is unclear. We found that ASC PCI patients were younger on average than HOPD PCI patients, which may reflect pre-procedural screening or limited ASC access among Medicare-age patients. Of the comorbidities we measured, however, only history of stroke was inversely associated with ASC treatment setting. We did not identify other baseline differences in measured comorbidities between HOPD and ASC PCI to suggest significant pre-procedural risk stratification in the latter.

Importantly, we also found that FFR was less likely to be performed in ASC PCI than in HOPD PCI after controlling for patient demographics, comorbidities, and pre-procedural medication use. This observation may be related to financial considerations or to lower prevalence of academic or teaching affiliations among ASCs (30). One might also expect decreased FFR use with more severe lesions for which the indication to treat is apparent with angiography alone. However, we believe it is unlikely that lesion severity was higher on average in ASC PCI than in HOPD PCI but acknowledge that the data do not allow us to make this determination. Nevertheless, neither intravascular imaging nor FFR are reimbursed under new CMS policies (29), even though FFR and intravascular ultrasound guidance of elective PCI for stable ischemic heart disease have been associated with improved long-term outcomes compared with conventional angiography alone (31,32). Long-term follow-up for adverse outcomes in this patient population is

CENTRAL ILLUSTRATION Outcomes of Elective Percutaneous Coronary Intervention in Ambulatory Surgery Centers and Hospital Outpatient Settings

Li, K. et al. *J Am Coll Cardiol Interv.* 2021;14(3):292-300.

Forest plot comparing outcomes in ambulatory surgery center (ASC) and hospital outpatient department (HOPD) percutaneous coronary intervention (PCI) following propensity score matching. The propensity-matched cohort consisted of 849 ASC and 1,698 HOPD PCIs. The difference in the primary composite outcome of 30-day myocardial infarction, bleeding and vascular complications, or hospital admission between groups was not statistically significant. The odds of bleeding and vascular complications alone were increased with ASC PCI. Data are graphed on a logarithmic scale. CI = confidence interval.

therefore indicated given the relatively low observed use of these diagnostic tools in the ASC setting.

STUDY LIMITATIONS. First, the volume of elective ASC PCI was low compared with HOPD PCI. Additionally, the MarketScan databases include only patients with commercial or Medicare Supplement insurance plans. It is therefore possible that the population of patients who will undergo ASC PCI under new Medicare policies will differ from the patients in the present study, which could limit the generalizability of our results. External validity may also be limited by bias arising in database creation or from unmeasured confounders, for which propensity score analysis did not control.

Second, the accuracy with which administrative claims indicate exposures and outcomes may be limited by variation in coding practices between HOPDs and ASCs, specificity of diagnosis codes, or lack of data on clinical characteristics such as target vessel, extent of stenosis, vascular access site, and the severity of patient comorbidities and outcomes. Procedural history (e.g., PCI, CABG) prior to index PCI was also limited by the duration of data collection.

We are reassured that the prevalence of measured comorbidities between HOPD and ASC PCI were similar in magnitude prior to matching and that our measured incidence of early MI, bleeding complications, and hospital admission is in line with what has been reported previously (3,33,34) in different populations. Such limitations could nevertheless bias results toward the null hypothesis and therefore reduce our ability to discern differences between ASC and HOPD groups.

Finally, the short follow-up associated with this analysis did not allow evaluation of differences in long-term outcomes that might result from higher bleeding rates and lower use of intravascular imaging and coronary physiology assessment.

Despite these limitations, we believe that this analysis provides an informative first look at the potential clinical implications of increased elective PCI volume in freestanding ASCs under Medicare, given the relative paucity of data in this area. Further work is needed to characterize procedures performed in this setting and validate findings from the present study as more robust data for this population become available.

CONCLUSIONS

In this study of commercially insured patients undergoing outpatient elective PCI, we found differences in age, geography, and insurance coverage between ASC and HOPD PCI. We additionally found decreased use of FFR in ASCs, a tool associated with improved long-term outcomes. After propensity score matching, we did not observe a difference between HOPD and ASC PCI in our primary composite outcome of MI, bleeding complications, and hospital admission. However, ASC PCI was associated with increased odds of bleeding complications when assessed as an individual outcome, supporting the need for risk stratification prior to treating patients in the free-standing setting. Future ASC-specific data collection will allow further study of this population.

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PERSPECTIVES

WHAT IS KNOWN? With PCI in ASCs now reimbursable under Medicare, further understanding of patients treated in this setting is warranted.

WHAT IS NEW? We found no difference between hospital outpatient and ASC PCI in a primary composite outcome of 30-day MI, bleeding complications, and hospital admission, though the risk for bleeding complications as an individual outcome was higher in ASC PCI. We also observed decreased use of FFR in ASC PCI. Pre-procedural risk stratification will likely be an important component of maintaining high quality of care in the free-standing setting.

WHAT IS NEXT? Prior studies suggest that PCI performed with same-day discharge and without on-site surgical support is safe, but there have been no studies of procedures performed in ASCs specifically.

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- KEY WORDS** health services research, ischemic heart disease, outcomes, PCI, percutaneous coronary intervention
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- APPENDIX** For a supplemental table and figures, please see the online version of this paper.