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CARDIAC CATHETERIZATION LABORATORIES IN AMBULATORY SURGICAL CENTERS

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Introduction

There is growing clinical acceptance of performing cardiovascular procedures in ambulatory surgery centers (ASCs). The impetus is lower costs, increased patient satisfaction, and similar safety outcomes for suitable patients compared to performing these procedures in hospitals.[1] Treating patients in an ASC protects them from exposure to nosocomial (hospital-acquired) infections, and patients treated in ASCs therefore have fewer surgical site infections.[2,3] Delays are also less likely because ASCs only perform scheduled elective procedures. They are not subject to interruptions due to unexpected emergency surgeries. All these factors have increased interest in developing cardiac catheterization laboratories (cath labs, CCLs) in ASCs.

This article summarizes guidance on safety, efficacy, and patient selection for cath labs in ASCs from medical professional societies and the Centers for Medicare and Medicaid Services (CMS). It also discusses Medicare payment policies and the regulatory landscape for ASC-based CCLs in states with and without Certificate of Need (CON) laws.

Cardiac catheterization procedures are used to diagnose or treat certain heart conditions. These conditions include clogged arteries, irregular heartbeat, coronary artery disease, congenital heart disease, heart failure, heart valve disease, and microvascular disease. The procedures use a thin, flexible tube called a catheter, which is guided through a blood vessel to the heart.[4] A variety of tools can be attached to the catheter.

Percutaneous coronary intervention (PCI) is a category of minimally invasive therapeutic procedures used to open obstructed coronary arteries. In 1977, the first PCI, also known as

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[1] Jennifer Lubell, "Cardiovascular Services: The Next Wave in ASCs?" May 17, 2019, https://www.ormanager.com/cardiovascular-services-next-wave-ascs/.
[2] Ambulatory Surgery Center Association, Outcomes Monitoring Project, 3rd Quarter 2011, https://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare.
[3] Thomas D. Wilson, "Benchmarking Study of 1,000,000 Surgeries in ASCs Demonstrates Minimal Surgical Site Infections, Emergency Department Visits, and Readmission Rates," ASC Communications, August, 24, 2017, https://montereysurgerycenter.com/wp-content/uploads/2017/09/Beckers-Article-Benchmarking-Aug-24-2017.pdf.
[4] "Cardiac Catheterization," Mayo Clinic, https://www.mayoclinic.org/tests-procedures/cardiac-catheterization/about/pac-20384695.

coronary angioplasty, was performed. PCI is used to treat unstable angina, acute myocardial infarctions, and multivessel coronary artery disease. It is now one of the most commonly performed cardiac procedures[5] and has replaced coronary artery bypass graft (CABG) procedures for many patients. In October 1994, the *International Classification of Diseases, Ninth Revision*, created a new code to distinguish between angioplasty via balloon and angioplasty with a stent, further advances in PCI techniques.[6] Other new techniques and devices to improve outcomes and shorten recovery times have been developed. These advances have allowed hospitals to perform PCI on an outpatient basis.

Positions of Professional Societies

Initially, therapeutic catheterization procedures were only performed in hospitals with open-heart surgery backup. As clinicians gained experience, professional organizations published position statements supporting performing therapeutic cardiac catheterization procedures in a broader range of facilities. This section discusses the expert consensus documents on diagnostic cardiac catheterization procedures and PCI published in the last thirteen years.

2007 SCAI Expert Consensus Document

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an expert opinion document on PCI in facilities without on-site surgical backup. After summarizing available data and reviewing existing literature and other recommendations, SCAI defined best practices for facilities performing PCI without on-site cardiac surgery. They also made recommendations for patient safety, specifically stating:

[5] George Stouffer III, "Percutaneous Coronary Intervention (PCI)," *Medscape*, updated November 27, 2019, https://emedicine.medscape.com/article/161446-overview.
[6] Chuck Shih and Elise Berliner, "Diffusion of New Technology and Payment Policies: Coronary Stents," *Health Affairs* 27, no. 6 (Nov./Dec. 2008): 1566–1576, https://doi.org/10.1377/hlthaff.27.6.1566.

> *This is not an open endorsement of PCI without on-site surgery and we do not support wide-spread use of PCI without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.*[7]

SCAI recommended that the local area's health needs should be the defining factor when deciding to provide PCI in a setting without on-site cardiac surgery. It should not be a decision based on financial factors. Performance outcomes of a PCI program should use national benchmarks to evaluate outcomes. PCI providers without on-site surgery should perform at least 100 procedures a year, and no provider should perform PCI in this type of facility until they have completed at least 500 PCI procedures in their lifetime.[8] SCAI recommended quality assurance programs through an independent facility or external agency and stressed the importance of data collection and analysis for future care.

2011 ACCF/AHA/SCAI Guideline for PCI

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) created a Task Force on Practice Guidelines to develop, update, and revise practice guidelines for cardiovascular disease and procedures. The intention of the task force was to keep pace with advances and innovations in interventional cardiology. In 2011, the committee updated its PCI recommendations to consider elective PCI in hospitals without on-site cardiac surgical backup. They recognized that primary and elective PCI can be performed with high success, a low mortality rate, and a low rate for emergency surgery at hospitals. Primary PCI would be "reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished."[9] The committee highlighted the importance of tracking complication rates and patient outcomes in all PCI programs, and the committee urged a PCI program without on-site cardiac surgery to be considered only "if this

[7] G.J. Dehmer, J.C. Blankenship, T.P. Wharton Jr., et al., "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions," *Catheterization and Cardiovascular Interventions* 69, no. 4 (Mar. 2007): 476, https://doi.org/10.1002/ccd.21097.
[8] Dehmer et al., "Current Status," 477.
[9] G.N. Levine, E.R. Bates, J.C. Blankenship, et al., "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions," *Journal of the American College of Cardiology* 58, no. 24 (Dec. 2011): e65, https://doi.org/10.1016/j.jacc.2011.08.007.

program will clearly fill a void in the healthcare needs of the community," not for financial or market gain.[10]

2012 ACCF/SCAI Expert Consensus Document

In 2012, the ACCF and SCAI updated their 2001 expert consensus document on cath lab standards.[11] The update was prompted by the evolution in clinical practice and technology of cardiac catheterization over the past decade.

With information showing "remarkably low risk now associated with diagnostic cardiac catheterizations," the 2012 document stated:

> *The 2001 ACCF/SCAI consensus document suggests limiting diagnostic procedures in laboratories without cardiovascular surgical backup to the very lowest-risk patients; the current document lifts almost all these restrictions.* ***Limitations related to age, congestive heart failure (CHF) status, the severity in stress test abnormalities, left ventricular (LV) function, and the presence of valve disease have all been removed.***[12]

The document provides quality assurance standards, including the use of national databases to provide benchmarks to guide safe practices for cardiac catheterization procedures. Other standards were also discussed, such as laboratory environments for cardiac catheterization at a facility without cardiovascular surgery, quality assurance issues, procedural issues, post-procedural issues, personnel issues, hybrid laboratories, ethical concerns, x-ray imaging and radiation safety, and concerns regarding pediatric catheterization patients.

The ACCF and SCAI encouraged an active quality assurance system and participation in national registries, such as the American College of Cardiology's (ACC's) National Cardiovascular Data Registry (NCDR). They stressed the importance of tracking patient

[10] Levine et al., "ACCF/AHA/SCAI Guideline," e44–e122.
[11] T.M. Bashore, S. Balter, A. Barac, et al., "2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents," *Journal of the American College of Cardiology* 59, no. 24 (June 2012): 2221–2305, https://doi.org/10.1016/j.jacc.2012.02.010.
[12] Bashore et al., "2012 Consensus Update," 2225. Emphasis added.

outcomes and other outcome-related indicators (e.g., structural, patient care, cost-related, etc.) and a "serious commitment from the facility administration to ensure a robust QA/QI program is in place and the program committee is active and aggressive regarding its responsibilities."[13]

Although the consensus document suggested safety measures to allow procedures to be performed in an outpatient setting, it did not change its recommendation that patients with pulmonary edema due to ischemia, patients with complex congenital heart disease, and pediatric patients be treated only in full-service facilities with cardiovascular surgery.[14]

The ACCF/SCAI consensus included specific recommendations for PCI. It supported performing elective and primary PCI procedures in a facility without cardiovascular surgery if the facility strictly adhered to national guidelines. Top recommendations were a working relationship with a larger cardiovascular surgical services facility and an emergency transportation system, including a comprehensive system for urgent transfer of patients for cardiovascular surgical support.[15] The document also recommended that such a facility offering PCI needs to maintain a strong, active quality assurance/quality improvement (QA/QI) program and be operational 24 hours a day, 7 days a week, if an ST-elevation myocardial infarction (STEMI) program is in place. It highlighted minimum caseload volumes and training for interventional procedures as important safety standards. Standards for patient selection, procedural issues related to patient preparation (e.g., awareness of appropriate protective care from communicable diseases), technical hemodynamic issues, vascular hemostasis, and medication use were identified as important safety factors. The document stated physicians should clearly communicate all risks, benefits, and alternatives before receiving patients' consent to the place of service. Consent forms need to highlight the potential for emergency surgery. The authors also included standards for identifying high-risk patients for vascular hemostasis in post-procedural issues, including the use of the NCDR database bleeding risk score for PCI.

[13] Bashore et al., "2012 Consensus Update," 2226.
[14] The consensus document defined "full-service" as hospitals with cardiovascular surgery, cardiovascular anesthesia, and consulting services in vascular, nephrology, neurology, and hematology (Bashore et al., "2012 Consensus Update," 2224).
[15] Bashore et al., "2012 Consensus Update," 2227.

2014 SCAI/ACC/AHA Expert Consensus Document

In 2014, the SCAI, the ACC, and the AHA writing committee prepared an update to SCAI's 2007 expert consensus document. The goals of this document were to:[16]

- Determine current trends in the prevalence of PCI without on-site surgery in the US;
- Summarize new literature related to the performance of PCI without on-site surgery;
- Review existing guidelines, expert consensus documents, competency statements, and other documents related to PCI without on-site surgery, and summarize all relevant information into one resource document;
- Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
- Evaluate the role of PCI without on-site surgery within the US health care system.

This document was prepared after the number of PCI procedures decreased from 2006 to 2014, while the number of facilities performing PCI without on-site surgery increased. After analyzing literature on primary PCI, the committee found no difference for in-hospital or 30-day mortality between sites with and without on-site cardiac surgery.[17] The authors found recent studies of PCI without on-site surgery showed "no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery." for conditions other than STEMI.[18]

The 2014 document combined various recommendations from earlier publications to develop a unified recommendation with requirements for facilities, personnel, and off-site surgical backup. For facility requirements, the group emphasized the importance of quality review programs and expanded on the 2013 PCI Competency Document. It recommended transportation improvements and defined the "satisfactory outcomes" a laboratory must maintain to avoid closure, since no national definition for "satisfactory outcome" existed.[19] It

[16] G.J. Dehmer, J.C. Blankenship, M. Cilingiroglu, et al., "SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention without On-site Surgical Backup," *Journal of the American College of Cardiology* 63, no. 23 (June 2014): 2624–2641, https://doi.org/10.1016/j.jacc.2014.03.002.
[17] Dehmer et al., "2014 Update," 2625.
[18] Dehmer et al., "2014 Update," 2627.
[19] Dehmer et al., "2014 Update," 2634.

encouraged implementation of the SCAI Quality Toolkit and Accreditation for Cardiovascular Excellence (ACE) certification to improve quality.

The committee adopted guidelines for personnel, including quality metrics for facilities and operators. Training recommendations for staff included minimum training hours and experience requirements for PCI programs without on-site surgery. A new recommendation stated existing physicians should train new interventional cardiologists joining established PCI programs until they are determined to have acceptable skills, judgment, and outcomes. Since team consultation can be difficult when performing PCI without on-site surgery because of the limited interaction between cardiologists and cardiac surgeons, the committee encouraged the use of telemedicine to replace in-person interactions.

The writing committee concluded the growth in PCI procedures without on-site cardiac surgery warrants evaluation of programs based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in the service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document.[20] The document concluded:

> *This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery," and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations.*[21]

2020 SCAI Position Statement

In May 2020, SCAI published a position statement on performing PCI in ASCs. A working group of SCAI members with "significant prior experience with PCI in an ASC" wrote the paper, which was "intended to provide guidance for the development of an ASC-based PCI

[20] Dehmer et al. "2014 Update," 2636.
[21] Dehmer et al., "2014 Update," 2636.

program."[22] The authors "reviewed relevant clinical guidelines and consensus papers" on PCI in an outpatient setting and outcomes data from randomized trials supporting same-day discharge after PCI. They concluded:

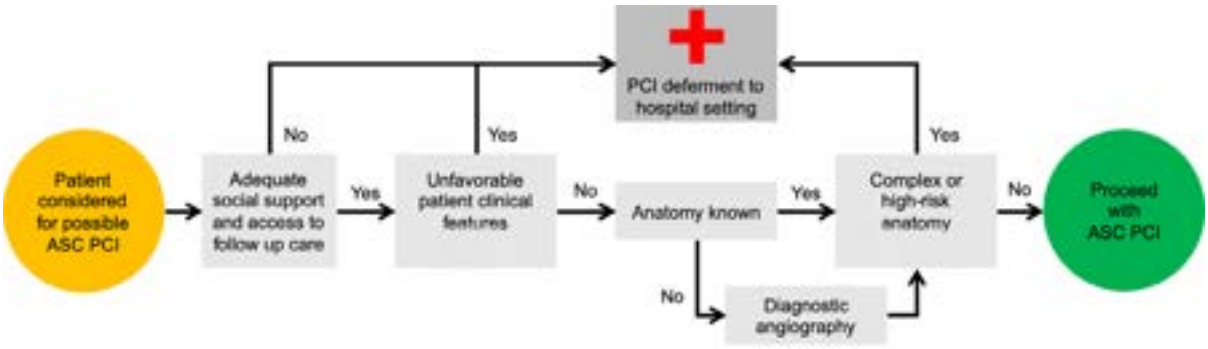
> *In appropriately selected patients for outpatient PCI, clinical outcomes for same-day discharge or routine overnight observation are comparable without any difference in short-term or long-term adverse events.*[23]

The document and its guidelines focused on PCI procedures in ASCs as a "foundation of principles to promote safe performance of elective PCI in ambulatory surgery centers."[24] To provide the highest quality of care in the safest environment, ASC-based cath labs should adopt the guidelines, policies, and best practices in the position statement. Patient selection characteristics and standards and quality assurance to bolster efficacy, safety, and accreditation were among the topics in the paper. They are discussed in more detail below.

Patient Selection

Not every patient is appropriate for PCI in an ASC. Careful patient selection is key to ensuring patient safety and good outcomes. SCAI's conceptual flow chart, reproduced below, provides a model for patient selection in an ASC.

SCAI Patient Selection Flow Chart



Source: Box et al., "SCAI Position Statement," 6.

[22] L.C. Box, J.C. Blankenship, T.D. Henry, et al., "SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers," *Catheterization and Cardiovascular Interventions* 96, no. 4 (May 2020), https://doi.org/10.1002/ccd.28991.
[23] Box et al., "SCAI Position Statement," 2.
[24] Box et al., "SCAI Position Statement," 8.

SCAI states that "patients with high-risk clinical features" and those with "complex or high-risk lesions characteristics" should not be treated in an ASC but in a hospital. Physicians should use the patient lesion characteristic guidelines in the table below when selecting patients for treatment at an ASC. Patients with unfavorable lesion characteristics should be treated in a hospital.

SCAI Patient Conditions and Lesion Characteristics Warranting PCI Deferment to a Hospital

Unfavorable Patient Conditions
• Decompensated CHF (NYHA class 3–4) • Recent TIA/stroke (<8 weeks) • Left ventricular ejection fraction < 30% • Chronic kidney disease with an estimated glomerular filtration rate < 45 ml/min/1.73 m2 • Anemia (Hgb < 9 g/dl) or coagulopathy (e.g., INR >1.5 or platelet count < 100 K) • Acute coronary syndrome • Severe pulmonary hypertension or disease (advanced COPD or patients on supplemental oxygen) • Unprotected left main stenosis or three-vessel CAD • Any cardiac or noncardiac signs of clinical instability • Significant PAD limiting femoral and radial access • Severe aortic stenosis • Severe contrast allergy • Operator judgment on other condition(s)
Complex or High-Risk Lesion Characteristics
• Bifurcation lesions with significant side branch involvement • Severe lesion calcification • Extremely angulated segment or excessive proximal tortuosity • Bypass graft lesions • Chronic total occlusions • Other vessel characteristics that the operator judges would impede stent deployment • Thrombus in target vessel or lesion • Unprotected left main lesions • Last remaining conduit • Possible need for upfront mechanical circulatory support

Source: Box et al., "SCAI Position Statement," p. 6.

Clinical staff should conduct a detailed assessment before a patient is scheduled for a procedure. This should include a morning-of-procedure assessment and a post-procedure assessment. Pre-procedure assessments should confirm the patient has appropriate clinical characteristics, adequate support at home, and transportation after the procedure. Post-procedure assessments should assess site hemostasis and whether the procedure was successful. Any patient needing treatment at a hospital per SCAI's guidelines should be referred or transported to a hospital.

Standards and Quality Assurance

Standards outlined in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards were adopted by the committee. The ACC CCL v2 accreditation, discussed in the "Accreditation" section below, incorporates the Consensus Document standards.[25] An ASC that attains CCL v2 accreditation meets the standards outlined in the 2012 Consensus Document.

A distinct post-procedure recovery room with adequate equipment, including telemetry, blood pressure cuffs and pulse oximetry, and additional emergency equipment[26] in a separate post-procedure room is necessary. All direct patient care staff should be American Cardiovascular Life Support (ACLS) certified, and all nursing services should be directed by a registered nurse with a BSN. The table below, reproduced from the SCAI position statement, summarizes key features of a high-quality ASC-based PCI program.

[25] American College of Cardiology, Cardiac Cath Lab Accreditation, available at https://cvquality.acc.org/accreditation/services/CCL.
[26] Box et al., "SCAI Position Statement," 4. Equipment includes pericardiocentesis tray, echocardiography/ultrasound, temporary transvenous pacemaker, covered stents, mechanical circulatory support, ACLS supplies, and an on-site provider with expertise in endotracheal intubation and airway management.

Key Features of a High-Quality ASC PCI Program

Pre-Procedural	Procedural	Post-Procedural
Appropriate informed consent, including risk of transfer for complications	Established criteria for high-risk coronary anatomy that require transfer for safe PCI performance	Appropriate documentation of required data elements for cath and PCI reporting
Appropriately trained staff and PCI operators	Appropriate training/supplies for conscious sedation	Registry participation to evaluate procedural outcomes and appropriateness
Established quality insurance program for continuous peer review of quality and outcomes	Emergency preparedness protocols in place	Established criteria for clinical indications for transfer to acute care facility
Written transfer agreements with hospitals and surgeons	Mock transfer drills with EMS and "receiving" hospital	Evaluation of acute care required within 1 month after discharge
Established clinical criteria for determination of high-risk patients	Ability for real-time image review for CT surgical consultation	Appropriate clinical follow-up scheduled within 1–2 weeks of PCI

Source: Box et al., "SCAI Position Statement," p. 7.

Accreditation

Cath labs in ASCs should meet the standards in the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards.[27] The ACC offers Cardiac Catheterization Laboratory v2 (CCL v2) accreditation incorporating the ACC and SCAI standards and other evidence-based quality initiatives.[28] Leading interventional cardiologists and cath lab administrators created CCL v2 accreditation[29] to improve care in cath labs in hospitals and ASCs. Attaining ACC CCL v2 accreditation ensures a cath lab meets the high standards of the ACC and SCAI.

[27] Bashore et al., "2012 Consensus Update," 2305.
[28] American College of Cardiology, "Features and Benefits of Cardiac Cath Lab Accreditation," https://cvquality.acc.org/accreditation/services/CCL/CCLBenefits#:~:text=Features%20and%20Benefits%20of%20Cardiac,based%20science%20with%20quality%20initiatives.
[29] American College of Cardiology, "Features and Benefits."

Accreditation for CCL v2 requires participation in the NCDR CathPCI Registry. This registry captures data on characteristics, treatments, and outcomes of patients who receive diagnostic cardiac catheterizations and PCI. Data captured by the registry measure adherence to ACC and AHA clinical practice guidelines, performance standards, and appropriate use criteria. The CathPCI Registry analyzes reported data and gives providers the necessary metrics. The data collected are not static. For example, CathPCI developed a new COVID-19 data set "to provide key insights on the quality of care and outcomes of heart disease in the COVID-19 era."[30]

Quality of care in an accredited ASC must equal or exceed that of a hospital cath lab. ACC accreditation has six essential components, each with mandatory requirements:

1. Governance
    - Designated medical director, with position description
    - Process to monitor and track physician credentials
    - Written charter
    - Annual staff education
    - Competencies for low-volume, high-risk procedures
    - Formation of multidisciplinary team and quarterly meetings
    - Preliminary and final report requirements
    - Requirements for sites without on-site cardiothoracic surgery
2. Quality
    - Quality Assurance and Process Improvement Plan (QAPI)
    - Requirements for new staff orientation
    - Process for inventory management and new products
    - Monitoring and tracking CathPCI Registry metrics
    - Infection control guidelines to reduce patient risk

[30] American College of Cardiology, National Cardiovascular Data Registry, Hospital Registries, CathPCI Registry, https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry.

- Formal process to monitor and track radiation exposure for patients, staff, and physicians
- Same-day discharge inclusion and exclusion criteria
- Process to track annual volumes

3. Pre-Procedure
    - Pre-procedural requirements and checklist
    - Defined screening to identify patients at risk for bleeding
    - Identify and address patients at risk for contrast-induced nephropathy or contrast reactions
    - Access site evaluation
    - Requirements for cardiovascular implantable electronic devices
4. Peri-Procedure
    - Procedural hemodynamic monitoring
    - Universal Time Out requirements
    - Guideline-driven medical therapy in the CCL
    - Protocol for peri-procedural complications and treatment modalities available
    - Process to ensure safe working equipment, availability of ventricular assist devices, and competencies
    - Coagulation monitoring
5. Post-Procedure
    - Communication process with patient's family
    - Process outlining post-procedure report requirements
    - Protocol for sheath management and medication administration
    - Process that identifies appropriate recovery for the CCL patient
    - Process to ensure discharge instructions provided, with all patients receiving a follow-up phone call within 24 hours
6. Clinical Quality
    - QAPI initiative that results in improvement in care and safety in at least two NCDR CathPCI Registry Measures

Evolution of CMS Payment Policy on Cardiac Catheterization Procedures

The Center for Medicare and Medicaid Services (CMS) and related federal agencies have for many years studied which cardiac procedures could be safely performed on hospital outpatients and on ASC patients. Once it deems procedures safe in an outpatient setting, CMS adds them to the list of outpatient procedures Medicare will pay for in a hospital, in an ASC, or in both. CMS payment policies are important not only because CMS is the largest single payor, but because private health plans tend to adopt CMS policies.

In 2005, the Agency for Healthcare Research and Quality (AHRQ) commissioned a technology assessment on cardiac catheterization in freestanding clinics. They assessed complication rates for diagnostic and interventional catheterization procedures, patient characteristics, and current state regulations. The results, as well as public comment, caused CMS to repeal section 20.25 of the National Coverage Determination (NCD) Manual, also known as the "Medicare National Coverage Policy for Cardiac Catheterization Performed in Other Than a Hospital Setting." The repeal removed the requirement for fiscal intermediaries (FIs) to request a Peer Review Organization review of a freestanding clinic before approving Medicare payment for cardiac catheterizations in that facility.[31] Determination of coverage for cardiac catheterization procedures performed outside a hospital became the decision of the local Medicare FI.[32]

In 2018, CMS paid ASCs for peripheral (non-cardiac) revascularization, pacemaker, and implantable defibrillator surgeries in Alaska, Arizona, California, Colorado, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Missouri, Nebraska, New Jersey, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Washington, and

[31] "Cardiac Catheterization Performed In Other Than A Hospital Setting (CAG-00166N)," CMS Decision Memo, January 12, 2006, https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=15&NcaName=Cardiac+Catheterization+Performed+In+Other+Than+A+Hospital+Setting&fromdb=true.

[32] "Cardiac Catheterization Performed in Other Than a Hospital Setting," CMS Manual System, Pub. 100-03: Medicare National Coverage Determinations, Transmittal 46, January 27, 2006, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R46NCD.pdf.

Wisconsin. The most commonly performed peripheral revascularization, pacemaker, and defibrillator procedures at ASCs and their Current Procedural Terminology (CPT) codes were:

- CPT code 33208: insertion of new or replacement permanent pacemaker with transvenous electrodes, atrial and ventricular (CMS paid for 709 procedures at ASCs)
- CPT code 33228: removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual-lead system (CMS paid for 682 procedures at ASCs)
- CPT code 33249: insertion or replacement of permanent implantable defibrillator system, with transvenous leads, single or dual chamber (CMS paid for 412 procedures at ASCs)

CMS has approved a growing list of cardiac catheterization procedures for Medicare payment in ASCs. Before approving payment for a procedure in an ASC, CMS publishes the proposed payment policy in the *Federal Register* as a proposed rule for public comment. Professional societies, individual physicians, and medical associations submit statements that support or oppose adding procedures to the list. CMS reviews and responds to the comments and the available data on safety and clinical appropriateness. It then publishes a final rule announcing which procedures it will pay for if done in an ASC.

In 2019, CMS published a list of twelve cardiac catheterization-related procedures[33] it proposed to pay an ASC if done on appropriate Medicare patients. CMS determined the twelve procedures did not represent a significant safety risk when performed in an ASC and would not require active medical monitoring and care requiring an overnight stay.[34] The final rule added five more CPTs, for a total of seventeen covered procedures. CMS started paying ASCs for these

[33] The CPT codes in the CY 2019 ambulatory surgical center final rule cover vascular, electrophysiology, and diagnostic cardiac cath procedures, and are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-FC, accessed August 18, 2022.
[34] 83 *Fed. Reg.* 59045 (Nov. 21, 2018).

procedures in calendar year (CY) 2019. The ASC Covered Procedures List (CPL) was expanded to include six additional CPT codes for PCI procedures.[35]

In 2019, CMS proposed adding twelve cardiac catheterization procedures to the ASC CPL. CMS described the procedures as:

> *Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.*[36]

After reviewing clinical characteristics of the twelve procedures and consulting with stakeholders about safety, CMS determined:

> *After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these 12 procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure.*[37]

Most commenters on the safety of the twelve proposed cardiac catheterization procedures agreed that beneficiary safety was not at risk and cost savings would be achieved by moving the twelve cardiac catheterization procedures out of the more expensive hospital setting to an outpatient setting. The ACC agreed with CMS's clinical assessment of safety in an ASC.[38]

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[35] These CPT codes include: 92920 (percutaneous transluminal coronary angioplasty, single major coronary artery or branch), 92921 (PTCA, each additional branch of a major coronary artery), 92928 (percutaneous transcatheter placement of intracoronary stents with coronary angioplasty, single major coronary artery or branch), 92929 (percutaneous transcatheter placement of intracoronary stents with coronary angioplasty, each additional branch), C9600 (percutaneous transcatheter placement of drug-eluting intracoronary stents with coronary angioplasty, single major coronary artery or branch), and C9601 (percutaneous transcatheter placement of drug-eluting intracoronary stents with coronary angioplasty, each additional branch).

[36] 83 *Fed. Reg.* 59044–59045 (Nov. 21, 2018).

[37] 83 *Fed. Reg.* 59045 (Nov. 21, 2018).

[38] C. Michael Valentine to Seema Verma, RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model [CMS-1695-P], September 24, 2018, p. 9, https://www.acc.org/-/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Latest-in-Cardiology/Advocacy-and-Policy/ACC_OPPS_Comments_Letterhead-9_24_18.pdf?la=en&hash=EAC2E950D960B5618C2166B325240EF5FF9D26F7.

Citing safety concerns, some commentors opposed moving these procedures to an ASC setting. One commentor suggested a requirement that ASCs meet facility standards that mirror hospital-based cardiac catheterization standards before allowing the twelve procedures to be covered. Other commentors expressed concerns that the additional procedures would cause "cherry picking," which would mean hospital outpatient departments (HOPDs) had sicker and higher-cost patients. CMS disagreed with the comments on increased risk to beneficiary safety, stating:

> *Many of these procedures are already performed safely in the physician's office setting. The procedures have been reviewed by CMS medical officers and we have assessed each against the regulatory safety criteria and believe that they meet all of those criteria. Further, we believe these procedures are clinically similar to peripheral endovascular procedures which are already currently included on the ASC CPL.*[39]

CMS determined the twelve procedures could be safely performed in an ASC because their clinical characteristics are similar to other procedures on the ASC CPL. CMS also noted that existing conditions of coverage for ASCs (e.g., regulation 42 C.F.R. §416.166(c)) protect patients because they prohibit ASC payment for procedures that generally result in substantial blood loss or major or prolonged invasion of body cavities, or directly involve major blood vessels.[40] In response to the "cherry-picking" comments, CMS agreed this could happen but did not believe it was a reason to prohibit procedures.

Commentors proposed adding cardiovascular procedures to the ASC CPL. CMS agreed to include five additional cardiac catheterization procedures, and stated:

> *We believe these procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, and are separately paid under the OPPS.*[41]

Seventeen cardiac catheterization procedures were added to the ASC CPL in 2019.

[39] 83 *Fed. Reg.* 59045 (Nov. 21, 2018).
[40] 83 *Fed. Reg.* 59045 (Nov. 21, 2018).
[41] 83 *Fed. Reg.* 59046 (Nov. 21, 2018).

After receiving comments in support and opposition, CMS determined in 2019 that certain PCI procedures, specifically the coronary CPT codes 92920 and 92928, "can be safely performed in the ASC setting, for certain Medicare patients," and that "expert consensus, clinical guidelines, and clinical studies establish that percutaneous coronary interventions can be safely performed in an ASC setting."[42] The ACC and SCAI wrote letters supporting the addition of PCI procedures. The ACC stated its agreement with "CMS's clinical assessment that these procedures can safely be performed in the ASC setting" and recommended ASCs follow guidance in the 2014 SCAI/ACC/AHA Expert Consensus Document to ensure quality of care. The ACC stated, "Allowing these PCI procedures to be performed in an ASC is in line with CMS's goals to expand access to services and encourage the delivery of care in the lowest cost setting."[43] Similarly, SCAI stated:

> *Elective, non-emergent percutaneous coronary angioplasty and coronary stenting procedures have relatively low complication rates and are not expected to pose a significant risk to Medicare beneficiary safety and do not typically require inpatient level care following the procedure.*[44]

SCAI noted the importance of ensuring that PCI patients in ASC settings receive the same quality of care as their counterparts in hospital outpatient settings. Its detailed recommendations for ensuring quality of care are discussed in the 2020 SCAI Position Statement.

Medicare began paying for PCI procedures in an ASC setting on January 1, 2020. In response to comments submitted by stakeholders in the 2018 Medicare Hospital Outpatient Prospective Payment System (OPPS)/ASC final rule comment period, CMS expanded the ASC payment system's definition of "surgery" to include "surgery-like" cardiac catheterization procedures with CPT codes outside of the surgical range.[45] CMS acknowledged certain

[42] 84 *Fed. Reg.* 61387 (Nov. 12, 2019).
[43] Richard Kovacs to Seema Verma, September 27, 2019 (RE: CMS-1717-P).
[44] Ehtisham Mahmud to Seema Verma, August 27, 2019 (RE: CMS-1717-P).
[45] Since implementation of the ASC prospective payment system, CMS has defined a "surgical" procedure as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as "surgery" (CPT codes 10000–69999) (72 *Fed. Reg.* 42478). Also included are "surgical" procedures described by Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS (72 *Fed. Reg.* 42478).

cardiovascular procedures outside of the CPT surgical range are similar to procedures within it. They also considered the AMA's statement advising against strict classification of procedures within a specific section of its CPT code manual.[46] Recognizing the CPT surgical range as a guide, as opposed to a strict determination, allowed flexibility to include "surgery-like" procedures in the ASC CPL.

Difference in Payment for HOPDs and ASCs

ASCs are a cost-saving alternative for cardiac procedures of interest because the Medicare allowed amounts in ASCs are lower than the allowed amounts for the same CPT codes in HOPDs. Attachment 1 compares the average outpatient allowed amount for CPT codes 33208, 33228, and 33249 at ASCs and at hospitals by state for Medicare patients.

- For CPT code 33208, average ASC allowed amounts varied from 64.47% to 79.37% of outpatient hospital allowed amounts.
- For CPT code 33228, average ASC allowed amounts varied from 71.60% to 87.33% of outpatient hospital allowed amounts.
- For CPT code 33249, average ASC allowed amounts varied from 82.93% to 93.85% of outpatient charges.

CMS calculates payment for outpatient cardiac procedures of interest differently for ASCs and hospitals, which translates to cost savings for Medicare and Medicare beneficiaries and for health plans and their members that base allowed amounts on Medicare fee schedules. CMS estimated that moving 5 percent of coronary interventions nationwide from a hospital outpatient setting to ASCs would reduce Medicare payments by about $20 million and beneficiary copays by about $5 million in 2020.[47]

Medicare employs the same methodology for determining ASC and outpatient hospital payment, but it applies a lower conversion factor in determining allowed amounts for ASCs. For

[46] 83 *Fed. Reg.* 59029 (Nov. 21, 2018).
[47] Todd Neale, "CMS Finalizes Rule Allowing Reimbursement of PCI in Ambulatory Centers," *tctMD/the heart beat*, November 4, 2019, https://www.tctmd.com/news/cms-finalizes-rule-allowing-reimbursement-pci-ambulatory-centers.

2022, the conversion factor for ASC payment ($49.92) is 60 percent of the hospital outpatient factor ($84.18). Allowed amounts for ASCs are further reduced by multiplying the base ambulatory payment classification (APC) weight by a weight scalar. In 2022, that weight is 0.8552.[48] The table below summarizes the difference between 2022 Medicare payments to hospitals versus ASCs for outpatient procedures.

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[48] 86 *Fed. Reg.* 63812 (Nov. 16, 2021).

Medicare Reimbursement for Outpatient Procedures at Hospitals and ASCs

	Outpatient Hospital	ASC
2022 Conversion Factor[49]	$84.18	$49.92
Step 1	Assign services to APC group based on resource requirements of services	
Step 2	APC Relative Weight	**88.5%** of APC Relative Weight
Step 3	**60%** of APC = Labor Portion	**50%** of APC = Labor Portion
Step 4	Determine Wage Index based on Geographic Location	
Step 5	Labor Portion x Wage Index	
Step 6	**40%** x APC = Non-Labor Portion	**50%** of APC = Non-Labor Portion
Step 7	Payment Rate = ((Labor Portion x Wage Index) + Non-Labor Portion) x Conversion Factor	

CMS has a different payment method for "device-intensive procedures" for which the device accounts for over 30 percent of the total payment. For these procedures, the ASC payment is divided into a device portion and a non-device portion. The ASC receives the same amount as a hospital for the device portion.[50] The non-device portion is paid at the standard ASC rate, using the methodology described above.

[49] "Ambulatory Surgical Center Services Payment System," MedPAC, October 2022, https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_ASC_FINAL_SEC.pdf; "Outpatient Hospital Services Payment System," MedPAC, October 2022, https://www.medpac.gov/wp-content/uploads/2022/10/MedPAC_Payment_Basics_22_OPD_FINAL_SEC_v3.pdf.
[50] "Ambulatory Surgical Center Services Payment System," MedPAC, October 2020, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/payment-basics/medpac_payment_basics_20_asc_final_sec.pdf.

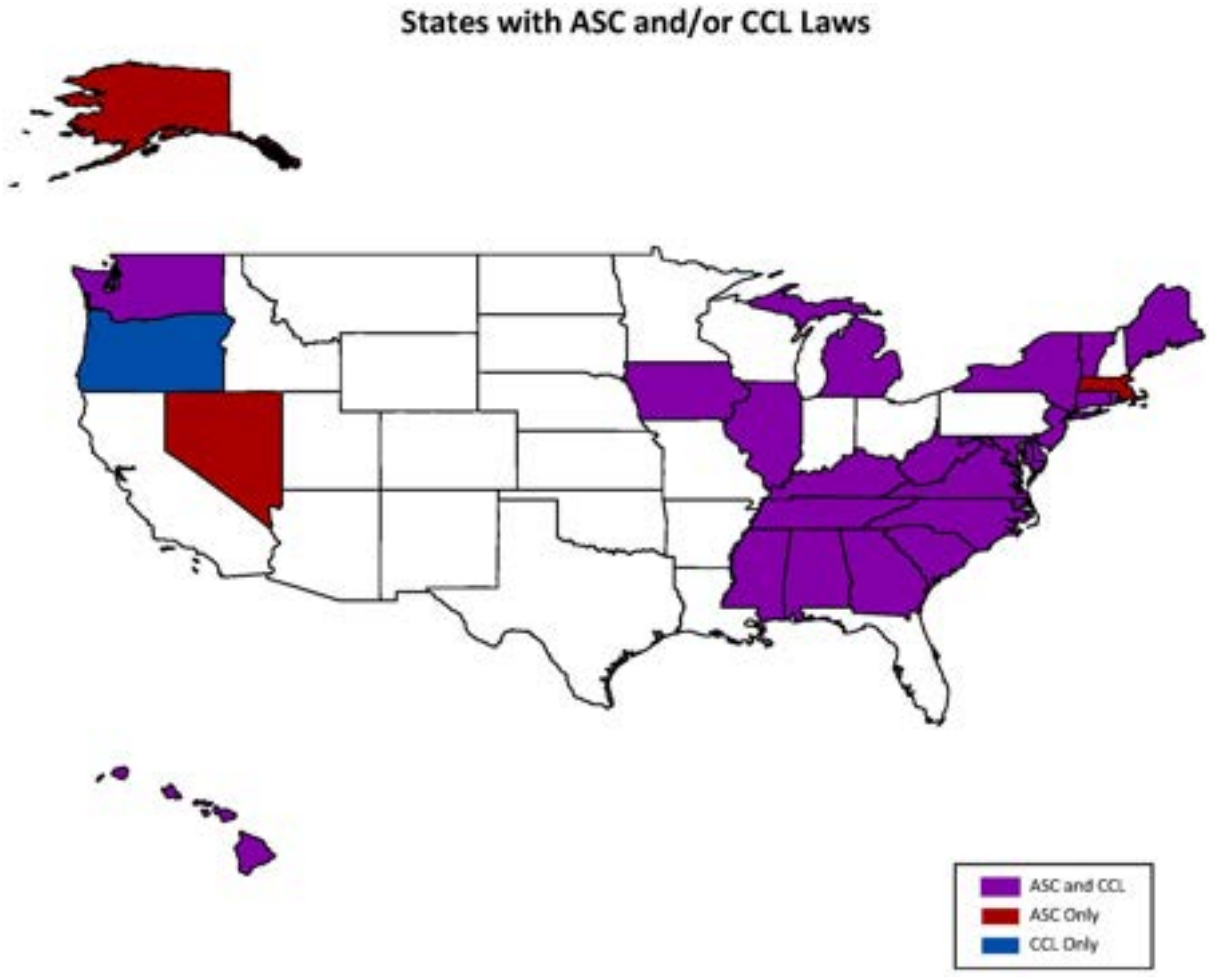
CMS is not the only payor that permits performing cardiac procedures in the ASC setting. With state licensure and payor agreements, several private payors, including United Healthcare, Cigna, and Humana, already pay for procedures such as coronary stenting in ASCs.

State Regulations Affecting Development of Cardiac Catheterization Laboratories

Although ASCs are widely accepted by clinicians and by Medicare as a setting for cardiac catheterization procedures, many states still have laws that restrict the development of cardiac cath labs in ASCs. Restrictions in state CON laws and state licensure laws prevent ASCs from performing cardiac catheterization procedures. It is expected there will be ongoing efforts to revise regulations in states that restrict such services, as payors and professional organizations continue to endorse therapeutic cardiac catheterization procedures in ASCs.

CON programs are intended to prevent overutilization, control costs, and improve quality by regulating new facilities and capital equipment purchases. Currently, 26 states have a CON law that regulates development of freestanding ASCs, and 24 states have CON regulations for development of cardiac cath labs.[51] Some states have CON policies that apply only to cardiac cath labs in certain settings. For example, cardiac catheterization services only require CON approval in Nevada if they are the addition to a facility in rural Nevada and expenditure is greater than $2 million.[52] CON policies restrict the introduction of new cardiac cath facilities, thus minimizing competitive pressures on existing facilities. The table below shows states with ASC and/or CCL laws.

[51] "Certificate of Need (CON) State Laws," National Conferences of State Legislatures, https://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx, accessed September 13, 2022.
[52] Nevada Revised Statutes (NRS) 439A – Planning for the Provision of Health Care, https://www.leg.state.nv.us/nrs/NRS-439A.html#NRS439A.



The most recent Medicare data RPC had as of the date of this report was for CY 2020, the first year Medicare paid for PCIs in ASCs. In 2020, ASCs in 28 states performed cardiac catheterization services on Medicare beneficiaries. PCIs were performed in ASCs in Florida, Louisiana, Missouri, Oklahoma, and Texas. None of these states have CON laws regulating ASCs or cardiac catheterization services.

Development of ASC-Based Cardiac Catheterization Services in States without CON Laws

ASCs in Florida are allowed to perform cardiac catheterization services, including PCI. Florida does not require CON approval to develop an ASC or a CCL. However, the Agency for Health Care Administration (AHCA) has adopted administrative rules with criteria for designating hospital programs as Adult Inpatient Diagnostic Cardiac Catheterization Level I

programs that can perform adult PCI without on-site cardiac surgery, and Level II programs that can perform PCI with on-site cardiac surgery. They require these programs to comply with the most recent ACC and AHA guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[53]

California has no CON law but currently restricts cardiac catheterization services to hospitals only.[54] On February 21, 2021, the California State Assembly introduced Assembly Bill 370,[55] "The California Outpatient Cardiovascular Patient Safety, Cost Reduction, and Quality Improvement Act" (the "Bill"). The Bill would have authorized the State Department of Public Health to grant certain ASCs permission to provide elective cardiac cath lab services and elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients. The Bill received support from the California Medical Association, the California chapter of the ACC, and the SCAI. The Service Employees International Union in California (SEIU CA), one of the most powerful groups in California politics, opposed the Bill.[56] The Bill did not get out of committee, and it died upon adjournment of the legislative session.

Development of ASC-Based Cardiac Catheterization Services in States with CON Laws

RPC has extensive experience working with clients in the southeastern US and is well-versed in the CON rules governing the introduction of new facilities and services in these states. In 2021, RPC aided a client in obtaining CON approval for Alabama's first non-hospital-based cardiac cath facility. The paragraphs below summarize the current regulations and CON activity for cardiac catheterization services in Alabama and several other southeastern states.

[53] "Licensed Hospital Programs," AHCA, https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/LicHospPrograms.shtml.
[54] California Health and Safety Code, Division 2, 1:1255.
[55] California Assembly Bill 370, LegiScan, https://legiscan.com/CA/text/AB370/2021.
[56] Stephen Abresch, "States Take Steps to Allow Cardiac Procedures in ASCs," ASC Focus, December 2021, https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/states-take-steps-to-allow-cardiac-procedures-in-ascs.

Alabama

The Alabama CON program regulates development of new ASCs and new cath labs. The CMS Physician and Other Supplier Public Use Data File shows Medicare beneficiaries had over 29,000 cardiac procedures of interest in Alabama in 2017. Almost 97 percent of these procedures were performed in hospitals, while the remainder were performed in physician-office–based laboratories. To date, no ASCs in Alabama have been approved to provide cath lab services.

The Heart and Vascular Institute of Alabama (HVIA) received CON Review Board approval for the state's first single-specialty cardiology ASC. The new ASC in Montgomery will provide endovascular and cardiac catheterization procedures. HVIA overcame heavy opposition from Montgomery hospitals with cardiac catheterization services. Barring a judicial reversal of the CON Board's decision, the new ASC is scheduled to open in 2024.

The ASC will initially perform only diagnostic procedures, due to restrictions in the Alabama State Health Plan that have been interpreted to allow PCI only in hospitals. HVIA submitted a proposed amendment to remove those restrictions and allow licensed ASCs to perform diagnostic and therapeutic services, including PCI. This would ensure the Alabama State Health Plan follows standards adopted by cardiology professional bodies such as the SCAI, AHA, and ACC.

Georgia

Georgia classifies adult cardiac catheterization services as a specialized service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). An ASC can be a DTRC. A CON is required to establish or expand adult cardiac catheterization services. Pediatric cardiac catheterization can only be provided in a pediatric tertiary hospital.[57] Applicants must document that existing licensed cardiac catheterization services will not perform less than 80 percent of

[57] Rules and Regulations of the State of Georgia, Georgia Administrative Code, Rule 111-2-2-.23: Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery, https://rules.sos.ga.gov/gac/111-2-2-.23.

maximum capacity because of the establishment of the new service.[58] Applicants must also demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent version of the ACC/AHA's "Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories." In 2013, two licensed DTRCs in Georgia were approved to perform outpatient cardiac catheterization procedures. There are no pending or approved applications for cardiac catheterization.[59]

Michigan

Michigan's CON Commission revised its review standards for cardiac catheterization services in June 2021. The updated rules allow freestanding surgical outpatient facilities to apply for a CON to perform PCI procedures. The new standards require an ASC to: (1) identify at least one interventional cardiologist performing procedures who meets a minimum volume threshold of at least 50 PCI sessions annually during the most recent 24-month period; (2) identify trained nursing and technical cath lab staff with experience treating acutely ill patients; (3) have a lab equipped with optimal imaging systems; and (4) obtain a written transfer agreement with a hospital that performs open heart surgery within 30 minutes' travel time.[60] Several CON applications have been filed, and ASCs in Michigan could begin performing PCI procedures by the end of 2022.

Mississippi

Mississippi was the first state to change its rules to allow PCI procedures in ASCs. Mississippi opened its first cardiovascular ASC in September 2022.[61] The 2020 Mississippi State Health Plan included two new licensing categories of ASCs allowed to perform PCI procedures.

[58] Rules and Regulations of the State of Georgia, Georgia Administrative Code, Rule 111-2-2-.21: Specific Review Considerations for Adult Cardiac Catheterization Services, https://rules.sos.ga.gov/GAC/111-2-2-.21.
[59] "2022," https://weblink.dch.georgia.gov/WebLink/Browse.aspx?id=969429&dbid=1&repo=HealthPlanning&cr=1, accessed October 25, 2022.
[60] Michigan Department of Health and Human Services, CON Review Standards for Cardiac Catheterization Services, §4:(2)(a).
[61] Jaylan Wright, "Mississippi's First Ambulatory Cardiovascular Surgery Center Opens," WJTV, September 28, 2022, https://www.wjtv.com/living-local/focused-on-health/mississippis-first-ambulatory-cardiovascular-surgery-center-opens/.

The influence of hospitals was apparent in this expansion, however. The new regulations allow cardiac catheterizations to be performed only by acute care hospitals, hospital-owned cardiac ambulatory surgical facilities (CASFs), or joint venture cardiac ambulatory surgical facilities (JV-CASFs).[62] An exception can be made for non-hospital–owned CASFs only where the applicant demonstrates support for the proposed project "from all acute care hospitals which offer cardiac catheterization services and/or PCI services that are located within a 25-mile radius of the proposed facility."[63] Mississippi does not regulate single-specialty ASCs through CON law.

Applicants must meet CCL requirements regardless of facility type. Any facility performing diagnostic cardiac catheterizations without open heart surgery capabilities must document formal referral agreements with nearby facilities to provide emergency cardiac services, maintain screening protocols to prevent high-risk patients from being catheterized in the facility, and document that the facility is not performing higher-complexity procedures. The volume threshold for diagnostic cath labs is 300 procedures by the facility's third year of operation. Therapeutic cardiac catheterization services may not be performed at any facility without open-heart surgery capability.

North Carolina

North Carolina requires a CON to initiate cardiac catheterization services or to purchase new or used cardiac cath equipment. To be approved for a CON to acquire fixed cardiac cath equipment, there must be a need determination in the State Medical Facilities Plan (SMFP) for cardiac cath equipment in the county. Cardiac cath units may be in an ASC.[64] All existing fixed cardiac cath equipment is in hospitals. In 2021, Wilmington Ambulatory Surgery Center filed a change of scope CON application to add a cardiac cath lab at its approved freestanding ASC in New Hanover County. The proposed project would have added a cath lab to the one-OR facility

[62] FY 2020 Mississippi State Health Plan, §515.06(2).
[63] FY 2020 Mississippi State Health Plan, §515.06(2).
[64] North Carolina G.S. 131E-176, https://www.ncleg.net/enactedlegislation/statutes/html/bysection/chapter_131e/gs_131e-176.html.

under development. The competitive application was denied, and the CON was awarded to a hospital.

South Carolina

South Carolina requires all cath labs performing both diagnostic and therapeutic procedures to be located in hospitals that provide open heart surgery. It also requires an applicant for a fixed diagnostic catheterization service to project at least 200 annual procedures by year 3 of operation, without reducing utilization at any existing diagnostic cath labs in the service area to fewer than 200 diagnostic cardiac catheterization procedures. Cath labs in facilities without on-site surgical backup must have formal policies for emergency transfer of patients to the nearest cardiac surgical facility, and must have written agreements with these facilities and with ambulance or emergency transport services. Requirements also govern the equipment and staffing standards of cardiac cath labs. An applicant proposing a new cath lab must demonstrate the safety and acceptability of cardiac catheterization procedures in this setting. No CON applications have been submitted for ASC-based cardiac cath labs.[65]

Tennessee

Tennessee allows freestanding ambulatory surgery treatment centers (ASTCs) to perform diagnostic cardiac catheterization procedures but not therapeutic procedures. Mobile cardiac cath units may perform therapeutic procedures only when the unit is on a hospital campus where open heart surgical services are available. Applicants must meet specific standards and criteria as described in the State Health Plan. These standards include a minimum volume threshold of 300 weighted diagnostic procedures per year, review protocols that screen for high-risk and unstable patients, and requirements that every physician must be a board-certified or

[65] The current (2020) South Carolina Health Plan includes wording that can be interpreted to exclude non-hospital facilities from submitting applications for cardiac cath services. Under General Standard 16.b(1), prospective applicants are referred to as "applicant hospitals." Per the South Carolina Department of Health & Environmental Control, the plan is scheduled for an update in November 2022, at which time this language may be revised to include non-hospital-based services.

board-eligible cardiologist and at least one cardiologist has performed an average of 75 or more diagnostic catheterization procedures each year for the past five years.[66]

On August 1, 2022, two CON applications were submitted for freestanding ASTC projects that would include diagnostic cardiac catheterization services. The Tennessee Health Facilities Commission reviewed these applications. Karing Hearts Cardiology Heart and Vascular Center applied for a single-specialty ASTC to be co-located with a cardiology medical office in Washington County, Tennessee. Their application was approved with the condition it will be limited to cardiac device implantation and related procedures and diagnostic cardiac catheterization.[67] Metropolitan Ambulatory Surgery Center applied for a single-specialty ASTC to initiate diagnostic cardiac catheterization services in Shelby County, Tennessee. Its application was denied on October 26, 2022, after receiving opposition from hospitals in Shelby County.[68]

Virginia

Virginia requires Certificate of Public Need (COPN) authorization for new cardiac cath labs, regardless of the facility type. The COPN application process and batching cycle is the same for hospitals and ASCs. New fixed-site cardiac catheterization services may not be approved unless all existing providers in the health planning district perform an average of 960 diagnostic-equivalent cardiac catheterization procedures per lab and the new service will perform an average of 500 procedures by year 2 of operation.[69] No new cardiac cath lab may be approved unless it is on the campus of a general or community hospital. Virginia has no existing outpatient cardiac cath facilities, and there have been no recent applications for ASC-based cardiac catheterization services.

[66] State of Tennessee, State Health Plan (2009 Edition), Appendix B – Revised and Updated Standards and Criteria for Cardiac Catheterization Services, https://www.tn.gov/content/dam/tn/health/documents/State_Health_Plan_2009.pdf.
[67] Agenda Results, State of Tennessee Health Facilities Commission, September 2022, https://www.tn.gov/content/dam/tn/hsda/documents/Agenda-Results-September2022.pdf.
[68] Email correspondence with Lowavia Eden-Hoback, October 26, 2022.
[69] Virginia State Medical Facilities Plan, 12 VAC 5-230-370.

Conclusion

Many cardiac catheterization procedures can be performed safely and effectively in an outpatient setting on appropriate patients. For patients, ASCs offer lower costs, lower risk of infection, and more convenient scheduling than HOPDs. Medicare and other major payors have recognized this and pay for these procedures in ASCs. s CON laws and other state laws still restrict development of cardiac cath labs in ASCs in many states, but the trend is toward expanding the number of states that allow cardiac cath labs and allowing therapeutic catheterization procedures in ASCs.