

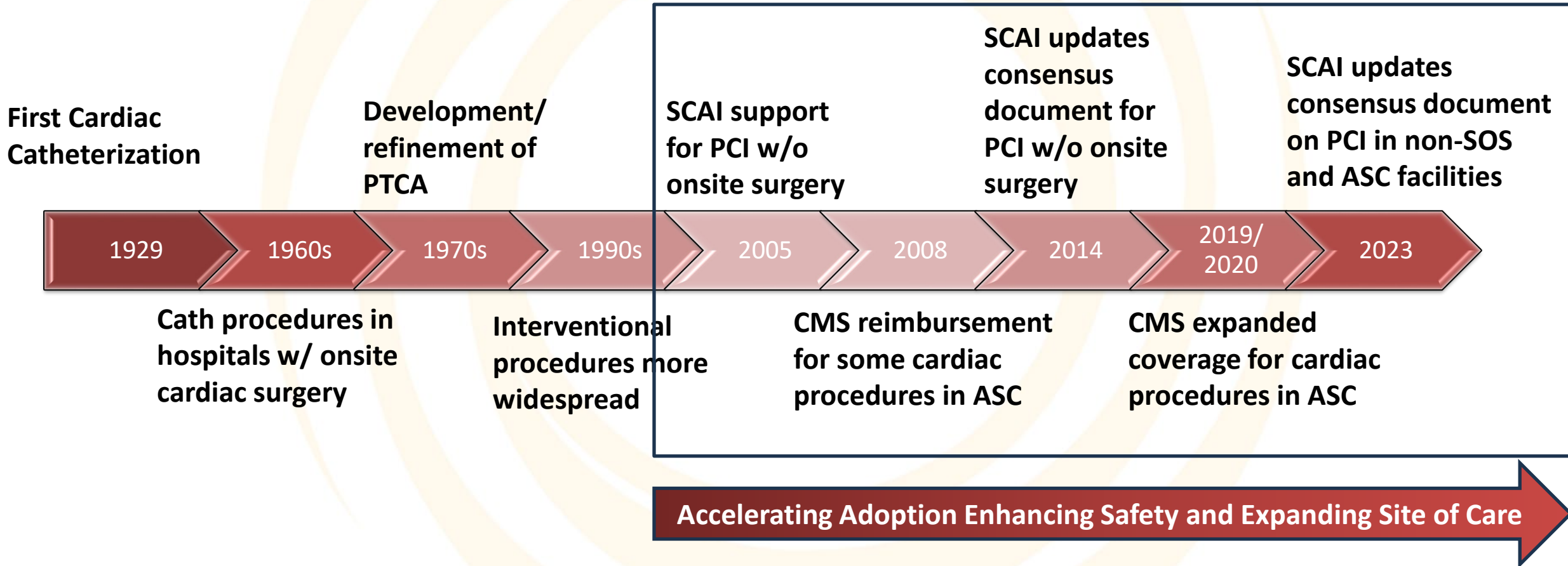
PCI WITHOUT ONSITE OPEN HEART SURGERY



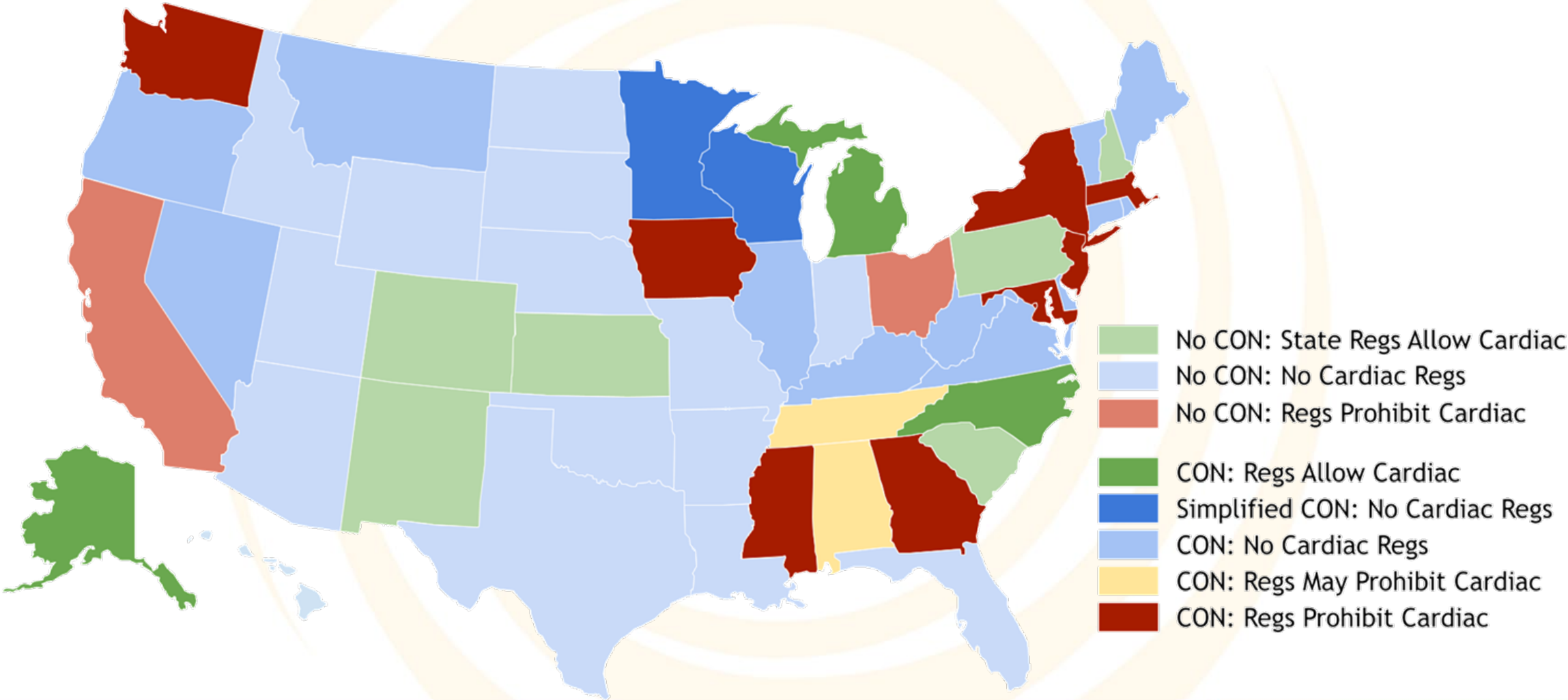
STATE OF THE UNION

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Timeline of Development / Adoption of Cardiac Catheterization & Coronary Intervention



Cardiac Procedures in the ASC



Overview of Select State Regulations



Pennsylvania
Exception procedure for PCI with offsite cardiac surgery and require accreditation



Michigan
Certificate of Need process and require accreditation



Georgia
Certificate of Need process (with exceptions) and a verification process



California
Application for Elective PCI with third party review



Oregon
Certificate of Need process based on cost, not services



Idaho
Optional designation for STEMI based on accreditation or state verification

Comparison of PCI Definitions

Washington	Pennsylvania	Michigan	Georgia	California
<p>Invasive but nonsurgical mechanical procedures and devices used by cardiologists for the revascularization of obstructed coronary arteries, including, but not limited to:</p> <ul style="list-style-type: none"> • Bare and drug-eluting stent implantation • PTCA • Cutting balloon atherectomy • Rotational atherectomy • Directional atherectomy • Excimer laser angioplasty • Extractional thrombectomy 	<ul style="list-style-type: none"> • PCI means therapeutic interventions for treatment of coronary artery disease, such as stent placement or angioplasty (including PTCA) and therapeutic catheterization 	<ul style="list-style-type: none"> • PCI means therapeutic cardiac cath procedures to resolve anatomic and/or physiologic problems in the coronary arteries of the heart, such as: <ul style="list-style-type: none"> • Balloon angioplasty • Atherectomy • Laser • Stent implantation • Thrombectomy 	<ul style="list-style-type: none"> • Cardiac catheterization means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient • Coronary angioplasty means a cardiac catheterization procedure to treat coronary artery disease using a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement, or other mechanical means to unblock an occluded coronary artery 	<ul style="list-style-type: none"> • Elective PCI means scheduled PTCA and stent placement • Primary PCI means PTCA and stent placement that is emergent in nature for acute AMI and that is performed before administration of thrombolytic agents • STEMI means ST segment elevation myocardial infarction, a type of heart attack, or myocardial infarction, that is caused by a prolonged period of blocked blood supply

Comparison of Need Methodologies

Category	Washington	Pennsylvania	Michigan	Georgia
Planning Area	<ul style="list-style-type: none"> Defined by DOH 	<ul style="list-style-type: none"> Defined by applicant 	<ul style="list-style-type: none"> Defined by applicant 	<ul style="list-style-type: none"> Defined by applicant
Minimum Volume Required	<ul style="list-style-type: none"> 200 	<ul style="list-style-type: none"> 200 	<ul style="list-style-type: none"> 200 (including 36 PCI for hospital applicants) 	<ul style="list-style-type: none"> 1300 procedure equivalents
Utilization Calculation	<ul style="list-style-type: none"> Divide population by 1000 Divide total PCI by that number for PCI use rate per thousand 	<ul style="list-style-type: none"> Determined by applicant 	<ul style="list-style-type: none"> Need based on actual procedures in the state (see below) 	<ul style="list-style-type: none"> Divide total cath on GA residents by total GA residents for cath rate Separate calculation to add non-GA resident cath
Need Calculation	<ul style="list-style-type: none"> Multiply PCI use rate per thousand by projected population to forecast demand Total inpatient and outpatient procedures equals capacity Every 200 procedures that demand exceeds capacity, 1 new program is needed (rounded down) 	<ul style="list-style-type: none"> Determined by applicant 	<ul style="list-style-type: none"> 100% of primary PCI & inpatients transferred for PCI at applicant 90% of DX cath patients who receive PCI at another facility within 30 days 50% of elective PCI performed by a committed physician at another hospital if DX cath not performed by applicant facility 	<ul style="list-style-type: none"> Multiply cath rates by projected population for projected need Convert to procedure equivalents (DX Cath=1, PCI=1.5, EP=2) Surplus or deficit of labs based on 1300 procedure equivalents per year
Other		<ul style="list-style-type: none"> Must have a plan to achieve 200 procedures per year 	<ul style="list-style-type: none"> Primary PCI for 1 year prior to application Different methodology for program expansion 	<ul style="list-style-type: none"> Aggregate utilization in planning area must be ≥85%

Comparison of Qualitative Approvals

Washington	Pennsylvania	Michigan	Georgia	California	Oregon	Idaho
None	<p>Hospitals must maintain accreditation in good standing.</p> <p>Several programs have been allowed to continue offering services despite not achieving the projected 200 PCI procedures, including some which formerly operated OHS programs.</p>	<p>Hospitals and ASCs must maintain accreditation in good standing.</p> <p>CON standards include door-to-balloon times of <90 minutes for ≥75% of patients with emergent STEMI (part of accreditation standards).</p>	<p>Hospitals must complete a verification process prior to initiating services.</p> <p>Exceptions to numeric need provided if actual utilization >90% of capacity for 2+ years or to overcome barriers:</p> <ul style="list-style-type: none"> • Cost: existing providers fail to offer services at a reasonable cost • Quality: existing providers fail to meet clinical outcomes • Financial Access: existing providers fail to provide indigent, charity, or Medicaid care for 2+ years • Geographic: low cath use rate, high disease rate, or other demographic factors 	<p>Hospitals must complete an application process, including a significant amount of materials related to the expected operation of the program.</p> <p>CDPH and independent third party (UC Davis) review submissions for completeness.</p>	<p>No significant approval process required, provided the CON for the cost of the project is approved.</p>	<p>No approval is required to initiate services.</p> <p>A list of “designated” centers is maintained for trauma, stroke, and STEMI care.</p> <p>Designation is optional and is granted based on maintaining third party accreditation or verification by the state.</p>



SCAI Cath Lab Best Practices: focuses on current patient-centered and evidence-based approaches to care

Optimize quality & outcomes through best practices, registries, risk calculators, and vascular access (radial first, vascular ultrasound)

Based on more than 23 randomized trials, the most recent data **fails to find any clinically significant differences in outcomes** of PCI at surgical versus non-surgical PCI centers

Source: 2021 SCAI Expert Consensus Statement on Best Practices in the Cardiac Catheterization Laboratory

2023 SCAI Consensus Document Highlights



- Defined by Levels of Services Offered
 - ASC/OBL, Level 1 and Level 2 Non-SOS hospital and Cardiac Surgery Facility
- Level 1 and 2 Non-SOS Hospitals Defined by Volume
 - Level 1 - < 200 PCIs Annually
 - Level 2 - > 200 PCIs Annually
- Cardiac Surgery Facility – Full Service Cardiovascular Program – Tertiary Facility
- STEMI/MI Care – Dictated by State Regulations
- Staff & Physician (Operator) Recommendations (Role, Years of Experience, Level of Service)
- Expansion of Procedures/Inclusion Criteria (Shockwave, CTOs, Unprotected Left Main)
- Quality Monitoring/Improvement (Registry Participation, Outcomes Review, Drills)
- Formal External Peer Review for Programs with ≤ 2 Operators

SCAI Recommendations Compared to Current Washington CN Requirements



Program Volume

Recommendation/ Typical Practice

- Follow State CON
- Distinct considerations for programs performing <200 PCI procedures/yr

Washington current CN Requirement

- Minimum cardiac cath volume ≥ 200 / yr
- Cannot reduce University of Washington volumes
- Existing programs meeting volume standard



Physicians

Recommendation/ Best Practice

- Board Certified
- Perform a minimum volume/yr
- Practice site & technology based on yrs of experience (e.g. rotational atherectomy)

Washington current CN Requirement

- Physicians perform ≥ 50 procedures/yr
- Sufficient physicians for both emergent and elective procedures to be performed



Staffing

Recommendation/ Best Practice

- 3-4 staff/room (roles include administration of sedation & airway monitoring, recorder, and circulator)
- Appropriate training (3-5 yrs experience)

Washington current CN Requirement

- Recruit staff without affecting existing programs
- Qualified, experienced staff with documented competencies treatment of acutely ill patients
- Coronary care, PCI technology, intubation and ventilator management experience

SCAI Recommendations Compared to Current Washington CN Requirements



Imaging

Recommendation/ Typical Practice

- High-quality image acquisition & digital archive systems
- Fixed imaging system recommended (vs. mobile)

Washington current CN Requirement

- “Optimal digital imaging systems”



Supplies & Devices

Recommendation/ Typical Practice

- Portable ultrasound available
- IVUS/ FFR
- Physiological monitoring equipment
- Appropriate inventory of interventional equipment (guide catheters, extension catheters, balloons, stents, covered stents, IVL/Shockwave)

Washington current CN Requirement

- Fully equipped with “all appropriate devices”



Rescue/ Support Equipment

Recommendation/ Typical Practice

- Minimum of an intra-aortic balloon pump (IABP)
- General resuscitation equipment (emergency airway kits, cardiac arrest & vasoactive medications, defibrillators)

Washington current CN Requirement

- IABP required

SCAI Recommendations Compared to Current Washington CN Requirements



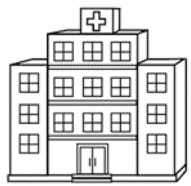
Transfer/ Transport Agreements

Recommendation/ Typical Practice

- Formal transport agreement w/EMS
- Formal transfer agreement w/facility providing OHS
- Transfer drills at least twice per yr

Washington current CN Requirement

- Formal transport agreement
- Formal partnership agreement w/facility providing OHS
- Timing standards with ≥ 2 drills/yr
- Quarterly review of all transport cases



Facility/ Operations

Recommendation/ Typical Practice

- Compliance with current FGI (Facility Guidelines Institute) and other industry standards
- Heart Team approach in place
- Informed consent (including language for notification of transfer)

Washington current CN Requirement

- One cath lab used primarily for cardiology
- Informed consent including risks of transfer and urgent surgery



Case Selection

Recommendation/ Typical Practice

- SCAI/ societal recommendations

Washington current CN Requirement

- System for patient selection resulting in positive outcomes

SCAI Recommendations Compared to Current Washington CN Requirements



Quality Assurance

Recommendation/ Typical Practice

- Participation in a national outcomes registry (NCDR)
- Quality outcomes (complications, procedural indicators)
- Robust quality program (internal/ external peer review, regular audits, regular drills)

Washington current CN Requirement

- Process for outcomes review and state or national benchmarking
- Documented quality improvement plan
- Reporting of requested information to Department of Health
- COAP and CHARS used for planning



Peer Review

Recommendation/ Typical Practice

- Formal external peer review for ≤ 2 providers

Washington current CN Requirement

- Formal case review with partnering surgical backup hospital (at minimum, all transferred cases)



Accreditation

Recommendation/ Typical Practice

- Incorporate professional societal standards and other evidence-based science
- Measure quality and monitor progress
- Effective to ease the burden and cost on the state (e.g. GA, ID, MI, MO, PA, NJ, SC)

Washington current CN Requirement

- No current requirement or recognition



QUESTIONS/ DISCUSSION

State Overview – Pennsylvania

- No Certificate of Need (repealed 1996)
- 28 PA Code Chapter 138 states **“A hospital may perform high-risk cardiac catheterization only if it has an open-heart surgical program onsite.”**
- Exception procedure adopted in 2013 and updated in 2015
- Standards consistent with societal recommendations (patient selection criteria, credentialing, training and competency, 24/7 availability, transfer agreements, program outcomes from NCDR)
- Require accreditation by an approved third-party organization to confirm compliance with all requirements
 - Annual reporting of volumes and accreditation status to PA DOH
 - Programs performing fewer than 200 PCI per year must be accredited every year
 - Programs performing greater than 200 PCI per year must be accredited every 2 years
- ASCs may perform PCI based on CMS approval without accreditation

State Overview – Michigan

- Certificate of Need
 - Must be approved for DX cath services already
 - Performed a minimum of 300 DX cath procedure equivalents in most recent 12 months if operating for more than 24 months
 - Must have approval for open heart surgery (**exception is available**)
 - Project a minimum of 200 PCI procedure equivalents (PCI without OHS)
- Without OHS, must offer **primary (STEMI)** PCI for 12 months before offering **elective** PCI, meet volume requirements (reduced to 200 PCI procedure equivalents), 2 cardiologists, societal recommendations, no existing service within 60 miles
- Maintain explicit quality measures (e.g. door-to-ballon within 90 minutes for $\geq 75\%$ of emergent PCI patients)
- Required accreditation by an approved third-party organization to confirm compliance with all requirements
- Accreditation is valid for 2 years
- ASCs (FSOFs) may perform PCI following similar approvals to hospitals

State Overview – Georgia

- Certificate of Need
 - Numerical need from a population-based formula (calculate state utilization rate, compare to projected population, adjust for out-of-state procedures, convert to procedure equivalents, determine surplus or deficit in the identified planning area)
 - Aggregate utilization rate must exceed 85% of capacity
 - Exceptions can be provided based on:
 - Utilization above 90% for 2 years
 - Remedying an “atypical barrier” to PCI services from existing providers
 - Cost barriers based on charges or reimbursement significantly higher than other providers
 - Quality barriers based on outcomes not in keeping with accepted clinical guidelines
 - Financial barriers based on failure to provide indigent, charity, or Medicaid care
 - Geographic barriers based on number of programs, disease prevalence, or other demographic factors within the planning area
 - Any other expansion complying with general considerations to which the Department wishes to grant an exception
- Meet societal recommendations, provide a written plan for access, maintain a transfer agreement, support reduction of community risk factors, meet minimum procedure volume (1,040 procedure equivalents within 3 years – DX=1, PCI=1.5, EP=2)
- Maintain explicit quality standards (e.g. door-to-balloon)
- Verification by an approved body that the program has met state standards

State Overview – California

- No Certificate of Need
- Previously not allowed unless a hospital offered cardiac surgery onsite
- As of January 1, 2015, an unlimited number of programs may be approved in the state
- Complete a rigorous application form which includes all related policies, procedures, algorithms, transfer agreements, job descriptions, and other pertinent information
- Perform or project a minimum of 200 PCI procedures per year (including 36 primary PCI procedures)
- California Department of Public Health reviews the application
- University of California Davis reviews the application

State Overview – Oregon & Idaho

Oregon

- Certificate of Need based on monetary threshold, not service
 - Assess need, access, cost alternatives, personnel, ability to recover expenses, cost impact, etc.
- PCI is permitted without open heart surgery onsite without additional specific approvals

Source: 2024 Oregon Health Planning Regulation

Idaho

- PCI Permitted w/o OHS on site, no regulations
- Non-CON state
- Designations for various levels of STEMI care
 - Level I+ can provide comprehensive STEMI care plus cardiogenic shock care
 - Level I can provide comprehensive STEMI care
 - Level II can stabilize and transfer STEMI patients
- Optional accreditation from a third-party provider or verification through the State of Idaho

Source: 2024 NCSL, Idaho Department of Health and Welfare

Comparison of Need Methodologies

Washington

- DOH defines planning areas across the state
- Divide total base year population by 1000
- Divide total number of PCIs performed on planning area residents by that result
- This number is the PCI use rate per thousand
- Multiply the planning area's use rate per thousand by the corresponding forecast year population to determine forecasted demand per year
- Utilize CHARS data to identify all inpatient procedures at CN approved hospitals
- Identify all outpatient procedures at CN approved hospitals using DOH survey data or by calculating difference between COAP and CHARS data
- Add inpatient and outpatient procedure totals to determine the planning area's current capacity
- Compare forecasted demand to current capacity to identify surplus or deficit of capacity
- Divide any surplus by 200 and round down to get the number of needed programs (<200 will not allow for an additional program)

Michigan

- Achieve 200 adult PCI procedures in the second 12 months of operation (hospital w/o OHS or ASC), including 36 emergent PCI cases (hospital only)
 - Primary PCI first (treated or transferred 36 STEMI patients in last 12 months, including thrombolytic eligible & emergent AMI transfers)
 - Elective PCI once 36 STEMI patients are treated & projecting 200 total PCI based on:
 - 100% of primary PCI
 - 100% of inpatients transferred for PCI
 - 90% of DX cath patients who receive PCI at another facility within 30 days
 - 50% of elective PCI performed by a committed physician at another hospital if DX cath not performed by applicant facility
- Describe applicant's volume projection methodology
- If any volume includes PCI from an existing program, must demonstrate that program will maintain compliance with volume standards
- Expansion and other applications require a different methodology with procedure equivalents

Georgia

- Cath Lab Capacity defined as 1300 procedure equivalents per lab per year
- Calculate current cath rate by dividing total number of cathes on GA residents by total GA population for most recent year of reported data
- Multiply current cath rate by projected population for the horizon year for projected cath procedures
- Adjust the projected total by adding out-of-state cathes based on percentage of total procedures performed on out-of-state patients for the most recent year
- Convert procedures to procedure equivalents (1 for DX cath, 1.5 for PCI, 2 for EP)
- Calculate surplus or deficit of labs based on 1300 capacity per lab
- Aggregate utilization in planning area must be $\geq 85\%$ of current lab capacity

All calculations based on adult PCI requirements

LEVEL 1 Non-SOS Hospital

2023 SCAI Document

Program Volume	Low Volume (< 200 PCIs) Cath Lab
Regulatory (CON)	Follow State CON
STEMI / MI Care	Follow State CON; Recommend 24/7/365 STEMI/MI Care
Case Selection Inclusion/Exclusion Criteria	Careful Case Selection; Rotational Atherectomy (Competent Operator); NEW Algorithm Provided
Equipment & Devices	Fixed Imaging; Balloons, Stents, Covered Stents, IVL (Shockwave), FFR, IVUS, Ultrasound
Rescue & Support Services	IABP, Post Care Unit (s), Code Team
Tertiary Support & Heart Team	Formal Tertiary Agreement; Heart Team Approach in Place
Transfer Agreement (EMS)	Formalized – 30 Minute Response
Operator Requirements & Credentialing	Experienced Interventional Cardiologists; 3-5 years Experience; Formal Credentialing and Volumes (Hospital Policy)
Staffing Requirements	Preferably 3-5 Years Prior Experience; 3 Staff/Room
Quality Assurance	Formalized, Reflect Hospital Process; Registry Participation – NCDR or State Registry
Peer Review	Formal PR - External Peer Review for Solo Operator
Reimbursement	CMS TABLE Provided

LEVEL 2 Non-SOS Hospital

2023 SCAI Document

Program Volume	Volume (> 200 PCIs) Often Multiple Cath Labs
Regulatory (CON)	Follow State CON
STEMI / MI Care	Follow State CON; MOST Level 2 Offer - 24/7/365 STEMI/MI Care
Case Selection Inclusion/Exclusion Criteria	Expanded Case Selection; CTOs, Unprotected Left Main, Degenerated Vein Grafts, Complex PCI, Rotational and Orbital Atherectomy; NEW Algorithm Provided
Equipment & Devices	Fixed Imaging, Balloons, Stents, Covered Stents; IVL (Shockwave), Coronary Atherectomy, FFR, IVUS, Ultrasound
Rescue & Support Services	IABP, pVAD (IMPELLA), ECMO, Post Care Unit (s), Code Team, 24/7 ICU/Anesthesia/Radiology/OR Support, Vascular/Thoracic Surgery
Tertiary Support & Heart Team	Formal Tertiary Agreement; Heart Team Approach in Place
Transfer Agreement (EMS)	Formalized – 30 Minute Response
Operator Requirements & Credentialing	Very Experienced Interventional Cardiologists; > 10 years Experience; Formal Credentialing and Volumes (Hospital Policy)
Staffing Requirements	Well Resourced, Well Trained, 4 Staff/Room
Quality Assurance	Formalized, Reflect Hospital Process; Registry Participation – NCDR or State Registry
Peer Review	Formal PR - External Peer Review for Solo Operator
Reimbursement	CMS TABLE Provided

ASC/OBL	2023 SCAI Document
Program Volume	Follow State CON
Regulatory (CON)	Follow State CON
STEMI / MI Care	N/A
Case Selection Inclusion/Exclusion Criteria	Elective PCI, Same Day PCI, Careful Case Selection
Equipment & Devices	Fixed Imaging, Balloons, Stents, Covered Stents, IVL (Shockwave); Strongly “Recommend” – FFR & IVUS, Ultrasound
Rescue & Support Services	IABP
Tertiary Support & Heart Team	Formal Tertiary Agreement; Heart Team Approach in Place
Transfer Agreement (EMS)	Formalized – 30 Minute Response
Operator Requirements & Credentialing	Newly Trained Physicians with < 3 Years Experience Should Not Perform PCI in an ASC
Staffing Requirements	Preferably 3-5 Years Prior Experience; 3 Staff/Room
Quality Assurance	Formalized, Reflect Hospital Process; Registry Participation – NCDR or State Registry
Peer Review	Formal PR - External Peer Review for Solo Operator
Reimbursement	CMS TABLE Provided

Therapeutic goals of PCI

- Patients with stable ischemic heart disease (SIHD):
 - Decreasing the risk for major adverse cardiovascular (CV) events (eg, myocardial infarction and death) and alleviating symptoms
- Appropriate Use Criteria (AUC)
 - Developed/ based on trial evidence, clinical guidelines, consensus
 - Comprised of 6 domains in assessing the appropriateness of revascularization
 - Classifications include:
 - Appropriate,
 - May be Appropriate, and
 - Rarely Appropriate (formerly Inappropriate)



CMS Reimbursement Chart

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C.L. Grines et al. / Journal of the Society for Cardiovascular Angiography & Interventions xxx (xxxx) xxx

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Table 4. Centers for Medicare & Medicaid Services designations of place of service and applicable reimbursement.^{43,44}

Place of service	CMS designation for place of service	Commercial payors	CMS covers	Facility CMS reimbursement	Provider CMS reimbursement
Inpatient hospital care	Place of service 21	All PCI	All PCI	DRG +	CPT
Outpatient hospital procedures	Place of service 22	All PCI (excluding CTO, STEMI)	All PCI (excluding CTO, STEMI)	APC	CPT
Ambulatory surgical centers	Place of service 24	Similar to CMS coverage with some contractual exceptions	Ambulatory PCI excluding CTO, bypass grafts, atherectomy	ASC	CPT
Physician office-based laboratory	Place of service 11	PCI in many states	Diagnostic heart cath only		CPT global payment

APC, ambulatory payment classifications; ASC, ambulatory surgery center; cath, catheterization; CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; CTO, chronic total occlusion; DRG, diagnosis-related group; STEMI, ST-elevation myocardial infarction.