



Specializing in High Quality Patient Care Since 2001

7091 Orchard Lake Road Suite 230 West Bloomfield, MI 48322
Phone: 248-538-7095 Fax: 248-538-7298

July 17, 2018

Attn: CON Commission
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: PACEMAKER AND ICD PLACEMENT IN AMBULATORY SURGERY CENTER (ASC) SETTING

To Whom It May Concern:

This testimony serves as a request for CON Commission members to consider allowing Permanent Pacemakers and Internal Cardiac Defibrillator (ICD) implant placement to be performed in an ambulatory surgery center (ASC) setting. The Commission shall consider unbundling the following minimally invasive procedures from Therapeutic Cardiac Catheterization Services category, making them permissible under Surgical Services:

- PERMANENT PACEMAKER IMPLANTATION, (placement only)
- ICD IMPLANTATION (SUBCUTANEOUS) (placement only)

American Surgical Centers II, LLC is a Medicare certified and AAAHC accredited ASC with a desire to perform the above stated minimally-invasive procedures. This ASC would like to propose and spearhead a pilot program where, with state's oversight and permission, the procedures above are performed to reflect an outcome no less safe than when performed in a catheterization lab or a hospital OR setting. American Surgical Centers II, LLC successfully renewed its 3-year CMS certification in January of 2018, a 3-year AAAHC accreditation in November of 2017, and a successful annual state survey in May 2018. As you may know, CMS and AAAHC mandate their facilities adhere to the highest standards of quality and patient care. A few standards include:

- Transfer agreement- written transfer agreement with a nearby hospital (3.5 mi distance) along with a protocol for immediate transfer.



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- Multiple emergency personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation available whenever there is a patient in the ASC. All ACLS-trained nursing staff onsite.
- We credentialed a Board-certified interventional cardiologist to oversee pacemaker and ICD placement units. American Surgical Centers has qualified physicians and a qualified anesthesia team onboard.
- Consistent measuring, analyzing, and tracking of quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.
- Safe and sanitary environment of care monitored by Safety and Professional Standard Committee
- Infection Control Program aiming to prevent, identify, and manage infections, monitored by a properly trained Infection Control Officer/RN serving as Director of Nursing. American Surgical Centers holds a record of zero incidents of infection in its 20 years of operation.
- Emergency preparedness-emergency plans, policies and procedures, consistent annual and quarterly training and testing. Successful passing of annual fire inspection in January 2018.

Lower Cost and Benefits:

As you may know, CMS approves pacemakers and ICDs to be performed in an ASC setting and many ASCs in other states are performing such procedures successfully. Regarding cost comparison, an important benefit to the patient will be the option to have this performed at a lower-cost ambulatory surgery center as oppose to a hospital.

CPT	Short Descriptor	MC ASC	MC HOPD
33206	Insert heart pm atrial	\$7,778.45	\$9,747.32
33207	Insert heart pm ventricular	\$7,831.96	\$9,747.32
33208	Insrt heart pm atrial & vent	\$8,010.02	\$9,747.32
33224	Insert pacing lead & connect	\$7,869.28	\$9,747.32
33226	Reposition l ventric lead	\$1,298.71	\$2,492.57
33249	Insj/rplcmt defib w/lead(s)	\$27,339.22	\$30,959.99



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We request that CON Commission further review the capability of properly equipped and certified ambulatory surgery centers to perform such procedures in a safe manner and propose a regulatory change. As stated above, our facility is CMS certified and AAAHC accredited, as well as equipped with cardiac and defibrillator management in both peri-operative and operating room suite to lend support to our interventional cardiologist.

In case a regulatory change is not possible, American Surgical Centers would request that CON Commission consider our offer for a pilot project that could play a role in future decisions. Feel free to contact us if you would like more information or to further discuss this matter.

Thank you for the opportunity to provide comments on CON Review Standards for Cardiac Catherization Services.

Sincerely,

A handwritten signature in black ink, appearing to read "John Bertall III". The signature is written in a cursive style with a horizontal line through it.

Management Team
American Surgical Centers II
7091 Orchard Lake Road Ste 230
West Bloomfield, MI 483222
Phone: 586-636-4090
Fax: 586-498-9460



Improving the health of the people in our communities by
providing quality, compassionate care to everyone, every time

July 24, 2018

Mr. James Falahee, JD
Chairman
Certificate of Need Commission
Michigan Department of Health and Human Services
333 S. Grand Avenue
Lansing, Michigan 48933

Dear Chairman Falahee,

Sparrow Health System greatly appreciates the Commission and Department's responsiveness to the concerns we, and others, shared regarding Open Heart Surgery and Cardiac Catheterization standards. Sparrow strongly supports all of the recommendations from the SAC and Department and believes these changes are in line with the goals of the Certificate of Need program and provide important updates based on changes in technology and practice. We very much appreciate the Department's desire to create consistency across CON standards and especially between Cardiac Cath and Open Heart Surgery programs.

We believe the proposed standards address our concerns regarding relocation zones and clarification on meeting minimum volumes for replacement hospitals. We also appreciate the SAC's clarification on keeping ICD and Pacemaker implantations within a licensed Hospital with cardiac catheterization services.

Respectfully,

Marlena Hendershot
Director of Strategic Planning
Sparrow Health System

From: Tony Murry <tonymurry@comcast.net>
Sent: Wednesday, July 18, 2018 3:59 PM
To: MDHHS-ConWebTeam
Subject: Support testimony for Device implantation (pacemakers/defibrillator) at ambulatory centers

My name is Tony Murry, a registered nurse in state of Michigan. I am writing this letter as a testimony in support of device implantation and generator changes (Pacemakers & Defibrillator) at ambulatory surgery centers (ASCs). I've been working as an R.N participating in device implantation for 20 years. I have been working within the hospital setting as an R.N. and working as a medical sales representative for medical device manufacturers. I have participated in device implantation at small and large outpatient hospitals that resemble ambulatory centers in scope, functionality and standards for quality of care. After a personal walk-through and facility evaluation of many ambulatory surgery center operations, I strongly believe that these facilities can provide a safe and properly equipped environment for these procedures.

My professional opinion is that device implantation at ambulatory surgery centers is a safe procedure. The practice in most hospitals, big and small is to do device implantation on an outpatient basis. The patient comes in for the implantation the same day and is discharged that same day. The implantation for a pacemaker or a defibrillator surgically is the same approach. The sedation given is conscious sedation, so the patient is not put under general anesthesia. Patients typically are able to ambulate 2 to 4 hours after the procedure and are discharged home. In small hospitals where I participated in device implantations, the procedures were done very safely and the patient satisfaction was very high. These implant procedures are very safe and the efficiency of doing them in a CMS-certified, accredited ambulatory surgery center setting is ideal and appropriate as it offers patients an additional option of care and provides a lower cost.

Thank you for allowing us to provide comments during the standards review. If you have any questions please don't hesitate to contact me.

Tony Murry R.N.

[248-330-6219](tel:248-330-6219)

Sent from my iPhone

Sent from my iPhone

July 16, 2018

James Falahee, Chairperson

Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

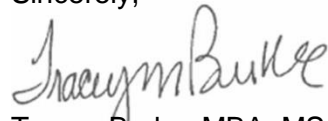
Dear Chairperson Falahee,

Thank you for this opportunity to provide written testimony regarding the proposed changes to the CON Review Standards for Cardiac Catheterization Services.

Specifically, Spectrum Health is pleased that the Commission has twice now supported the Cardiac Catheterization Standards Advisory Committee's language to keep pacemakers and implantable cardioverter defibrillator implant procedures in licensed hospitals. While the Centers for Medicare & Medicaid Services very recently started reimbursing for these services when performed in ambulatory surgical centers, we have strong reservations about these procedures being performed in a location where an appropriate surgeon, broader cardiac services, and experienced staff may not be immediately available to intervene if an emergent need arose. As an example, a well-known complication of device implantation is pericardial tamponade, which cannot be safely treated in the ambulatory setting.

We also want to reiterate our support for all of the other changes recommended by the SAC and supported by the Commission at the March and June meetings. Again, thank you for the opportunity to provide feedback on the CON Review Standards for Cardiac Catheterization Services. Spectrum Health appreciates the Commission's ongoing support for the safety and quality of care for Michigan's residents.

Sincerely,



Tracey Burke, MBA, MSA, RVT, RDMS
Vice President, Cardiovascular Health



Dr. Penny Wilton, MBBS, FANZCA, FRCA, FFICM, MBA
Vice President, Department Chief, Cardiovascular Health

Aug. 15, 2018

Attn: CON Commission
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: SUPPORT OF PACEMAKER AND ICD PLACEMENT IN AMBULATORY SURGERY CENTER (ASC) SETTING

To Whom It May Concern:

I am writing to clarify my letter July 16, 2018, sent for support of pacemakers and ICD placement in ambulatory surgery center (ASC) setting.

1. The letter was inadvertently sent on clinic stationary containing the DMC and Wayne State Logo and
2. The content and opinions expressed in my letter, is my own and not that of the DMC or Wayne State.

I have attached a copy of the same letter, without Logos. I apologize for any confusion or inconvenience this may have caused. Please feel free to contact me for any further information.

8/15/2018

X Randy A Lieberman, MD

Randy A Lieberman, MD

Signed by: Lieberman, Randy

Randy A Lieberman, MD FACC
Professor of Medicine
Dept. Of Int. Med: Division of Cardiology
Wayne State University School of Medicine
Detroit, Mi
rlieberm@med.wayne.edu
Cell phone: 248-981-7096

Randy A. Lieberman, M.D.
Professor of Medicine
Division of Cardiology
Board Certified Cardiac Electrophysiology

Attn: CON Commission
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: SUPPORT OF PACEMAKER AND ICD PLACEMENT IN AMBULATORY SURGERY CENTER (ASC) SETTING

To Whom It May Concern:

As a board-certified cardiologist and board-certified electrophysiologist, licensed in state of Michigan, I am writing in support of CON Commission permitting pacemaker and defibrillator implants to be performed in an ambulatory surgery center setting. I have for years been performing pacemaker and defibrillator implants on an outpatient basis, under conscious sedation, with a minimum number of hours of post-op care, i.e. my patients are discharged the same day. Having had the opportunity to tour many ambulatory surgery centers, I can confidently state their high standard for patient care and state-of-the-art equipment can provide the same safe and efficient environment for these minimally-invasive procedures, as the inpatient center. Knowing that ambulatory surgery centers are heavily regulated by the state, CMS, and various highly-reputable accrediting bodies provides me further confidence that these facilities will be monitored for patient safety, properly staffed with qualified doctors and nurses, and fully prepared for emergency situations.

Furthermore, the transition of my implant practice to an out patient practice as noted above, I have noted a decrease in hospital/inpatient related complications, including IV issues, narcotic/sedative, urinary tract Foley use, and medication complications.

While the concern is that unstable patients will not be provided the care of an inpatient facility, the experience of Orthopedic, GI, Vascular and Cardiac do not support this. Unstable patients will by default still be evaluated in the ER or hospital setting, and only the ambulatory patient being evaluated by a physician for stable symptoms will be provided care in the ASC.

I urge the CON Commission of Michigan to further review this request and bring about a regulatory change allowing pacemaker and ICD placement to be performed in an ASC setting, as

Randy A. Lieberman, M.D.
Professor of Medicine
Division of Cardiology
Board Certified Cardiac Electrophysiology

has been allowed in other states for many years. Do not hesitate to contact me with any questions or concerns.

Sincerely,

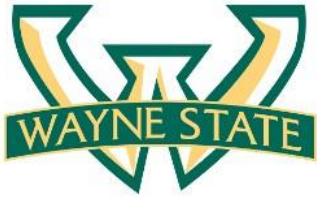
8/15/2018

X Randy A Lieberman, MD

Randy A Lieberman, MD

Signed by: Lieberman, Randy

Randy A Lieberman, MD
311 Mack Avenue Suite 63100
Detroit Michigan 48201
Email: rlieberm@med.wayne.edu
Phone: 313-832-0700



School of Medicine

Randy A Lieberman, MD

Professor of Medicine
Dept. of Internal of Medicine
Division of Cardiology



July 16, 2018

Attn: CON Commission
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: SUPPORT OF PACEMAKER AND ICD PLACEMENT IN AMBULATORY SURGERY CENTER (ASC) SETTING

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While the concern is that unstable patients will not be provided the care of an inpatient facility, the experience of Orthopedic, GI, Vascular and Cardiac do not support this. Unstable patients

Randy A Lieberman, MD

Professor of Medicine
Dept. of Internal of Medicine
Division of Cardiology

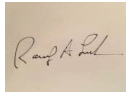
will by default still be evaluated in the ER or hospital setting, and only the ambulatory patient being evaluated by a physician for stable symptoms will be provided care in the ASC.

I urge the CON Commission of Michigan to further review this request and bring about a regulatory change allowing pacemaker and ICD placement to be performed in an ASC setting, as has been allowed in other states for many years. Do not hesitate to contact me with any questions or concerns.

Sincerely,

7/19/2018

X



Signed by: Lieberman, Randy

Randy A Lieberman, MD

311 Mack Avenue Suite 63100 Detroit Michigan 48201

Email: rlieberm@med.wayne.edu

Phone: 313-832-0700



EDITH & BENSON FORD HEART & VASCULAR INSTITUTE
Henry Ford Hospital & Medical Centers

Division of
Cardiovascular Medicine

Henry Ford Hospital
2799 W. Grand Blvd.
Detroit, MI 48202
(313) 916-2737 Office

July 16, 2018

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) remains supportive of the recommended language changes for the Certificate of Need Cardiac Catheterization services standards. Specifically, the revised language allowing pacemaker and ICD implantation only be done in hospitals with Cardiac Catheterization service approval and the relocation language which aligns relocation of Cardiac Catheterization services in conjunction with an Open Heart services program.

The revised language clarifying what types of facilities can perform pacemaker and ICD implantation reflects the formal recommendations of the Standards Advisory Committee.

These revisions will ensure high quality, safe and convenient services for our patients.

Thank you for the opportunity to provide public comments.

Respectfully,

A handwritten signature in black ink, appearing to read "Dr. Henry Kim", with a long horizontal flourish extending to the right.

Dr. Henry Kim
Henry Ford Medical Group
Division Head- Cardiology, CARDIOVASCULAR MEDICINE
2799 W. Grand Blvd
Detroit, MI 48202