MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Thursday, September 21, 2017

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Mukherji called the meeting to order at 9:31 a.m. and asked for introductions of Commissioners and staff.

A. Members Present:

Suresh Mukherji, MD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN
James B. Falahee, Jr., JD
Tressa Gardner
Debra Guido-Allen, RN
Robert Hughes
Marc Keshishian, MD
Melanie LaLonde

B. Members Absent:

Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Health and Human Services Staff Present:

Tulika Bhattacharya
Matt Lori
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Keshishian, seconded by Commissioner Falahee, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of June 15, 2017

Motion by Commissioner Falahee, seconded by Commissioner Mittlebrun, to approve the minutes as presented. Motion carried.

V. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services – Draft Language & Public Hearing Report

Ms. Rogers gave an overview of the public hearing and draft language (Attachments A and B).

A. Public Comment

1. Jorgen Madsen, Great Lakes Lithotripsy
2. Dave Clark, patient
3. Rick Hughes, Greater Michigan Lithotripsy (GML)
4. Theresa Perry, Greater Michigan Lithotripsy
5. Paula Reichle, Sparrow Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Keshishian to request the Department to look at similar to MRI conversion language using lesser numbers and if that could be for a tax-exempt, not for profit hospital, operating a 24/7 emergency department and bring back to the Commission. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Surgical Services – Vascular Access Presentation by Fresenius

Dr. Miller provided the presentation (Attachment C).

A. Commission Discussion

Discussion followed.

VII. Surgical Services – Draft Language & Public Hearing Report

Ms. Rogers gave an overview of the public hearing and draft language (Attachments D and E).

A. Public Comment

None.

B. Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Keshishian to take final action on the language as presented (Attachment E) and move forward to the JLC and the Governor for the 45-day review period. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Brooks-Williams, seconded by Mittlebrun to have the Department work with Fresenius to draft language regarding vascular access for a future meeting and to add exemptions for 10(2)(a) and (b) under Section 10(2)(e). Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Cardiac Catheterization Standard Advisory Committee (CCSAC) – Interim Report (Written Only)

Chairperson Mukherji mentioned the written report (Attachment F) from Shukri David, MD, CCSAC Chairperson.

IX. Hospital Beds Standard Advisory Committee (HBSAC) – Interim Report (Written Only)

Chairperson Mukherji mentioned the written report (Attachment G) from Renee Turner-Bailey, HBSAC Chairperson.

X. Legislative Report

None.

XI. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment H)
    a. Cardiac Catheterization Services (Attachment I)
    b. Megavoltage Radiation Therapy (MRT) Services (Attachment J)
2. Quarterly Performance Measures (Attachment K)

XII. Legal Activity Report

Mr. Potchen provided an update on the CON legal activity.

XIII. Future Meeting Dates:

December 7, 2017, January 25, 2018 (Special Commission Meeting), March 15, 2018, June 14, 2018, September 20, 2018, & December 6, 2018

XIV. Public Comment

None.

XV. Review of Commission Work Plan

Ms. Rogers provided an overview of the changes to the Work Plan (Attachment L).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Gardner to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 10 - Yes, 0- No, and 0- Abstained.

XVI. Adjournment

Motion by Commissioner Hughes, seconded by Commissioner Guido-Allen, to adjourn the meeting at 11:16 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Michigan Department of Health and Human Services (MDHHS or Department)
MEMORANDUM
Lansing, MI

Date: August 28, 2017

TO: The Certificate of Need (CON) Commission

FROM: Brenda Rogers, Special Assistant to the CON Commission, Office of Planning, CON Policy, MDHHS

RE: Summary of Public Hearing Comments on Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the UESWL Services Standards at its June 15, 2017 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed UESWL Services Standards on August 3, 2017. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from five individuals on behalf of three organizations.

Written Testimony:

1.) Jorgen Madsen, Great Lakes Lithotripsy

- Supports the draft language.

2.) Alan Buergenthal, Greater Michigan Lithotripsy

- Can support the draft language as long as the requirement to have performed an average of 1,000 procedures annually over the last three years is included for converting from mobile to fixed UESWL services.

3.) Paul Entler, DO, Sparrow Hospital

- Supports the draft language with a lower volume threshold to convert from mobile to fixed UESWL services.

4.) David Clark, on behalf of Sparrow Hospital

- Supports the draft language with a lower volume threshold to convert from mobile to fixed UESWL services.

5.) Paula Reichle, Sparrow Hospital

- Supports the language as passed at the March Commission meeting with a conversion threshold of 500, not 1,000, or alternately supports deregulation of UESWL services.

Department Recommendation:

The Department supports the language as presented at the June 15, 2017 CON Commission meeting.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an UESWL service/unit under Part 222 of the Code. Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

(b) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(c) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(e) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (~~MDCH~~MDHHS).

(f) "Existing mobile UESWL unit" means a CON-approved and operational UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(g) "Existing UESWL service" means the utilization of a CON-approved and operational UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.

(h) "Existing UESWL unit" means the utilization of a CON-approved and operational UESWL unit.

(i) "Hospital" means a health facility licensed under Part 215 of the Code.

(j) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

(k) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

(l) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association or successor organization. The database consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(m) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(n) "Planning area" means the state of Michigan.
(o) “Region” means the geographic areas set forth in Appendix B.
(p) “Renewal of a lease” means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a change in the parties to the lease.
(q) “Retreatment” means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.
(r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope that may or may not include laser technology.
(s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.
(t) “UESWL service” means either the CON-approved utilization of a UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
(u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or replacement of an existing UESWL service or the renewal of a lease.

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) EITHER ~~On~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.
(v) On-site crash cart.
(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.
(vii) EITHER ~~O~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.

(2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1)(B):
(a) THE APPLICANT IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.
(b) THE APPLICANT HAS PERFORMED AT LEAST 1000 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.
(c) THE APPLICANT SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.

(d) THE APPLICANT SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE BECOMES OPERATIONAL.

Section 4. Requirements to replace an existing UESWL unit(s)

Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s) from the existing site to a different site, OR a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.

(1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.

(2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:
(a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.
(b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 10.

(3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:
(a) The existing equipment clearly poses a threat to the safety of the public.
(b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.
(c) The existing equipment is fully depreciated according to generally accepted accounting principles.

(4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):
(a) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.
(b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).
(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).
(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.

(5) An applicant proposing to ~~relocate~~ REPLACE ~~its~~ AN existing FIXED UESWL service and its unit(s) TO A NEW SITE shall demonstrate that the proposed project meets all of the following:
(a) ~~The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).~~
~~(b)~~ The UESWL service to be ~~relocated~~ REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS THE REQUIREMENT IN SUBSECTION (d)(i) OR (ii).

(~~c~~b) The site to which the UESWL service will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).

(~~d~~c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be ~~relocated~~REPLACED.

(~~e~~d) The UESWL service and its unit(s) to be ~~relocated~~ REPLACED performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:~~.~~

(i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

(ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR

(iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.

(~~f~~e) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these standards.

(6) An applicant proposing to ~~relocate~~ REPLACE a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) The existing UESWL service from which the UESWL unit(s) is to be ~~relocated~~ REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The site to which the UESWL unit(s) will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).

(c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the fixed UESWL unit to be ~~relocated~~REPLACED.

(d) Each existing UESWL unit(s) at the service from which a unit is to be ~~relocated~~ REPLACED performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

(e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these Standards.

(f) For volume purposes, the new site shall remain associated with the existing UESWL service for a minimum of three years.

(7) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

Section 5. Requirements for approval to expand an existing UESWL service

Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 7(1)(c).

Section 6. Requirements to acquire an existing UESWL service or an existing UESWL unit(s)

Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(1) ~~An~~ THE applicant ~~proposing to acquire an existing fixed or mobile UESWL service and its unit(s)~~ shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs ~~demonstrate that A~~IF THE proposed project meets ~~all~~ ONE of the following:

(a) ~~For an application for the proposed~~IT IS THE first acquisition of ~~an~~ THE existing fixed or mobile UESWL service~~,~~ for which a final decision has not been issued after May 2, 1998~~, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs~~. ~~The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.~~

(b) THE EXISTING FIXED OR MOBILE UESWL SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE UESWL SERVICE SHALL REMAIN AT THE SAME SITE.

(2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except ~~the first~~ AN application approved pursuant to subsection (~~a~~1), ~~for which a final decision has not been issued after May 2, 1998~~, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(~~2~~3) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(b) The requirements of Section 3(1)(c) have been met.

(4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

Section 7. Additional requirements for approval for mobile UESWL services

Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

(a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (b).

(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.

(2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 10 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, are located in that region(s).

(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).

Section 8. Requirements for Medicaid participation

Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of service if a CON is approved.

Section 9. Project delivery requirements terms of approval for all applicants

Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved UESWL units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

(b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(g) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(3) Compliance with the following access to care requirements:

(a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(i) Not deny any UESWL services to any individual based on inability to pay or source of payment,

(ii) Provide all UESWL services to any individual based on clinical indications of need for the services, and

(iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(4) Compliance with the following monitoring and reporting requirements:

(a) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

(c) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) Compliance with the following mobile UESWL requirements, if applicable:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(6) The agreements and assurances required by this Section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 10. Methodology for projecting UESWL procedures

Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section 11. Requirements for MIDB data commitments

Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate.

The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 18~~SEPTEMBER 25, 2014 and effective on ~~June~~ DECEMBER 22, 2014.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.~~09~~104.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determining statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining "urban/rural" adjustment factor:

(i) For each hospital, assign urban/rural status based on the ~~2000 census~~COUNTY CLASSIFICATIONS FOUND IN APPENDIX C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.

(iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.

(iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of records in "urban" and "rural" by dividing the respective number of records by the total number of records for that zip code. Multiply the population of each zip code by its respective "urban" and "rural" proportions.

(v) Aggregate the records and populations from step (b)(iv) separately by "urban/rural" status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately. Calculate the "urban" and "rural" discharge rates per 10,000 (DRU and DRR, respectively) by dividing the total number of records by the total population for each status, then multiplying by 10,000.

(vii) Divide the urban discharge rate by the rural discharge rate (DRU/DRR) to calculate the "urban/rural" adjustment factor. Multiply the statewide adjustment factor identified in step (a)(iii) by the "urban/rural" adjustment factor. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

APPENDIX B

Counties assigned to each region are as follows:

Region	Counties			
1	Livingston	Monroe	Macomb	Oakland
	St. Clair	Washtenaw	Wayne	
2	Clinton	Eaton	Hillsdale	Ingham
	Jackson	Lenawee		
3	Barry	Berrien	Branch	Calhoun
	Cass	Kalamazoo	St. Joseph	Van Buren
4	Allegan	Ionia	Kent	Lake
	Mason	Mecosta	Montcalm	Muskegon
	Newaygo	Oceana	Osceola	Ottawa
5	Genesee	Lapeer	Shiawassee	
6	Arenac	Bay	Clare	Gladwin
	Gratiot	Huron	Iosco	Isabella
	Midland	Ogemaw	Roscommon	Saginaw
	Sanilac	Tuscola		
7	Alcona	Alpena	Antrim	Benzie
	Crawford	Charlevoix	Cheboygan	Emmet
	Gd. Traverse	Kalkaska	Leelanau	Manistee
	Missaukee	Montmorency	Oscoda	Otsego
	Presque Isle	Wexford		
8	Alger	Baraga	Chippewa	Delta
	Dickinson	Gogebic	Houghton	Iron
	Keweenaw	Luce	Mackinac	Marquette
	Menominee	Ontonagon	Schoolcraft	

APPENDIX C

Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquett	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
592.0	Calculus of Kidney	N20.0	Calculus of Kidney
		N20.2	Calculus of Kidney with Calculus of Ureter
592.1	Calculus of Ureter	N20.1	Calculus of Ureter
		N20.2	Calculus Of Kidney with Calculus of Ureter
592.9	Urinary Calculus	N20.9	Urinary Calculus, Unspecified
		N22	Calculus of Urinary Tract in Diseases Classified Elsewhere

"ICD-9-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification Of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.

Presentation to Michigan Certificate of Need Commission

Fresenius Managed Vascular Access Centers

September 21, 2017

CMS Costs and ESRD Seamless Care Organizations ("ESCOs")

Attachment C

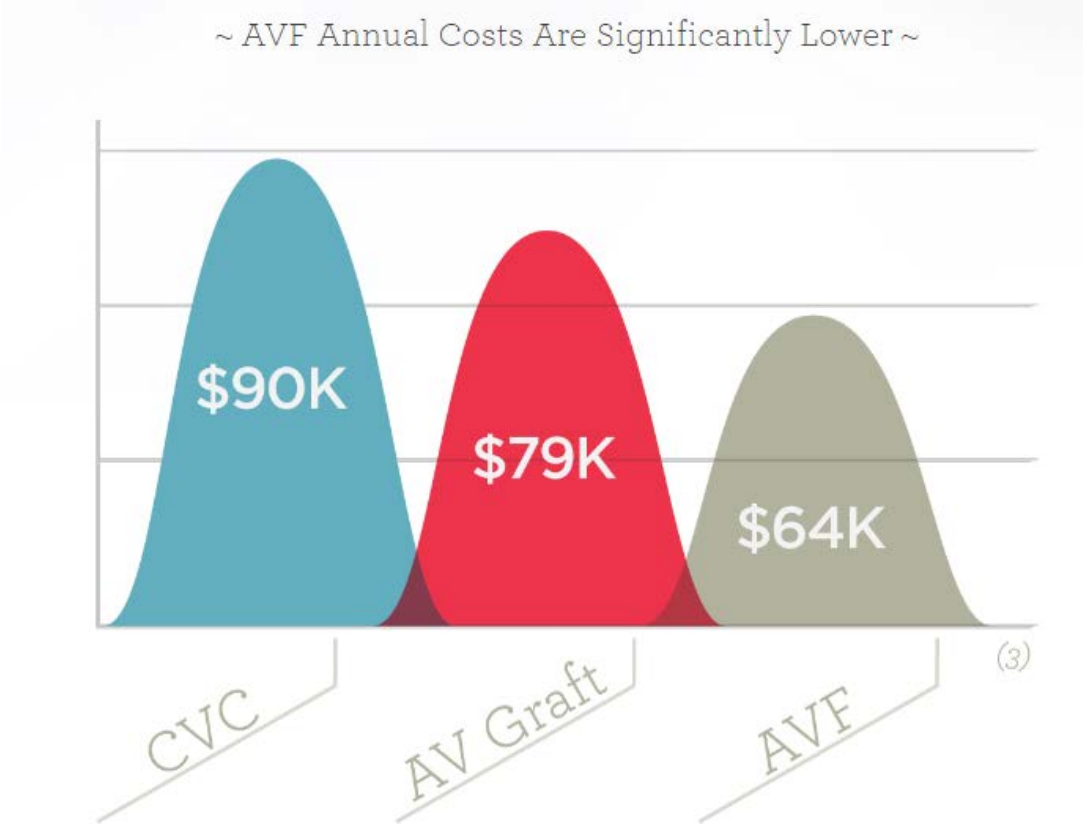
- In 2014, ESRD beneficiaries comprised less than 1% of the Medicare population
  - BUT, these beneficiaries accounted for an estimated 7.2% of total Medicare fee-for-service spending
  - Cost over $32.8 billion
    - ESRD patients have complex health needs with multiple co-morbidities
      - Beneficiaries often require visits to multiple providers and follow multiple care plans, all of which can be challenging for beneficiaries if care is not coordinated
      - Poor care coordination impacts patient outcomes and is resulting in high Medicare costs
    - Because ESRD status is an independent eligibility criterion for Medicare benefits (regardless of age), ESRD beneficiaries may be of various ages
    - Medicare is the primary payor for ESRD care

Renal focused ASCs are Central to CMS Concept of ESRD Seamless Care Organizations ("ESCOs")

- To address high costs for ESRD beneficiaries and to improve the quality of care and patient outcomes, CMS has sponsored the Comprehensive ESRD Care Initiative
  - CMS supports the creation of alternative payment models and has created new concept known as "ESRD Seamless Care Organizations" ("ESCOs")
  - Fresenius is now participating in 26 ESCOs
- ESCOs seek to address:
  - Poor health outcomes for ESRD patients due to underlying disease complications and co-morbities
  - High rates of hospital admission and readmissions, as well as a mortality rate that is higher than that of the general Medicare population for patients with ESRD
- **The type of vascular access is a major contributor to morbidity, mortality and cost associated with dialysis**

The “Gold Standard” of Vascular Access is an AVF
Fewer than 20% of patients initiate dialysis with a functioning AVF

- Catheters have 0.9-2.0 infection episodes per patient-year
  - Infections translate directly into increased cost
  - Cost of treating one catheter-related episode of bacteremia is approximately $45,000
- “Fistula First” Goal : drive catheter rates down and increase fistula rates

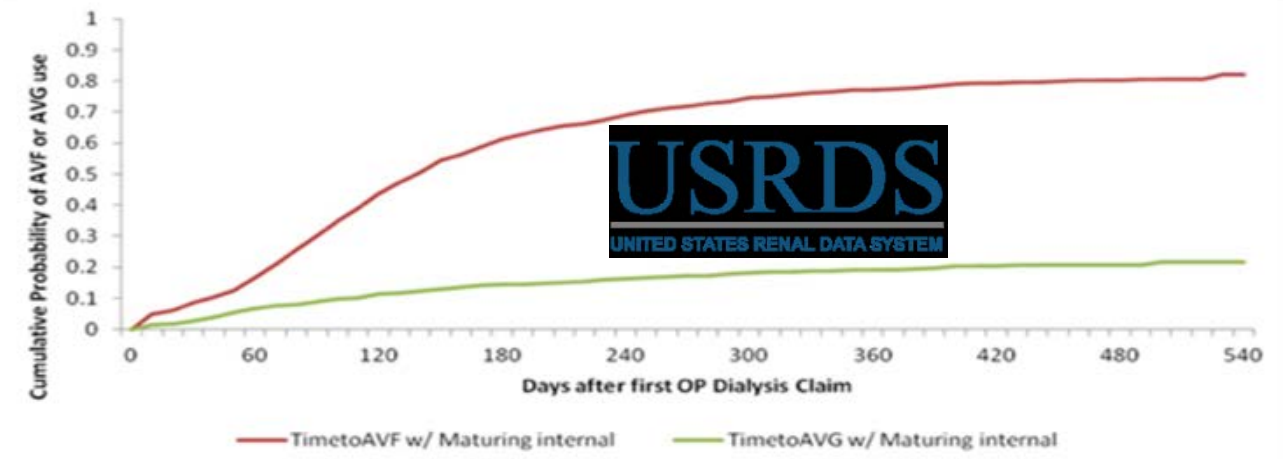


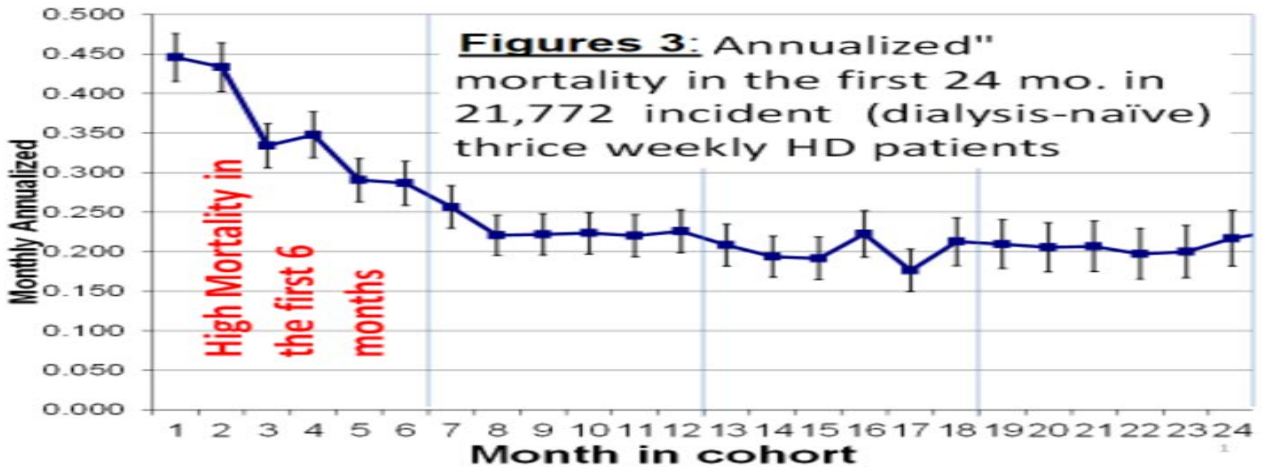
USRDS 2010

[1]Dobson A, El-Gamil A, Shimer M, DaVanzo J. 2013

Without Care Coordination, Catheter Exposure Time is Prolonged

Time to Fistula or Graft Use in patients initiating dialysis with a catheter and a maturing AVF/AVG





Without Care Coordination

	Current Uncoordinated	Fresenius Coordinated Care
Consultation	Independent VS office	Affiliated vascular practice
Vein Mapping	Interventional suite	RASC
Access Creation	Hospital	RASC
Wound check	Independent VS office	RASC
Fistula Maturation	Interventional suite	RASC
Fistula cleared for use	Independent VS office	RASC
Catheter Removal	Interventional suite	RACS

With Care Coordination (Fresenius pilot data)

Center	# patients	CET (mean days)
Pilot center 1	83	45
Pilot center 2	78	90
FKC (Enterprise US)	17,860	120

CET defined = time from catheter insertion to removal

Traditional ASCs Do Not Meet Special Needs of Dialysis Patients

Attachment C

Renal focused ASC

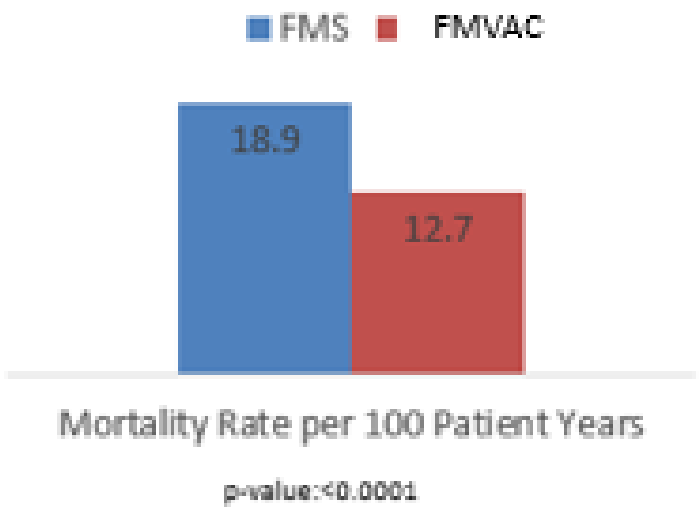
- Primarily care for Medicare (60%) and Medicaid patients (20%)
- Reduces fragmentation of care between multiple sites of service
- Routinely treat ASAIII patients
- Renal patients require dedicated physicians and staff
  - Chronically ill patients with multiple co-morbidities are most vulnerable to transition of care issues
- Allows for concentration and specialization
  - Enables the same interventional care team to create, follow, repair and maintain the ESRD patient's vascular access
  - *Allows for coordination of care*

Traditional ASCs

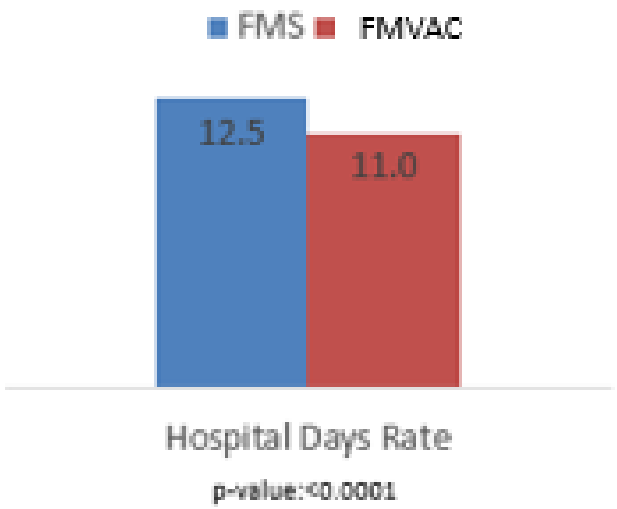
- Depend on a high level of commercial payers and low level of Medicare and Medicaid
- Do not routinely treat fragile patients who are chronically ill (ASAIII), have amputations and often have chronic infections
- Multiple practices competing for room time does not support the level care needed for this fragile patient population
- *Do not perform procedures on patients who have missed dialysis*
- *Do not routinely accommodate urgent/ emergent cases such as thrombectomies*

Coordinated Care in OBS has Improved Quality Access Outcomes: FMS vs FMS seen at Fresenius-Managed Vascular Access Clinics (FMVAC)

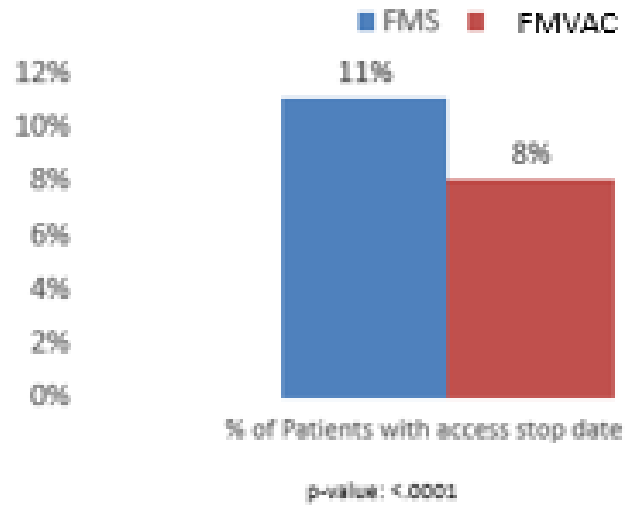
Attachment C



33% Lower Mortality Rate



12% Lower Hospital Days Rate



Fewer patients with access stop date

What can the Commission do to Help?

- Allow us to work with the Department to develop a solution.
- Let us bring that solution back to you for your consideration at the December meeting.

Michigan Department of Health and Human Services (MDHHS or Department)
MEMORANDUM
Lansing, MI

Date: August 28, 2017

TO: The Certificate of Need (CON) Commission

FROM: Brenda Rogers, Special Assistant to the CON Commission, Office of Planning, CON Policy, MDHHS

RE: Summary of Public Hearing Comments on Surgical Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the Surgical Services Standards at its June 15, 2017 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Surgical Services Standards on August 3, 2017. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from three organizations.

Written Testimony:

1.) Gregg Miller, MD, Azura Vascular Care

- Supports the draft language. Azura would like the CON Commission to consider additional changes regarding renal-focused ambulatory surgery centers (ASCs) as "the current CON Standards for Surgical Services impose an insurmountable barrier to implementation of a renal-focused ASC and the CMS coordinated care model."

2.) Barbara Bressack, Henry Ford Health System (HFHS)

- Can support the draft language if applicants are also exempt from Section 11(2)(a) and (b).

3.) John Shull, Spectrum Health

- Can support the draft language if applicants are also exempt from Section 11(2)(a) and (b).

Department Recommendation:

The Department supports the language as presented at the June 15, 2017 CON Commission meeting.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services . The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. For purposes of these standards:

(a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(b) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) “Dedicated endoscopy or cystoscopy operating room” means a room used exclusively for endoscopy or cystoscopy cases.

(h) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (~~MDCH~~MDHHS).

(i) “Emergency Room” means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(j) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

(k) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(l) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a certified ASC.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.

(n) "Hospital" means a health facility licensed under Part 215 of the Code.

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(r) "Offer" means to perform surgical services.

(s) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.

(t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(v) “Procedure room” means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor.

(w) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a surgical service or one or more operating rooms.

(x) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(y) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(jj) "Surgical service" means performing surgery in a surgical facility.

(z) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(aa) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or more recent data that can be validated by the Department.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. Compliance with CON minimum volume requirements established by these standards shall be determined based on the average number of surgical cases, hours of use, or both, per operating room of the surgical service as permitted by these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(v).

(v) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(iv).

(vi) A hybrid ORCCL shall have 0.5 excluded for each room meeting the requirements of section of these standards. A surgical facility will not be limited to the number of hybrid ORCCLS within a single licensed facility.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsectionS (2)(a)(iv), (v), AND (vi) but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), and (iii).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or

hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements to initiate a surgical service

Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not offered surgical services within the 12-month period immediately preceding the date an application is submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the following, as applicable to the proposed project.

(1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.

(3) An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) for the number of surgical cases projected under subsection (1).

(a) SECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT.

Section 5. Requirements to replace a surgical service

Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes relocating an existing surgical facility or one or more operating rooms to a new geographic location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services. The term does not include the renovation of an existing surgical service or one or more operating rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant proposing to replace shall demonstrate:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(b) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan statistical area county and has one or two operating rooms.

(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall submit notification to the Department on a form provided by the Department. An applicant under this subsection shall not be required to comply with subsections (1) and (2).

(6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or micropolitan statistical area county.

(b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be relocated have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or,

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.) or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.

(8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation,.

(9) An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) for the number of surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

Section 6**. Requirements to expand an existing surgical service**

Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following as applicable, to the proposed project.

(1) An applicant shall demonstrate the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,216 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to 438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00 OR), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases would equate to 438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00 OR.)

(b) All proposed operating rooms are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has two, three, or four ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 979 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,400 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All proposed operating rooms are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has only one operating room.

(4) An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) for the number of surgical cases, or hours of use, projected under subsections (1) and (2).

Section 7. Requirements to acquire an existing surgical service

Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant agrees and assures to comply with all applicable project delivery requirements.

(2) For the first application proposing to acquire an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in compliance with the applicable volume requirements set forth in these standards. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition.

(3) For any application proposing to acquire an existing surgical service except the first application, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall be required to be in compliance with the applicable volume requirements on the date the application is submitted to the Department.

(4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

Section 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)

Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current con review standards for open heart surgery services.

(2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the facility, the applicant is in compliance with Section 6 of these standards.

(3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in compliance with the provisions of Section 5, if applicable.

(4) The applicant meets the applicable requirements of the CON review standards for cardiac catheterization services.

(5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

Section 9. Requirements for Medicaid Participation

Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

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

Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(i) The designation of ORs as defined by the standards shall not be changed without prior notification to the Department.

(ii) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(v) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(vi) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(ix) An applicant shall have written policies and procedures for advising patients of their rights.
(x) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.
(xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.
(xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.
(B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.
(C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) Compliance with the following access to care requirements:
(a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
(b) not deny surgical services to any individual based on ability to pay or source of payment;
(c) provide surgical services to any individual based on the clinical indications of need for the service.
(d) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.
(e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter or attest that the applicant has been unable to contract with Medicaid managed care products at current Medicaid rates.

(4) Compliance with the following monitoring and reporting requirements:
(a) Existing operating rooms shall perform an average of at least:
(i) 1,042 surgical cases per year per operating room verifiable by the Department, or
(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room verifiable by the Department, or
(iii) Be in compliance using the applicable weighted averages under Section 5.
(b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or five OR'S shall perform an average of at least:
(i) 839 surgical cases per year per operating room verifiable by the Department or
(ii) 1,200 hours of use per year per operating room verifiable by the Department.
(c) The applicant shall participate in a data collection System established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.
(d) The surgical service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 11. Documentation of projections

Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume projections were developed and shall include only those surgical cases performed in an OR.

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

(2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will continue to be in compliance with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation, expansion, or replacement of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or replacement of the surgical service proposed by an applicant.

(e) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN THREE YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.

(~~e~~f) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 12. Effect on prior CON review standards; comparative reviews

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~December 15, 2011~~SEPTEMBER 25, 2014 and effective on ~~February 27, 2012~~DECEMBER 22, 2014.

APPENDIX A

Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

September 11, 2017

Interim Report to the Michigan Department of Health and Human Services from the Cardiac Catheterization Standard Advisory Committee (CCSAC)

The committee has had two meetings, Thursday, July 13, 2017 and Monday, August 14, 2017. There was a quorum present at both meetings. At the first meeting, introductions, background on the committee, conflicts of interest were reviewed, the charges were reviewed. Basic CON overview was presented. Review and discussion of the charges followed by assignments. There were eight charges and at that meeting charge #1, charge #5, and charge #4 were assigned.

At the August 14th meeting a quorum was present. Please review the minutes for details of the meetings. In summary, charge #5 determine the weight if it is appropriate to incorporate additional interventional procedures that are not currently identified in Section 11. Dr. Simon Dixon provided an overview, Dr. Dixon was to obtain additional information from the local hospitals for final consideration. Discussion followed and recommendations will be made at the next meeting.

Discussion of charge #1, which is to determine if modifications are necessary in section 10 (5) (f) specifically whether or not this section should apply only to facilities that do not have onsite open heart surgery. Dr. Selke provided an overview. Discussion followed. A motion by Dr. Dixon and seconded by Dr. Gurm was to make section 10 (5) (f) applicable to only those without onsite open heart surgery. The motion carried in a vote of nine yes and zero for no and no abstinences. Charge #2 determined if pacemakers and implantable cardio defibrillators should be allowed to be performed in ambulatory surgical centers or only in a licensed hospital. Dr. David will provide an update at the next CCSAC meeting on September 14th.

Shukri David, MD, FACC
Chairperson of the Cardiac Catheterization Services Standard Advisory Committee

DD: 09/11/2017
DT: 09/11/2017
SD/cct/cs

Hospital Beds Standard Advisory Committee (HBSAC)
Report to the Certificate of Need Commission

September 21, 2017

Mr. Chairman,

The Hospital Beds Standard Advisory Committee (HBSAC) was approved by the Commission on March 16, 2017. The HBSAC has convened and conducted meetings on July 20 and August 24. During the July meeting, the charges were reviewed and discussed. Follow up questions were asked and clarifying information was requested from the Department. It was agreed to form subgroups which would review, research and bring pertinent information related to charge #2, "*Review and update, if necessary, the language throughout section 12, titled "Additional requirements for applications included in comparative reviews""*, as well as charge #4, "*Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary*." Review of this information, and further discussion will take place at the September meeting. In addition, related to charge #3 "*Review and update, if necessary, the space lease and lease renewal at hospitals*", the Department agreed to bring comparable language from the Nursing Home CON Standards for the committee's review at the August meeting.

During the August meeting, the committee reviewed charge #1, namely, "*Review and update or eliminate, if necessary, the language in section 6(4)(f), which states, "Applicants proposing to add new hospital beds under this subsection shall demonstrate to the Department that they have pursued a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA. At the time an application is submitted to the Department, the applicant shall demonstrate that contact was made by one certified mail return receipt for each organization contacted."* A motion was made and was carried to eliminate the language in Section 6(4)(f). The committee also reviewed language provided by the department showing comparable lease and lease renewal language from the Nursing Home CON standards. The next HBSAC meeting is scheduled for September 28.

Respectfully submitted,

Renee Turner-Bailey, M.H.S.A.
International Union, UAW

CERTIFICATE OF NEED

3rd Quarter Compliance Report to the CON Commission

October 1, 2016 through September 30, 2017 (FY 2017)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	3rd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	84	230
Approved projects contacted on or before anniversary date	64	117
Approved projects completed on or before 1-year follow up	76%	
CON approvals expired	35	73
Total follow up correspondence sent	246	711
Total approved projects still ongoing	293	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

- The Department is conducting statewide compliance reviews for Cardiac Catheterization Services and Megavoltage Radiation Therapy Services/Units utilizing 2015 CON Annual Survey data. After evaluating the annual survey data, review standards' requirements, and responses to additional questionnaire, the Department has identified the CON approved facilities for compliance investigations. The Department is in the process of completing compliance conference calls with each of these identified facilities. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

- Saint Mary's Health Care - During the follow-up review of an approved CON, it was noted that the facility had installed and operated a replacement fixed Computed Tomography (CT) Scanner without CON approval. The facility was required to establish an internal process to ensure that CON covered equipment receives approval prior to start of operations, and involve education about CON processes and requirements. The facility was required to pay a civil fine of $71,260.

Source: Certificate of Need Evaluation Section, Michigan Department of Health and Human Services.

Certificate of Need (CON) Statewide Compliance Review

Cardiac Catheterization (CC) Services

As part of the cardiac cath statewide compliance review, the Department reviewed all 60 facilities that offer CC services based on data reported in the 2015 CON Annual Survey. The 60 facilities that we reviewed were approved under 7 different CC review standards dating back to February 15, 1997. The table below is the breakdown of the facilities under each CC standard:

Review Standards Effective Date	No. of Facilities Approved
February 15, 1997	2
August 4, 2003	2
June 4, 2004	4
February 5, 2008	7
February 27, 2012	5
June 2, 2014	8
September 14, 2015	32

After reviewing 60 facilities, 32 received conference calls to discuss the compliance review findings and 2 of these resulted in closing out the investigation without any further action. The overview of the compliance issues are listed below:

- 11 facilities reported volumes that are below overall cath lab volume requirements.
- 4 facilities reported that they do not have 24-hour on-call availability.
- 26 facilities reported that their Physicians and/or Cath Lab Director(s) did not meet their individual volume requirements.

The Department is in discussions with these 30 facilities to come up with a plan for resolution of the compliance investigations.

Pages 2 and 3 are the breakdown of the 30 facilities by Health Service Area (HSA) and the compliance issues identified by the Department.

FACILITY NAME	STANDARDS	# of CC LABS	COUNTY	COUNTY DESIGNATION	CC SERVICE LEVEL	COMPLIANCE ISSUES
HSA 1: SOUTHEAST MICHIGAN						
HOSPITAL 1	June 2, 2014	3	Macomb	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 2	Sept. 14, 2015	11	Oakland	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 3	June 4, 2004	1	Oakland	Metro	Diagnostic	- Low CCL Volume. - No 24-Hour On-Call Availability.
HOSPITAL 4	Sept. 14, 2015	1	Oakland	Metro	Diagnostic	- Low CCL Volume. - Individual Physician Volumes. - Director of CC Services Volumes.
HOSPITAL 5	June 2, 2014	4	Oakland	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 6	Sept. 14, 2015	2	Oakland	Metro	Diagnostic w/ Primary PCI	- Low CCL Volume. - Individual Physician Volumes.
HOSPITAL 7	June 2, 2014	1	St. Claire	Metro	Diagnostic	- Low CCL Volume. - No Director of CC Services.
HOSPITAL 8	Feb. 27, 2012	3	St. Claire	Metro	Therapeutic	- Individual Physician Volumes. - Director of CC Services Volumes.
HOSPITAL 9	Feb. 25, 2008	1	St. Claire	Metro	Diagnostic	- Low CCL Volume. - No 24-Hour On-Call Availability.
HOSPITAL 10	Sept. 14, 2015	1	Wayne	Metro	Diagnostic w/ Primary PCI	- Individual Physician Volumes. - Director of CC Services Volumes.
HOSPITAL 11	Sept. 14, 2015	2	Wayne	Metro	Diagnostic w/ Primary PCI	- Individual Physician Volumes.
HOSPITAL 12	Feb. 25, 2008	2 Ped	Wayne	Metro	Therapeutic	- Low CCL Volume.
HOSPITAL 13	Sept. 14, 2015	7	Wayne	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 14	June 2, 2014	6	Wayne	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 15	Sept. 14, 2015	8	Wayne	Metro	Therapeutic	- Individual Physician Volumes. - Director of CC Services Volumes.
HOSPITAL 16	June 2, 2014	3	Wayne	Metro	Therapeutic	- Individual Physician Volumes.
HSA 2: MID-SOUTH MICHIGAN						
HOSPITAL 17	Sept. 14, 2015	5	Ingham	Metro	Therapeutic	- Low CCL Volume. - Individual Physician Volumes.
HOSPITAL 18	June 2, 2014	3	Jackson	Metro	Therapeutic	- Individual Physician Volumes.

FACILITY NAME	STANDARDS	# of CC LABS	COUNTY	COUNTY DESIGNATION	CC SERVICE LEVEL	COMPLIANCE ISSUES
HSA 4: WEST MICHIGAN						
HOSPITAL 19	Sept. 14, 2015	9 Adult 1 Ped	Kent	Metro	Therapeutic	- Individual Physician Volumes.
HSA 5: GENESEE-LAPEER-SHIAWASSEE						
HOSPITAL 20	Feb. 27, 2012	6	Genesee	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 21	Feb. 27, 2012	4	Genesee	Metro	Therapeutic	- Individual Physician Volumes.
HOSPITAL 22	Feb. 15, 1997	1	Lapeer	Metro	Diagnostic	- Low CCL Volume. - No Director of CC Services. - Individual Physician Volumes.
HSA 6: EAST CENTRAL MICHIGAN						
HOSPITAL 23	Feb. 25, 2008	1	Clare	Micro/Rural	Diagnostic	- Low CCL Volume. - Individual Physician Volumes.
HOSPITAL 24	Feb. 15, 1997	1	Gratiot	Micro/Rural	Diagnostic	- Low CCL Volume. - Individual Physician Volumes.
HOSPITAL 25	Feb. 25, 2008	1	Huron	Micro/Rural	Diagnostic	- Individual Physician Volumes. - No 24-Hour On-Call Availability.
HOSPITAL 26	Feb. 25, 2008	1	Isabella	Micro/Rural	Diagnostic	- Individual Physician Volumes.
HOSPITAL 27	Feb. 27, 2012	1	Ogemaw	Micro/Rural	Diagnostic	- No 24-Hour On-Call Availability. - Director of CC Service Volumes.
HOSPITAL 28	Sept. 14, 2015	5	Saginaw	Metro	Therapeutic	- CCL Facility Certification - Individual Physician Volumes.
HOSPITAL 29	Feb. 25, 2008	5	Saginaw	Metro	Therapeutic	- Individual Physician Volumes.
HSA 7: NORTHERN LOWER MICHIGAN						
HOSPITAL 30	Aug. 4, 2003	1	Alpena	Micro/Rural	Diagnostic	- Low CCL Volume. - Individual Physician Volumes. - Director of CC Services Volumes.

Certificate of Need (CON) Statewide Compliance Review

Megavoltage Radiation Therapy (MRT) Services

As part of the MRT statewide compliance review, the Department reviewed all 68 facilities that offer MRT services based on data reported in the 2015 CON Annual Survey. The 68 facilities that we reviewed were approved under 7 different MRT review standards dating back to June 4, 1993.

After reviewing 68 facilities, 27 received conference calls to discuss the compliance review findings. 21 of the conference calls were regarding low volume, 1 was lacking proper accreditation and 5 resulted in closing out the investigation without any further action.

The Department is in discussions with these 22 facilities to come up with a plan for resolution of the compliance investigations. The table below is the breakdown of the facilities under each MRT standard:

Review Standards Effective Date	No. of Facilities Approved
June 4, 1993	1
April 28, 2000	9
January 30, 2006	9
November 13, 2008	11
November 21, 2011	12
May 24, 2013	17
September 14, 2015	9

Page 2 is the breakdown of the 22 facilities by Health Service Area (HSA) and the compliance issues identified by the Department.

FACILITY NAME	STANDARDS	# of UNITS	COUNTY	COUNTY DESIGNATION	COMPLIANCE ISSUES
HSA 1: SOUTH EAST MICHIGAN					
FREESTANDING 1	April 28, 2000	1	Oakland	Metro	Low Volume
FREESTANDING 2	April 28, 2000	1	Wayne	Metro	Low Volume
FREESTANDING 3	April 28, 2000	1	Wayne	Metro	Low Volume & No Simulation Capabilities
FREESTANDING 4	November 13, 2008	2	Oakland	Metro	Low Volume
FREESTANDING 5	November 21, 2011	2	Oakland	Metro	Low Volume
FREESTANDING 6	November 21, 2011	1	Macomb	Metro	Low Volume
HOSPITAL 7	November 21, 2011	2	Oakland	Metro	Low Volume
HOSPITAL 8	November 13, 2008	1	Oakland	Metro	Low Volume
HOSPITAL 9	May 24, 2013	2	Macomb	Metro	Low Volume
HOSPITAL 10	May 24, 2013	4	Wayne	Metro	Low Volume
FREESTANDING 11	September 14, 2015	1	Monroe	Metro	Low Volume
HOSPITAL 12	September 14, 2015	1	Wayne	Metro	Low Volume
HOSPITAL 13	September 14, 2015	2	Macomb	Metro	Low Volume
HSA 2: MID-SOUTH MICHIGAN					
HOSPITAL 14	April 28, 2000	1	Lenawee	Micro/Rural	Low Volume
HSA 3: SOUTHWEST MICHIGAN					
HOSPITAL 15	May 24, 2013	2	Calhoun	Metro	Low Volume
HSA 4: WEST MICHIGAN					
HOSPITAL 16	May 24, 2013	3	Kent	Metro	Low Volume
HSA 5: GENESEE-LAPEER-SHIAWASSEE					
FREESTANDING 17	May 24, 2013	N/A	Genesee	Metro	Accreditation
FREESTANDING 18	January 30, 2006	1	Lapeer	Metro	Low Volume
FREESTANDING 19	May 24, 2013	3	Genesee	Metro	Low Volume
HSA 6: EAST CENTRAL MICHIGAN					
HOSPITAL 20	November 21, 2011	1	Isabella	Micro/Rural	Low Volume
FREESTANDING 21	September 14, 2015	1	Gratiot	Micro/Rural	Low Volume
HSA 7: NORTHERN LOWER MICHIGAN					
HSA 8: UPPER PENINSULA					
HOSPITAL 22	June 4, 1993	1	Dickinson	Micro/Rural	Low Volume

CERTIFICATE OF NEED

3rd Quarter Program Activity Report to the CON Commission

October 1, 2016 through September 30, 2017 (FY 2017)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	83	N/A	249	N/A
Letters of Intent Processed within 15 days	83	100%	248	99%
Letters of Intent Processed Online	83	100%	249	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	58	N/A	210	N/A
Applications Processed within 15 Days	58	100%	207	99%
Applications Incomplete/More Information Needed	35	60%	142	68%
Applications Filed Online*	56	100%	190	100%
Application Fees Received Online*	15	27%	52	27%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	47	100%	140	100%
Substantive Applications	18	100%	72	100%
Comparative Applications	0	N/A	0	N/A

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	17	100%	48	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	3rd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	91	N/A	168	N/A
FOIA Requests Processed on Time *	91	100%	168	100%
Number of Applications Viewed Onsite	1	N/A	3	N/A

FOIA – Freedom of Information Act.

*Request processed within 5 days or an extension filed.

Source: Certificate of Need Evaluation Section, Michigan Department of Health and Human Services.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2017											
	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Commission Meetings	Special Meeting		Meeting			Meeting			Meeting			Meeting
Bone Marrow Transplantation (BMT) Services										Public Comment for 2018 Review		
Cardiac Catheterization Services	Discussion	SAC Nomination & Selection Period					SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report
Heart/Lung and Liver Transplantation Services										Public Comment for 2018 Review		
Hospital Beds	Discussion		Discussion	SAC Nomination & Selection Period			SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report
Magnetic Resonance Imaging (MRI) Services										Public Comment for 2018 Review		
Open Heart Surgery (OHS)	Discussion											Report/ Draft Language Presented/Potential Proposed Action
Psychiatric Beds and Services										Public Comment for 2018 Review		
Surgical Services	Discussion					Report/ Draft Language Presented/Proposed Action		Public Hearing	Report/ Potential Final Action			
Urinary Extracorporeal Shock Wave Lithotripsy Services		Public Hearing	Proposed Action		Public Hearing	Report/Draft Language Presented/ Proposed Action		Public Hearing	Report/ Potential Final Action			
New Medical Technology Standing Committee	Department Monitoring					Department Monitoring			Department Monitoring			
FY2017 CON Annual Report												Present to Commission

For Approval September 21, 2017

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS), Policy, Planning & Legislative Services, Office of Planning, 5th Floor South Grand Bldg., 333 S. Grand Ave., Lansing, MI 48933, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2018
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2020
Neonatal Intensive Care Services/Beds (NICU)	December 9, 2016	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2019

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.