MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Wednesday, December 20, 2017

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Chairperson David called the meeting to order at 9:40 a.m.

A. Members Present:

Shukri David, MD, Chairperson – Ascension | Michigan
Ernest Balcueva – American Heart Association
Lynne F. Carter, MD – Blue Cross Blue Shield of Michigan
Michele L. Davis – Electrical Workers' Joint Board of Trustees
Simon Dixon, MD – Beaumont Hospital
Henry E. Kim, MD – Henry Ford Health System
Ryan D. Madder, MD – Spectrum Health
Kristopher J. Selke, DO – Mercy Health & St. Joseph Mercy Health System
Ibrahim Shah, MD – McLaren Greater Lansing (arrived at 10:20am)
Sunita Vadakath, MD – MidMichigan Health

B. Members Absent:

Hitinder S. Gurm, MD – University of Michigan
Theodore L. Schreiber, MD – Detroit Medical Center

C. Michigan Department of Health and Human Services Staff present:

Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Agenda

Motion by Dr. Dixon, seconded by Dr. Kim to approve the agenda as modified (Dr. Dixon will present for Item VII.). Motion Carried.

IV. Review and Approval of November 9, 2017 Minutes

Motion by Dr. Dixon, seconded by Ms. Davis to approve the minutes as presented. Motion Carried.

V. WebEx Presentation on Accreditation

Amy Westfall, American College of Cardiology (ACC) Accreditation Services, provided a presentation. (See Attachment A)

Discussion followed.

VI. Discussion of Charge #2: Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals

Chairperson David presented on the topic. (See Attachments B and C)

Discussion followed.

Motion by Dr. Madder, seconded by Dr. Kim to clarify the language in Section 2(1)(c) by adding "in a licensed hospital" after "interventional radiology laboratory or operating room". Motion Carried in a vote of 8-Yes, 0 - No, and 1- Abstained.

VII. Review of simple ablation procedures at hospitals without on-site surgery

Dr. Dixon presented on the topic. (See Attachments D and E – Letters from Drs. Morady and Castle)

Discussion followed.

Motion by Dr. Dixon, seconded by Dr. Selke to allow performance of right-sided ablations as referenced in Dr. Morady's letter in hospitals without on-site surgery: right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation. Motion Carried in a vote of 10-Yes, 0 - No, and 0- Abstained.

VIII. Next Steps

The SAC did a walkthrough of the draft language and modified where needed.

Motion by Dr. Selke, seconded by Dr. Dixon to move the recommendations forward to the Commission. Motion carried in a vote of 10- Yes, 0- No, and 0- Abstained.

Dr. Dixon agreed to assist the Department with the modifications made at today's meeting.

IX. Public Comment

1. Akshay Khandelwal, MI Chapter of ACC

X. Adjournment

Meeting adjourned at 11:15 a.m.

ACC Accreditation Services™

Formerly

Society of Cardiovascular Patient Care (SCPC)

Cardiac Cath Lab v1

Amy Westfall MBA, BSN, RN, CCRN

Cath Lab Service Line Specialist

AMERICAN COLLEGE of CARDIOLOGY

CCL v1 Accreditation

- Ensures standardization of processes across the care continuum for the cath lab patient.
- Utilizes NCDR CathPCI® Registry data to demonstrate trends in clinical care to facilitate hardwiring processes with evidenced based guidelines. Establishes meaningful metrics.
- The Essential Components link process improvement to patient outcomes.
- Promotes ongoing quality improvement through regular examination of policies and the adoption of national guidelines; policies are reflective of current practice.
- Houses all documents in one location, promotes readiness for regulatory assessments.

CCL Accreditation can help your program:

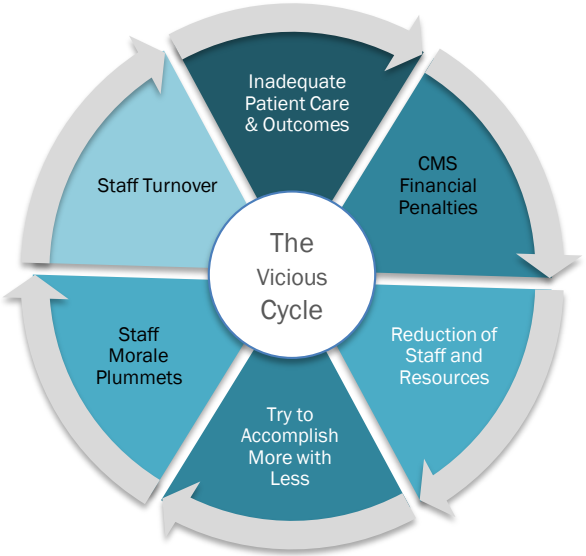
- Outpatient market share shift. Communicating ways to support your services to patients across care settings.
  - According to the Advisory Board Cardiovascular Round Table research.
- Accreditation will convey your commitment to quality and provide an advantage in a competitive market.
  - Leverage for physician and patient outreach.
- Focus on internal processes and pathways
  - Reduce unnecessary care variation/reduce waste for cost management and improve quality.
- Improve patient experience.
  - Are your patients really looking for a cleaner room? Or do they seek communication, and indicators of teamwork and coordination by their caregivers?
- Help balance cost control and revenue growth:
  - Inventory/supply management
  - Streamline pathways to improve efficiencies
  - Balanced approach

Based on The Advisory Board: What providers are thinking, C-suite executives.

Attachment A

From Volume to Value

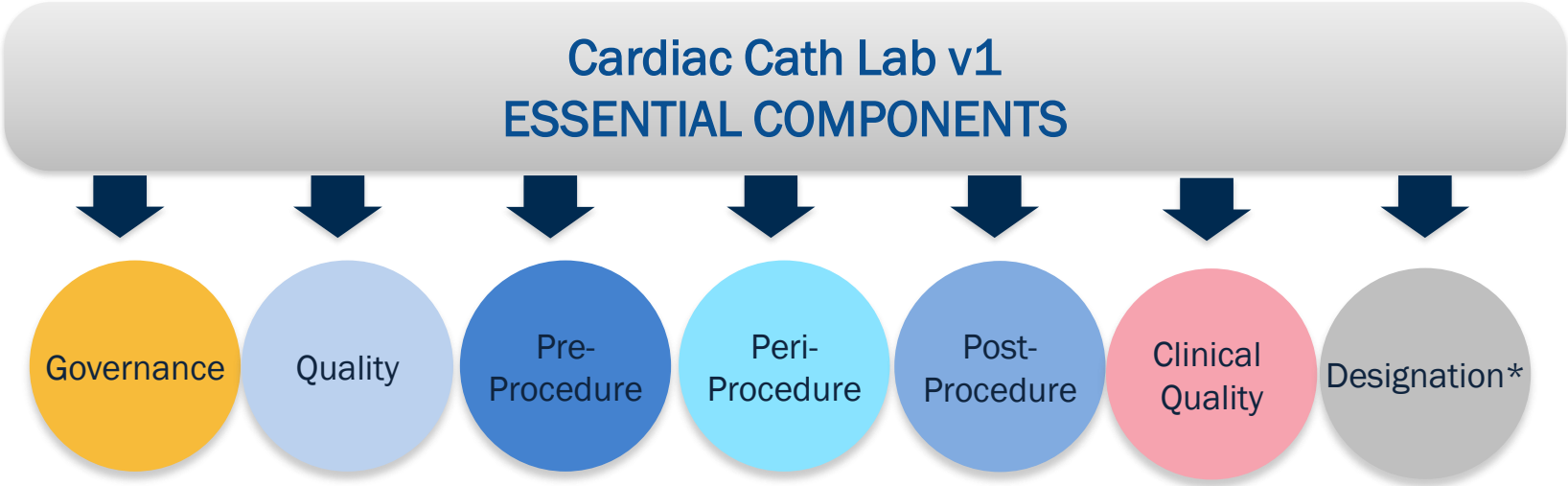
Why Hospitals Are Currently Struggling



Successful Programs Use These Elements

AMERICAN COLLEGE of CARDIOLOGY

Framework: CCL v1



*Under development

Governance

- Program personnel
- Credentialing
- CMEs
- Charter
- Multi-disciplinary committee
- Committee meetings
- Annual education/low volume high risk

Quality

- Comprehensive CCL specific Quality Assessment Performance Improvement (QAPI) program
- Supply Inventory
- NCDR CathPCI Executive Summary Metrics
- Infection Control
- Radiation Safety

Pre-Procedure

- Assessment of bleeding risk
- Checklists
- Access site evaluation: transradial/femoral
- Lab findings
- Time out
- Sedation
- Contrast allergy
- CIN
- Diabetic patient

Peri-Procedure

- Medication protocols
- Hemodynamic monitoring
- Peri-procedural complications
- Equipment PMs
- ACT procedures

Post-Procedure

- Patient and family communication of findings
- Immediate post recovery
- Hand off process
- Sheath protocol
- Closure devices
- Site management
- Patient discharge education
- Same day DC for PCI

Clinical Quality: Meaningful Metrics

- The facility demonstrates a quality assessment process improvement (QAPI) initiative that resulted in improvement in the care and safety of the cardiac cath lab patient in at least two measures reflected in the NCDR Cath/PCI measures.

- This process change will be demonstrated by an improvement trend in the most recent six months of data.

- The facility will be required to present a PI plan at the site review on one of the PI initiatives.

How will accreditation bring value to your PROGRAM?

- **P**ositions your hospital to meet the burdens of this patient population
- **R**ecognizes patient-centered focus across the care continuum (not just in the lab)
- **O**rganizes resources needed to improve processes related to the care of the CCL patient
- **G**athers key players to discuss gaps in care and improvement in processes
- **R**eflects commitment to developing your CV service line strategic plan
- **A**ligns processes with evidence-based practice to improve quality, reduce variations in care and reduce cost
- **M**onitors, in real time, important outcome and performance measures

AMERICAN COLLEGE of CARDIOLOGY

AMERICAN COLLEGE *of* CARDIOLOGY

CCSAC -Ambulatory Devices

SHUKRI DAVID, MD

12/20/2017

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH CERTIFICATE OF NEED (CON) REVIEW STANDARDS

FOR CARDIAC CATHETERIZATION SERVICES

"Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or **the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.**

ASC (CMS)

- An ASC must be certified and approved to enter into a written agreement with CMS. Participation as an ASC is limited to any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. An unanticipated medical circumstance may arise that would require an ASC patient to stay in the ASC longer than 24 hours, but such situations should be rare.

Addendum AA -- Final ASC Covered Surgical Procedures for CY 2017 (Including Surgical Procedures for Which Payment is Packaged)

HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	July 2017 Payment Indicator	July 2017 Payment Weight	July 2017 Payment Rate
33206	**Insert heart pm atrial**	Y	J8	171.7594	$7,729.69
33207	**Insert heart pm ventricular**	Y	J8	169.0505	$7,607.78
33208	**Insrt heart pm atrial & vent**	Y	J8	173.0402	$7,787.33
33210	**Insert electrd/pm cath sngl**	Y	G2	81.6168	$3,673.00
33211	**Insert card electrodes dual**	Y	J8	125.6987	$5,656.82
33212	**Insert pulse gen sngl lead**	Y	J8	126.1978	$5,679.28
33213	**Insert pulse gen dual leads**	Y	J8	170.9117	$7,691.54
33214	**Upgrade of pacemaker system**	Y	J8	168.507	$7,583.32
33215	**Reposition pacing-defib lead**	Y	G2	28.3614	$1,276.35
33216	**Insert 1 electrode pm-defib**	Y	J8	115.8743	$5,214.69
33217	**Insert 2 electrode pm-defib**	Y	J8	121.4486	$5,465.55
33218	**Repair lead pace-defib one**	Y	G2	30.7522	$1,383.94
33220	**Repair lead pace-defib dual**	Y	G2	30.7522	$1,383.94
33221	**Insert pulse gen mult leads**	Y	J8	282.7891	$12,726.36
33222	**Relocation pocket pacemaker**	Y	A2	17.154	$771.98
33223	**Relocate pocket for defib**	Y	A2	17.154	$771.98
33224	**Insert pacing lead & connect**	Y	J8	171.5475	$7,720.15

Addendum AA -- Final ASC Covered Surgical Procedures for CY 2017 (Including Surgical Procedures for Which Payment is Packaged)

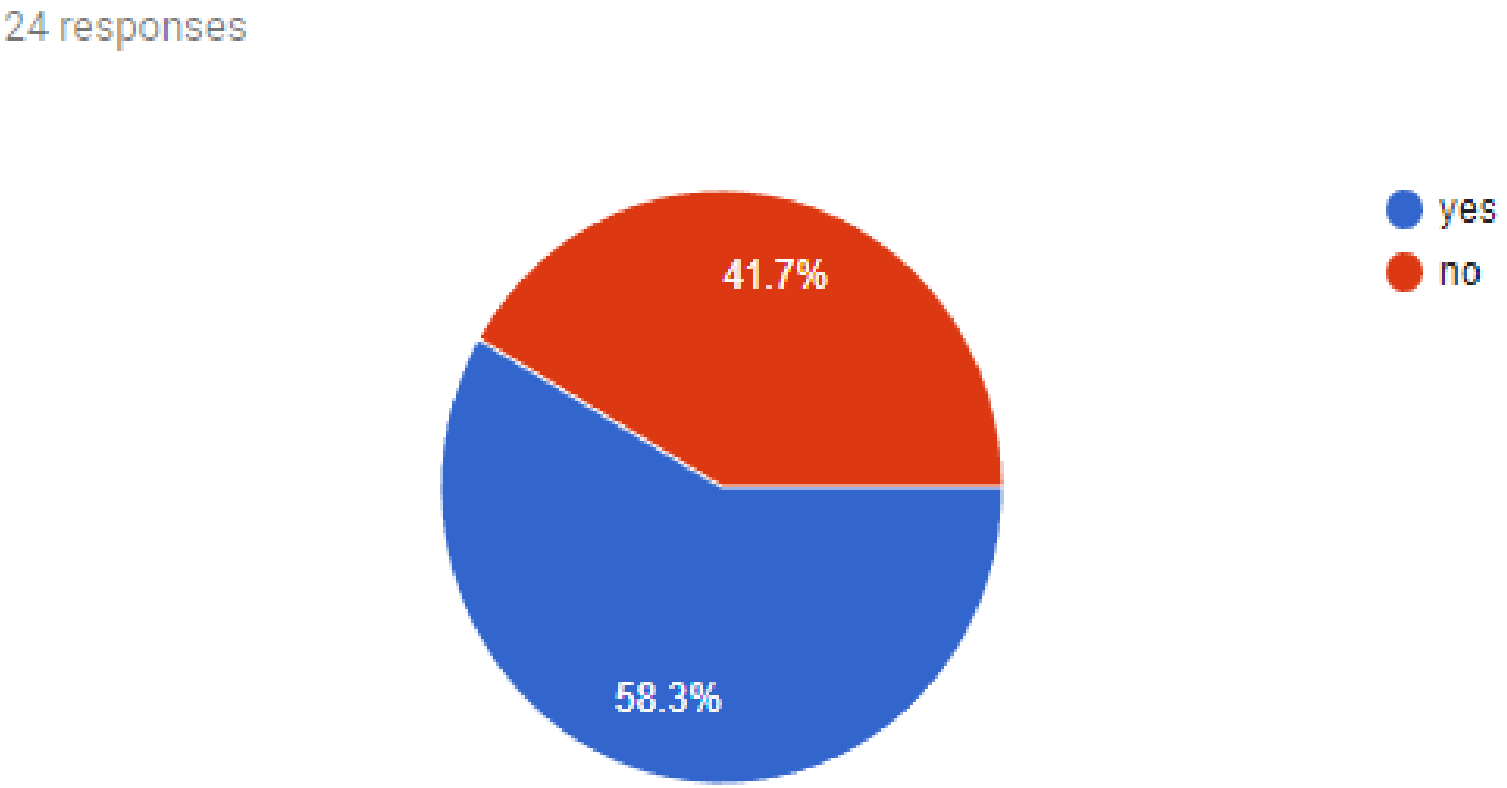
Attachment B

33225	**L ventric pacing lead add-on**	N	N1		
33226	**Reposition l ventric lead**	Y	G2	28.3614	$1,276.35
33227	**Remove&replace pm gen singl**	Y	J8	125.6641	$5,655.26
33228	**Remv&replc pm gen dual lead**	Y	J8	169.1336	$7,611.52
33229	**Remv&replc pm gen mult leads**	Y	J8	275.1537	$12,382.74
33230	**Insrt pulse gen w/dual leads**	Y	J8	432.1536	$19,448.21
33231	**Insrt pulse gen w/mult leads**	Y	J8	594.7232	$26,764.33
33233	**Removal of pm generator**	N	G2	81.6168	$3,673.00
33234	**Removal of pacemaker system**	N	G2	30.7522	$1,383.94
33235	**Removal pacemaker electrode**	N	G2	30.7522	$1,383.94
33240	**Insrt pulse gen w/singl lead**	Y	J8	429.9213	$19,347.75
33241	**Remove pulse generator**	N	G2	30.7522	$1,383.94
33249	**Insj/rplcmt defib w/lead(s)**	Y	J8	593.5518	$26,711.61
33262	**Rmvl& replc pulse gen 1 lead**	Y	J8	426.0314	$19,172.69
33263	**Rmvl & rplcmt dfb gen 2 lead**	Y	J8	430.2751	$19,363.67
33264	**Rmvl & rplcmt dfb gen mlt ld**	Y	J8	596.2254	$26,831.93
33270	**Ins/rep subq defibrillator**	Y	J8	591.2686	$26,608.86
33271	**Insj subq impltbl dfb elctrd**	Y	J8	131.7999	$5,931.39
33273	**Repos prev impltbl subq dfb**	Y	G2	30.7522	$1,383.94
33282	**Implant pat-active ht record**	Y	J8	136.272	$6,132.65
33284	**Remove pat-active ht record**	N	G2	6.4771	$291.49

Survey

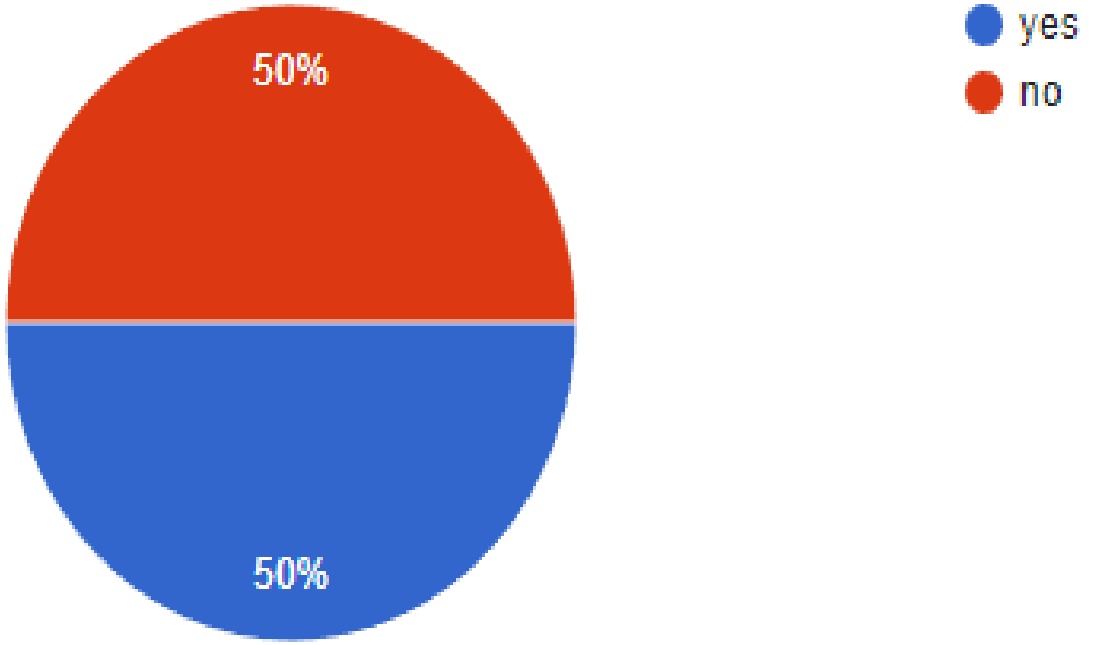
- Sent out a survey to 50 Electrophysiologists in Michigan
- 24 responses
- Three YES/NO questions with comments:
  - Should pacemaker implantation be allowed in an ASC?
  - Should ICD implantation be allowed in an ASC?
  - Should pacemaker and/or ICD replacement be allowed in an ASC?

Should pacemaker implantation be allowed in an ASC?



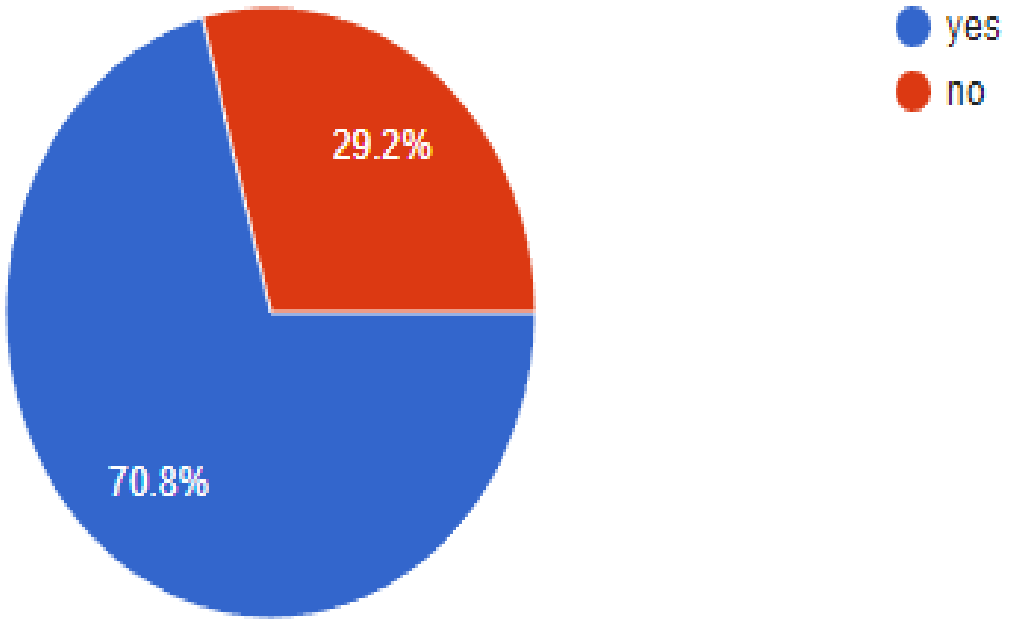
Should ICD implantation be allowed in an ASC?

24 responses

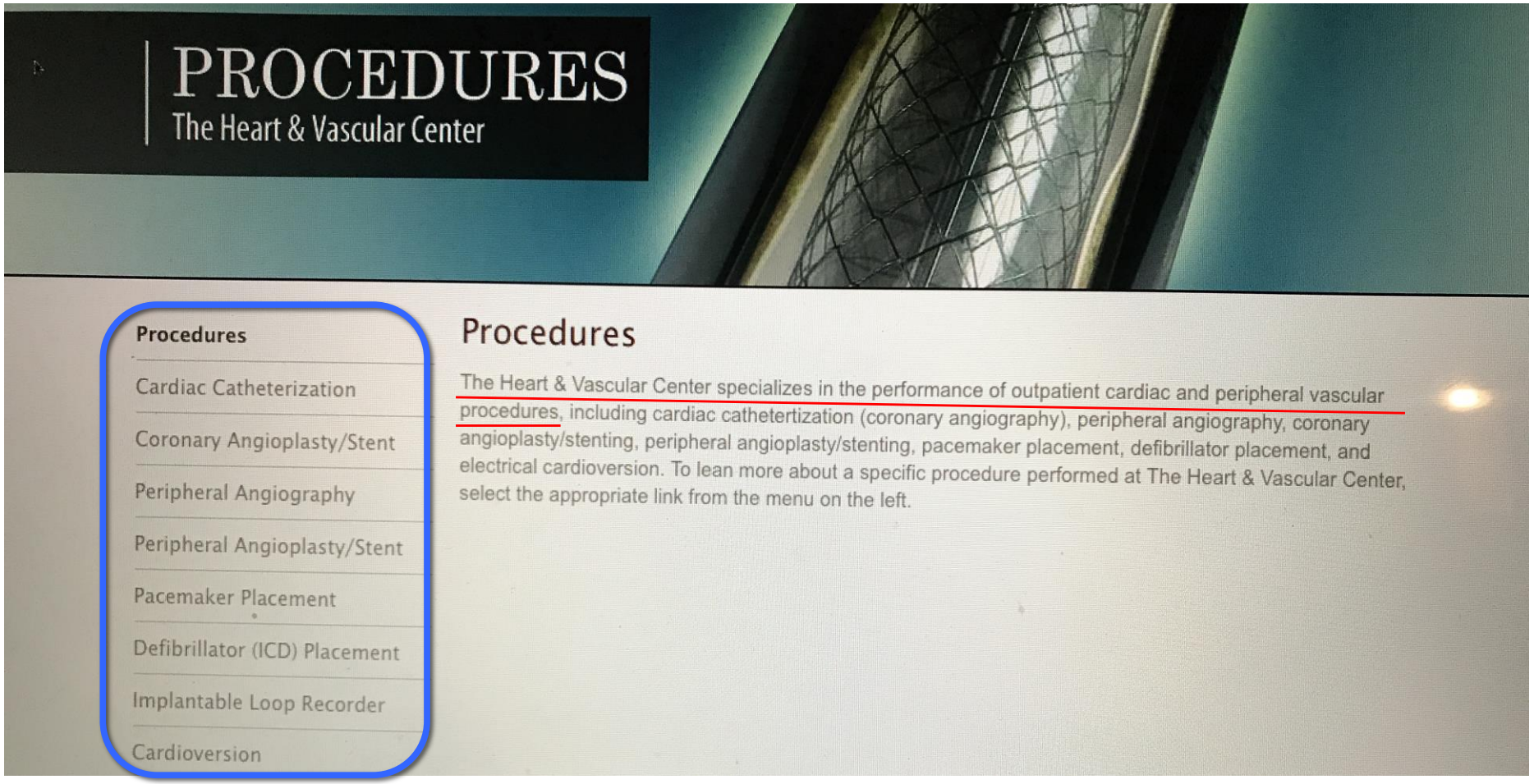


Should pacemaker and/or ICD replacement be allowed in an ASC?

24 responses



This is occurring ALREADY

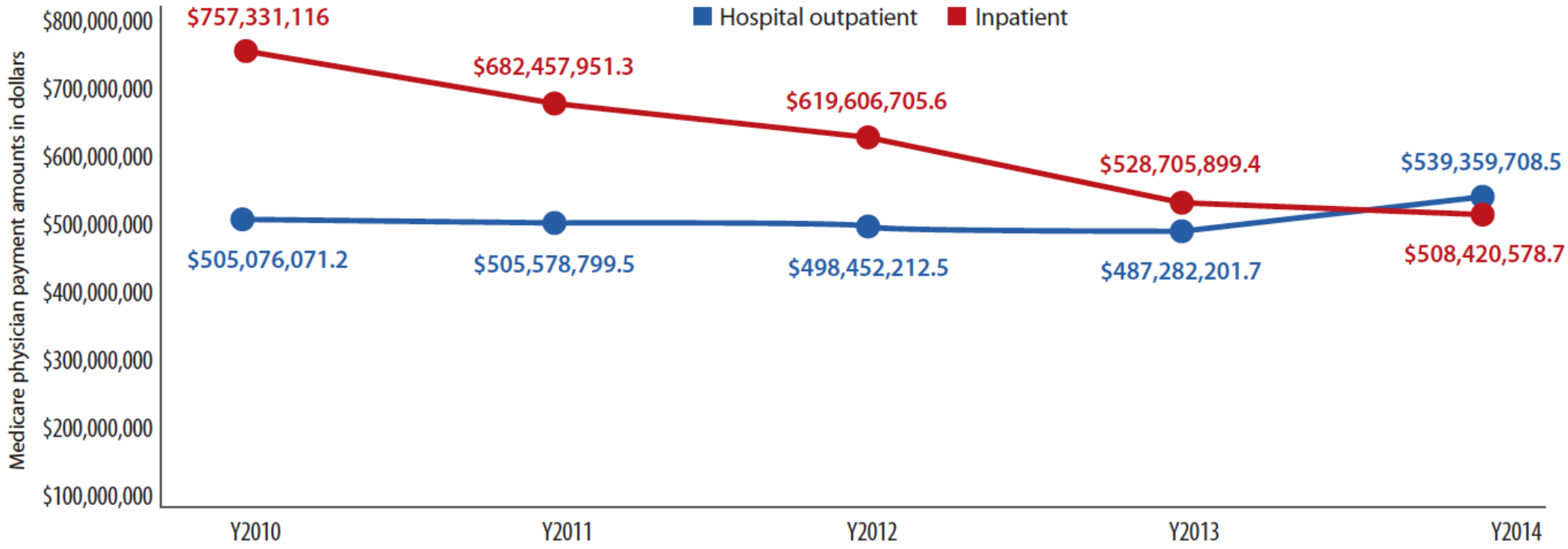


Attachment B

OUTPATIENT CARDIOLOGY CARE ↑↑↑↑

MORE OUTPATIENT CARDIOLOGY TREATMENT

More patients are receiving interventional cardiology treatment in hospital outpatient settings as evidenced by Medicare payments to physicians (total dollars paid to physicians) for hospital outpatient cardiology services. In 2014, payments to physicians for hospital outpatient cardiology services exceeded payments to physicians for hospital inpatient cardiology services.



Source: *Physician/Supplier Procedure Summary, 2013–2014.*

Annual Savings from Procedures Performed in ASCs

% of Common ASC Procedures Currently Performed at ASCs	48%
Current Annual Savings	$37.8 B
Potential Additional Annual Savings	$38.2 B
Potential Additional Annual Savings from Optimal Migration to ASCs	$55.6 B

https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/ambulatory-centers-cost.aspx

Recommendation

- Hitinder and Alice tried to help but very difficult to get the data without a substantial cost

- **Given that outpatient care is the trend in cardiology, that defined codes and payment are already approved by CMS, that there are no obvious data suggesting adverse outcomes, and given the fact that these procedures are already occurring throughout the country we recommend to continue as is and take no further action against performing EP procedures with existing codes/ payment in an ASC.**

Section 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

(c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.

(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, aN ~~minimum~~ AVERAGE of AT LEAST 50 adult therapeutic cardiac catheterization ~~procedures~~ SESSIONS per year AVERAGED OVER THE MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ~~to and~~ annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization ~~procedures~~ SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN'S VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND A THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR PURPOSES OF THIS SUBSECTION.

(e) Each physician credentialed by a hospital to perform pediatric cardiac catheterizations shall perform, as the primary operator, aN ~~minimum~~ AVERAGE of AT LEAST 50 pediatric cardiac catheterization ~~procedures~~ SESSIONS per year AVERAGED OVER THE MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ~~to and~~ annually thereafter. The annual case load for a physician means pediatric cardiac catheterization ~~procedures~~ SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE,TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION

PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN'S VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

(F) EACH PHYSICIAN CREDENTIALED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY SHALL PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY PER YEAR AVERAGED OVER THE MOST RECENT 2 YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALED. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THERAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY, IN ANY COMBINATION OF HOSPITALS. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN'S VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND A THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR PURPOSES OF THIS SUBSECTION.

(~~f~~G) An adult diagnostic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physicians~~:

(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
(iii) have ~~each~~ performed a minimum of 100 adult diagnostic cardiac catheterization~~s~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.

(~~g~~H) An adult therapeutic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physicians~~:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
(iii) have ~~each~~ performed a minimum of 50 adult therapeutic cardiac catheterization ~~procedures~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.

(~~h~~I) A pediatric cardiac catheterization service shall have ~~an appropriately trained~~ AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physician~~:
(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
(ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and

(iii) has trained consistently with the recommendations of the American College of Cardiology.

(~~i~~J) A pediatric cardiac catheterization service shall maintain a quality assurance plan as outlined in the most current ACCF/SCAI Guidelines.

(~~j~~K) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 100 catheterizations SESSIONS per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(~~k~~L) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(~~l~~M) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate with a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes.

Highlighted text indicates text added based on vote of SAC 11/9/17

Attachment D

University of Michigan
Cardiovascular Center

Division of Cardiology
Clinical Electrophysiology Section
Cardiovascular Center
CVC Cardiovascular Medicine
1500 E. Medical Center Dr., SPC 5853
Ann Arbor, MI 48109-5853

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(734) 936-7026 fax
(734) 647-7321 clinic appts.

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Krit Jongnarangsin, MD
Assistant Professor
(734) 761-7499

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Director,
Clinical Electrophysiology
Service
(734) 936-5840

Frank Pelosi, Jr., MD
Assistant Professor
Director, Electrophysiology
Fellowship Program
(734) 763-7392

October 12, 2007

Metro Health Hospital
Dan Witt
Director of Heart & Vascular Center
5900 Byron Center Ave SE
Wyoming, MI 49519

Dear Mr. Witt:

Recently, I have been informed that the State of Michigan has a regulation prohibiting catheter-based radiofrequency ablations from being performed in hospitals that do not have on-site cardiac surgery programs. The rationale behind this rule is not clear, nor is it evidence based. Ablation is simple arrhythmias such as AV node reentry, AV reentry, right-sided atrial flutters, atrial tachycardia and ablation of the AV node have well established safety records. The risk of cardiac perforation is exceedingly low. In addition, if a perforation were to occur, this is almost always successfully treated with percutaneous pericardiocentesis (a procedure performed by cardiologists).

Neither the Heart Rhythm Society, nor the American College of Cardiology have policies in place prohibiting qualified electrophysiologists from performing these procedures at facilities without on-site cardiac surgery. Given this, I recommend reconsideration of this policy.

Sincerely,

Fred Morady

Fred Morady, MD
Professor of Internal Medicine

Cleveland Clinic

Westlake Family Health Center

February 25, 2008

Metro Health Hospital
Mr. Dan Witt
Director of Heart and Vascular Center
5900 Byron Center Ave SE
Wyoming, MI 49519

Dear Mr. Witt:

I am writing in regards to an issue that has been brought to my attention recently. Apparently in the state of Michigan, catheter based ablations are not allowed unless the hospital attempting to perform these has an on site cardiac open heart program.

Performing simple ablations of the AV node reentry, atrial tachycardia, AV reentry, right-sided atrial flutters and AV node are in my professional opinion not considered high risk. Evidence based medicine has shown repeatedly there is a very low rate of complications for these procedures in the Cath Lab, and surgical standby is not needed.

Furthermore, there is nothing in the American College of Cardiology or the Heart Rhythm Society recommendations that state the above procedures should have on site cardiac open heart surgery available.

With all of this said, I am comfortable in recommending that the state of Michigan reconsider their current standards related to this issue to allow for simple radiofrequency ablations under the direction of qualified Electrophysiologists, without the need for onsite cardiac surgery.

Sincerely,

Lon W. Castle, MD
Director of Cleveland Clinic Western Region
EP Labs/Device Clinics

LWC/lmh

The Cleveland Clinic Foundation
30033 Clemens Road / w110
Westlake, Ohio 44145
Tel 440 899-5555