Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Thursday, April 26, 2018
Time: 9:30 a.m.
Location: South Grand Building
333 S. Grand Avenue, 1st floor
Grand Conference Room
Lansing, MI 48933

■ ■ ■

CON Review Standards for Cardiac Catheterization Services

The proposed language changes include the following:

1. Updated the Department name throughout the document.
2. Added “hospital” after “applicant” throughout the document, as applicable, for clarity.
3. Added “/congenital” after “pediatric” throughout the document, as applicable, for clarity.
4. Section 2(1) - Added and modified definitions as follows:
   - (a) “ADULT CARDIAC CATHETERIZATION SERVICE” MEANS PROVIDING CARDIAC CATHETERIZATION SERVICES ON AN ORGANIZED, REGULAR BASIS TO PATIENTS AGE 18 AND ABOVE, AND FOR ELECTROPHYSIOLOGY PROCEDURES TO PATIENTS AGE 15 AND OLDER.
   - (b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers ~~, high speed film changers~~ and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.
   - (~~b~~c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room IN A LICENSED HOSPITAL.
   - (~~c~~d) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric/CONGENITAL cardiac catheterizations.
   - (e) “CARDIAC CATHETERIZATION SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC CARDIAC OR PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY. THE TERM SESSION APPLIES TO BOTH ADULT AND PEDIATRIC/CONGENITAL CATHETERIZATIONS.
   - (h) “COMPLEX THERAPEUTIC SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT UNDERGOES ONE OR MORE OF THE FOLLOWING PROCEDURES:
     (i) PCI FOR CHRONIC TOTAL OCCLUSION
     (ii) TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE
     (iii) ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION

- (j) "DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURE" INCLUDES RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING SUCH AS INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT), OR NEAR-INFRARED SPECTROSCOPY (NIRS) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY, AND ELECTROPHYSIOLOGY STUDY.
- (~~gk~~) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. ~~Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic).~~ A hospital that provides diagnostic cardiac catheterization services may also perform ~~implantations of cardiac~~ permanent pacemaker~~s~~ and ICD ~~devices~~ IMPLANTATION (THERAPEUTIC PROCEDURES).
- (l) "DIAGNOSTIC CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.
- (m) "DIAGNOSTIC PERIPHERAL PROCEDURE" INCLUDES ANGIOGRAPHY OR HEMODYNAMIC MEASUREMENTS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART).
- (n) "DIAGNOSTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (~~il~~p) "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI~~, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation~~ on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in ~~circulation~~ Circulation 2014, 129:2610-2626 and its update or further guideline changes. A HOSPITAL THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.
- (~~mt~~) "Pediatric/CONGENITAL cardiac catheterization service" means providing cardiac AND ELECTROPHYSIOLOGYcatheterization services on an organized, regular basis to infants and children ages 18 and below~~, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below,~~ and ~~others~~ PATIENTS BORN with congenital heart disease ~~as defined by the ICD-9-CM codes (See Appendix B for ICD-10-CM Codes) of 426.7 (anomalous atrioventricular excitation), 427.0 (cardiac dysrythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory system)~~.
- (u) "PERCUTANEOUS CORONARY INTERVENTION" (PCI) MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE CORONARY ARTERIES OF THE HEART. A PCI SESSION MAY INCLUDE SEVERAL PROCEDURES INCLUDING BALLOON ANGIOPLASTY, ATHERECTOMY, LASER, STENT IMPLANTATION AND THROMBECTOMY. THE TERM DOES NOT INCLUDE THE INTRACORONARY ADMINISTRATION OF DRUGS, FFR OR IVUS WHERE THESE ARE THE ONLY PROCEDURES PERFORMED.
- (v) "PERIPHERAL CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC PROCEDURES IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART) WHEN PERFORMED IN A CARDIAC CATHETERIZATION LABORATORY.
- (~~n~~w) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an EMERGENT BASIS ON A ~~acute myocardial infarction (AMI)~~ patient with ~~confirmed~~ ST-SEGMENT elevation, ~~or~~ new left bundle branch block~~ on an emergent basis~~, ECG EVIDENCE OF TRUE POSTERIOR MI, OR CARDIOGENIC SHOCK.

- (~~o~~x) "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A HOSPITAL THAT PROVIDES PRIMARY PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.
- (~~p~~y) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.
- (z) "STRUCTURAL HEART PROCEDURE" MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS OF THE HEART VALVES OR CHAMBERS. PROCEDURES INCLUDE: BALLOON VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, TRANSCATHETER VALVE REPAIR, TRANSCATHETER VALVE IMPLANTATION, PARAVALULAR LEAK CLOSURE, LEFT ATRIAL APPENDAGE OCCLUSION, PFO/ASD/VSD/PDA CLOSURE, ALCOHOL ABLATION OF CARDIAC TISSUE, EMBOLIZATION OF CORONARY FISTULAE AND ABNORMAL VASCULAR CONNECTIONS IN THE HEART.
- (~~q~~aa) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. ~~Procedures include pci, ptca, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, icd device implantations, transcatheter valve, other structural heart disease procedures, PTCA with coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.~~
- (bb) "THERAPEUTIC CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: PCI (ELECTIVE, EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.
- (cc) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.
- (dd) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (ee) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION, ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION, PACEMAKER/ICD IMPLANTATION, AND PCI.

5. Section 5(3) - Added language to replace a cardiac catheterization service to a new site simultaneously with an open heart surgery service. *(This language will only apply to those cardiac catheterization services that are being replaced simultaneously with an open heart surgery service. An open heart surgery service must have a diagnostic and therapeutic cardiac catheterization service.)*
6. Section 10(2) – Project delivery requirements have been updated.
   - (d) EACH PHYSICIAN CREDENTIALED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY

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

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

- (~~f~~g) An adult diagnostic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physicians~~:
  (i) are trained consistent with the recommendations of the American College of Cardiology;
  (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
  (iii) have ~~each~~ performed a minimum of 100 adult diagnostic cardiac catheterization~~s~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (~~g~~h) An adult therapeutic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physicians~~:
  (i) are trained consistent with the recommendations of the American College of Cardiology;
  (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
  (iii) have ~~each~~ performed a minimum of 50 adult therapeutic cardiac catheterization ~~procedures~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (~~h~~i) A pediatric/CONGENITAL cardiac catheterization service shall have ~~an appropriately trained~~AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. The Department may accept other evidence or shall consider it appropriate training if the staff physician~~:

7. Section 10(5)(c) – Language has been updated to exclude patients with cardiogenic shock.
8. Section 10(5)(f) – Modified language to make it applicable to only those catheterization labs providing primary PCI services without on-site OHS service and for catheterization labs providing elective PCI services without on-site OHS service.
9. Section 10(5)(i) – Modified language for clarity.
10. Section 11 – Updated procedure type, procedure equivalent, and added a description for the procedure type.
11. Removed Appendix B as it's no longer needed given the revised definition for "pediatric/congenital cardiac catheterization service."
12. Other technical edits.

CON Review Standards for Hospital Beds

The proposed language changes include the following:

1. Updated the Department name throughout the document.
2. Section 2(1) - Added and modified definitions as follows:
   - (v) "INPATIENT REHABILITATION FACILITY BED" OR "IRF BED" MEANS A LICENSED HOSPITAL BED WITHIN AN IRF HOSPITAL OR UNIT THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE) PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT INPATIENT REHABILITATION HOSPITAL IN ACCORDANCE WITH 42 CFR PART 412 SUBPART P.
   - (~~ll~~mm) "RENEWAL OF LEASE" MEANS EXECUTION OF A LEASE BETWEEN THE LICENSEE AND A REAL PROPERTY OWNER IN WHICH THE TOTAL LEASE COSTS EXCEED THE CAPITAL EXPENDITURE THRESHOLD.
   - (oo) "REPLACE IRF BEDS" MEANS A CHANGE IN THE LOCATION OF ALL IRF BEDS FROM AN EXISTING SITE TO A NEW SITE WITHIN THE REPLACEMENT ZONE FOR IRF BEDS.
   - (~~mm~~pp) "Replacement zone" means a proposed licensed site that is (i) in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles (5 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles (10 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.
3. Section 6(4)(a) - Added language to allow for beds received under high occupancy to be replaced to a new IRF hospital site under Section 7(6).

- (a) The beds are being added at the existing licensed hospital site, OR ARE BEING REPLACED TO A NEW IRF HOSPITAL SITE BEING CREATED UNDER SECTION 7(7) AS PART OF THE SAME CON APPLICATION.

4. Section 6(4)(f) - Removed language that required applicants adding new hospital beds under high occupancy to pursue a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA as it's not deemed necessary.
5. Section 7 – Added language to replace IRF beds to a new site as follows:
   - (2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site, TO REPLACE ALL LICENSED IRF BEDS TO A NEW SITE, to replace a portion of the licensed beds at the existing licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the licensed beds, which may include a new site across a highway(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26.
   - (6) IF THE APPLICATION INVOLVES THE DEVELOPMENT OF A NEW LICENSED IRF HOSPITAL SITE, AN APPLICANT PROPOSING TO REPLACE IRF BEDS WITHIN THE REPLACEMENT ZONE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION:
   - (a) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT SHALL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.
   - (b) THE APPLICANT HOSPITAL HAS DEMONSTRATED, AT THE TIME OF THE CON FILING, IT IS OPERATING UNDER HIGH OCCUPANCY AS GOVERNED BY SECTION 6(4) OF THESE STANDARDS.
   - (c) THE APPLICANT HAS DEMONSTRATED, AT THE TIME OF CON FILING, THAT THE BEDS TO BE REPLACED ARE EITHER IRF BEDS THAT MEET THE TITLE XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS AS AN IRF HOSPITAL, OR HIGH OCCUPANCY BEDS BEING REQUESTED UNDER SECTION 6(4) AS PART OF THE SAME CON APPLICATION.
   - (d) THE NEW IRF HOSPITAL WILL HAVE AT LEAST 40 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF 200,000 OR MORE; OR AT LEAST 25 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF LESS THAN 200,000.
   - (e) AS PART OF THE PHASING OF THE REPLACEMENT OF IRF BEDS TO THE NEW SITE, THE APPLICANT MAY RETAIN, FOR 36-MONTHS FROM THE TIME OF ACTIVATION OF THE NEW SITE, UP TO EIGHT IRF BEDS AT THE EXISTING HOSPITAL SITE. ANY IRF BEDS AT THE EXISTING SITE THAT HAVE NOT BEEN TRANSITIONED TO THE NEW SITE WITHIN THE 36-MONTH TIME PERIOD SHALL NOT BE UTILIZED FOR INPATIENT REHABILITATION AND SHALL REVERT BACK TO ACUTE MEDICAL-SURGICAL HOSPITAL BEDS.
   - (f) THE PROPOSED PROJECT TO BEGIN OPERATION OF A NEW SITE, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
   - (g) THE EXISTING HOSPITAL SITE SHALL DELICENSE THE SAME NUMBER OF IRF BEDS PROPOSED BY THE APPLICANT FOR LICENSURE IN THE NEW IRF HOSPITAL.
   - (h) APPLICANTS PROPOSING A NEW IRF HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.
   - (i) THE NEW IRF HOSPITAL SHALL BE ASSIGNED TO THE SAME HOSPITAL GROUP AS THE HOSPITAL WHERE THE IRF BEDS ORIGINATED.
   - (j) IF THE IRF HOSPITAL APPROVED UNDER THIS SUBSECTION CEASES OPERATION AS AN IRF HOSPITAL, THE BEDS LICENSED AS PART OF THE NEW IRF HOSPITAL MUST BE DISPOSED OF BY ONE OF THE FOLLOWING MEANS:
   - (i) RELOCATE THE REPLACED IRF BEDS BACK TO THE SITE OF ORIGIN;
   - (ii) RELOCATE ALL IRF BEDS APPROVED UNDER HIGH OCCUPANCY TO THE SITE OF ORIGIN IN SUBSECTION (i) IF THEY ARE TO BE UTILIZED AS AN IRF BED; OR
   - (iii) DELICENSE ANY IRF BEDS APPROVED UNDER HIGH OCCUPANCY IF THEY ARE NOT TO BE UTILIZED AS AN IRF BED.
6. Section 9(5) – Added language to the project delivery requirements for replacement of IRF beds to a new site as follows:
   - (5) AN APPLICANT APPROVED FOR THE REPLACEMENT OF IRF BEDS UNDER SECTION 7(6) TO A NEW NON-CONTIGUOUS SITE SHALL BE IN COMPLIANCE WITH THE FOLLOWING:

- (a) THE REPLACED IRF BEDS SHALL MAINTAIN THEIR PPS EXEMPT INPATIENT REHABILITATION HOSPITAL STATUS.
- (b) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT WILL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.

7. Section 12 – Updated comparative review criteria.
8. Old Section 13 – Removed and combined with Section 12.
9. New Section 13 – Added language for the renewal of a lease similar to other CON Review Standards.
10. New Section 14(4) – Added new language for the applicant to certify that the requirements for hospitals found in the Minimum Design Standards for Health Care Facilities of Michigan will be met when the architectural blueprints are submitted for review and approval by Licensing and Regulatory Affairs (LARA). This is similar to other CON Review Standards.
11. Removal of Appendix D Limited Access Areas as it's located on the State of Michigan CON web site. All references have been updated to reflect the State of Michigan CON web site. Appendix E is now Appendix D ICD-9-CM TO ICD-10-CM Code Translation.
12. Other technical edits.

CON Review Standards for Open Heart Surgery (OHS) Services

The proposed language changes include the following:

1. Updated the Department name throughout the document.
2. Added language under new Section 4 – Requirements to replace an existing OHS Service. This language will not increase the number of OHS services in the state, instead it will allow current OHS providers to replace their service to a new location and discontinue service at the previous location. This language is consistent with language in other CON review standards.
   - SEC. 4. REPLACE AN EXISTING ADULT OR PEDIATRIC OHS SERVICE MEANS RELOCATING AN EXISTING ADULT OR PEDIATRIC OHS SERVICE TO A NEW GEOGRAPHIC LOCATION OF AN EXISTING LICENSED HOSPITAL. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING OHS SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.
   - (1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE THE FOLLOWING:
   - (a) THE EXISTING OHS SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.
   - (b) THE PROPOSED NEW SITE IS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.
   - (c) THE APPLICANT IS SIMULTANEOUSLY REPLACING ITS OHS SERVICE AND ITS CARDIAC CATHETERIZATION SERVICE TO THE PROPOSED NEW SITE.
   - (d) THE PROPOSED NEW SITE IS WITHIN THE SAME PLANNING AREA OF THE SITE AT WHICH AN EXISTING OHS SERVICE IS LOCATED.
   - (e) THE EXISTING OHS SERVICE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF OPEN HEART SURGICAL CASES SET FORTH IN SECTION 8 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT UNLESS THE OHS SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE.
   - (f) THE CARDIAC CATHETERIZATION AND OHS SERVICES SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.
3. Other technical edits.

■ ■ ■

Oral or written comments may be presented in person at the hearing on Thursday, April 26, 2018, or submitted in writing by sending an email to the following email address:
MDHHS-CONWebTeam@michigan.gov

Please submit written comments no later than 5:00 p.m., Thursday, May 3, 2018.

If your comment is in written form at the hearing, please provide a copy of your testimony.

If you have any questions or concerns, please contact Tania Rodriguez at 517-335-6708.

Be sure all cellular telephones are turned off or set to vibrate during the hearing.

The hearing location is accessible for persons with physical disability. Interpreters will be available for the hearing impaired, if requested, seven days in advance.

4/3/2018