

## 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, July 28, 2022

**Time:** 9:30 a.m.

**Topic:** Public Hearing for Magnetic Resonance Imaging (MRI) and Megavoltage Radiation Therapy (MRT)

**Location:** South Grand Building  
333 S. Grand Avenue, 1<sup>st</sup> Floor  
Conference Room 1A  
Lansing, MI 48933

**Virtual:** **Members of the public may attend virtually**  
Feel free to join from your PC, Mac, Linux, iOS or Android:  
<https://us06web.zoom.us/j/81236264415>

Or by Telephone:  
USA (216) 706-7005  
USA (866) 434-5269 (US Toll Free)  
Conference code: 1567580



### **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES**

The proposed language changes include the following:

1. Section 2(1): Modified/added definitions as follows:

(h) "CRITICAL ACCESS HOSPITAL" OR "CAH" MEANS, A HOSPITAL DESIGNATED BY CMS PURSUANT TO 42 CFR 485.606.

(q) "HOSPITAL-BASED PORTABLE MRI" MEANS AN MRI UNIT THAT CAN BE TRANSPORTED INTO PATIENT CARE AREAS (E.G., DEDICATED NEUROSCIENCE UNIT, ICU, OPERATING ROOM) TO PROVIDE IMAGING OF THE BRAIN.

(mm) "Planning area" means

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county, OR IS DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH).

(ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the proposed site is in a rural or micropolitan statistical area county, OR IS DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH).

(oo) "REFERRING LICENSED HEALTHCARE PROFESSIONAL" MEANS:

(i) THE DOCTOR OF RECORD WHO ORDERED THE MRI PROCEDURE(S) AND EITHER TO WHOM THE PRIMARY REPORT OF THE RESULTS OF AN MRI PROCEDURE(S) IS SENT, OR IN THE CASE OF A TEACHING FACILITY, THE ATTENDING DOCTOR WHO IS RESPONSIBLE FOR THE HOUSE OFFICER OR RESIDENT THAT REQUESTED THE MRI PROCEDURE; OR

(ii) A NON-PHYSICIAN LICENSED HEALTHCARE PROFESSIONAL ACTING WITHIN THE SCOPE OF THEIR PRACTICE.

2. Section 3(2): Updated requirements to initiate a fixed MRI service to include reduced emergency department visits required for an applicant hospital in a rural or micropolitan statistical area county or an applicant designated by CMS as a Critical Access Hospital:

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:

(A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.

(B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

(A) The proposed site is a hospital licensed under Part 215 of the Code.

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR 10,000 VISITS IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA OR IS DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), within the most recent 12-month period for which data, verifiable by the Department, is available.

3. Section 3(4): Added requirement for applicants proposing to initiate host site on a new or existing mobile MRI service who currently operate an existing fixed MRI service. Also created exception for Critical Access Hospitals to allow same reduced adjusted procedures

as applicants in rural/micropolitan statistical area counties:

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or

(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and

(c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(d) AN APPLICANT THAT OPERATES AN EXISTING FIXED MRI SERVICE AND IS PROPOSING TO INITIATE A MOBILE MRI HOST SITE AT THE SAME SITE SHALL NOT BE REQUIRED TO PROJECT AVAILABLE ADJUSTED PROCEDURES IF IT MEETS THE FOLLOWING REQUIREMENTS:

(i) EACH MOBILE MRI SERVICE(S) THAT PROPOSES TO PROVIDE MOBILE MRI SERVICES TO THE APPLICANT'S SITE CURRENTLY SERVES AND WILL CONTINUE TO SERVE AT LEAST TWO MOBILE HOST SITES.

4. Section 4: Modified the replacement criteria for an existing MRI unit:

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of the MRI system magnet THAT IS under an existing service contract. The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

5. Section 4(1): Modified the definition for "Upgrade an existing MRI unit":

(1) "Upgrade an existing MRI unit" means any equipment change that does not involve a change in, or replacement of, the MRI SYSTEM MAGNET, does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit).

6. Section 4(4): Added requirement for applicants proposing to replace an existing MRI host site to a new location to exclude those initiated under Section 3(4)(d), as these applicants are not required to project available adjusted procedures. Also created exception for Critical Access Hospitals to allow same radial distance requirements as applicants in rural/micropolitan statistical area counties:

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

- (a) The applicant currently operates the MRI mobile host site to be relocated.
- (b) The MRI mobile host site to be relocated has been in operation as of the date an application is submitted to the Department.
- (c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county OR IS DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH).
- (d) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.
- (e) THE APPLICANT CONFIRMS THAT THE HOST SITE WAS NOT INITIATED UNDER SECTION 3(4)(d).

7. Section 5(1): Modified requirements for applicants proposing to expand an existing MRI service:

- (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:
  - (a) Each existing MRI unit on the network has performed at least an average of 7,000 MRI adjusted procedures per MRI unit.
  - (b) Each existing fixed MRI unit at the current site has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.
  - (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.
  - (d) THE APPLICANT OPERATES BOTH A FIXED MRI AND MOBILE MRI HOST SITE AT THE SAME SITE; AND
    - (i) THE SITE COLLECTIVELY PERFORMED AT LEAST AN AVERAGE OF 9,000 MRI ADJUSTED PROCEDURES PER EXISTING FIXED MRI UNIT WHEN ITS FIXED AND MOBILE HOST SITE MRI ADJUSTED PROCEDURES ARE COMBINED.
    - (ii) IT IS PROPOSING TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE PROPOSED FIXED MRI UNIT BECOMES OPERATIONAL.

8. New Section 13: Added requirements for all applicants proposing to initiate, replace, or acquire an FDA-approved hospital-based portable MRI unit:

- (1) AN APPLICANT IS LIMITED TO THE INITIATION, EXPANSION, REPLACEMENT, OR ACQUISITION OF NO MORE THAN TWO HOSPITAL-BASED PORTABLE MRI UNITS.
- (2) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.
- (3) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS.
- (4) THE APPLICANT HOSPITAL IS DESIGNATED AS A LEVEL I OR II TRAUMA FACILITY BY THE AMERICAN COLLEGE OF SURGEONS AND HAS BEEN CERTIFIED

AS A COMPREHENSIVE STROKE CENTER BY THE JOINT COMMISSION, THE ACCREDITATION COMMISSION FOR HEALTH CARE, INC., OR DET NORSKE VERITAS OR HAS CARED FOR MORE THAN 500 ACUTE STROKE PATIENTS IN THE MOST RECENT 12-MONTH PERIOD IF LOCATED IN A METROPOLITAN COUNTY OR 300 ACUTE STROKE PATIENTS IN THE MOST RECENT 12-MONTH PERIOD IF LOCATED IN A RURAL OR MICROPOLITAN COUNTY.

(5) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 15 OF THESE STANDARDS.

(6) THE AUTHORIZED FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT WILL NOT BE SUBJECT TO MRI VOLUME REQUIREMENTS.

(7) THE APPLICANT MAY NOT UTILIZE MRI PROCEDURES PERFORMED ON AN FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

9. Section 15(4): Modified/added monitoring and reporting requirements. Also created exception for Critical Access Hospitals to allow same reduced annual utilization as applicants in rural/micropolitan statistical area counties:

(a) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) 5,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (A), (B) OR (C),

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

(C) 2,000 MRI ADJUSTED PROCEDURES PER UNIT PER YEAR FOR MRI SERVICES WITH ONE FIXED UNIT LOCATED OUTSIDE THE 20-MILE RADIUS FROM THE NEXT CLOSEST FIXED MRI SERVICE.

(ii) 3,500 MRI adjusted procedures per unit for mobile MRI services.

(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

(iv) Each mobile host site in a rural or micropolitan statistical area county OR DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site.

(v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI unit approved pursuant to Section 9.

10. New Section 15(7): Added monitoring and reporting requirements for applicants approved under Section 3(4)(d):

(7) AN APPLICANT APPROVED UNDER SECTION 3(4)(d) SHALL AGREE THAT THE SERVICES PROVIDED BY THE MOBILE MRI SERVICE(S) ARE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS:

(a) EACH MOBILE MRI SERVICE(S) THAT PROVIDES MOBILE MRI SERVICES TO THE APPLICANT'S SITE ALSO SERVES AND WILL CONTINUE TO SERVE AT LEAST TWO MOBILE HOST SITES.

11. New Section 15(8): Added monitoring and reporting requirements for applicants approved under Section 13:

(8) AN APPLICANT APPROVED UNDER SECTION 13 SHALL BE IN COMPLIANCE WITH THE FOLLOWING:

(a) THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT CAN ONLY BE USED BY A QUALIFYING PROGRAM FOR BRAIN SCANNING OF PATIENTS BEING TREATED IN A DEDICATED NEUROSCIENCE UNIT, AN ADULT OR PEDIATRIC INTENSIVE CARE UNIT (ICU) AND/OR AN OPERATING ROOM.

(b) THE APPROVED APPLICANT MUST HAVE AN INSTITUTIONAL MRI SAFETY COMMITTEE.

(c) THE APPROVED APPLICANT MUST PROVIDE ANNUAL REPORTS TO THE DEPARTMENT BY APRIL 30TH OF EACH YEAR FOR THE PRECEDING CALENDAR YEAR, WHICH INCLUDE AT LEAST ALL OF THE FOLLOWING VISITS PERFORMED ON THE FDA-APPROVED HOSPITAL-BASED PORTABLE MRI UNIT:

(i) NUMBER OF ADULT VISITS (AGE  $\geq$  18).

(ii) NUMBER OF PEDIATRIC VISITS (AGE  $<$  18).

(iii) NUMBER OF VISITS PERFORMED IN AN ICU.

(iv) NUMBER OF VISITS PERFORMED IN A DEDICATED

NEUROSCIENCE UNIT.

(v) NUMBER OF VISITS PERFORMED IN AN OPERATING ROOM.

12. Section 16(1): Modified added values for MRI procedures on a sedated patient:

(d) For each MRI procedure performed on a sedated patient:

(i) 0.75 SHALL BE ADDED TO THE BASE VALUE FOR CONSCIOUS SEDATION;

OR,

(ii) 1.50 SHALL BE ADDED TO THE BASE VALUE FOR GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS.

13. Section 16(2): Modified to include exception for Critical Access Hospitals:

(a) For a site located in a rural or micropolitan statistical area county, OR A SITE DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, OR A SITE DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, OR A SITE(S) DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

14. Section 18: Revise appearance of “doctor” to “LICENSED HEALTHCARE PROFESSIONAL”:

(1)(c) Determine the number of available MRI adjusted procedures that each referring LICENSED HEALTHCARE PROFESSIONAL may commit from each service to an application in accordance with the following:

(ii) For each LICENSED HEALTHCARE PROFESSIONAL referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring LICENSED HEALTHCARE PROFESSIONAL made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each LICENSED HEALTHCARE PROFESSIONAL, subtract any available adjusted procedures previously committed. The total for each LICENSED HEALTHCARE PROFESSIONAL cannot be less than zero.

(B) ...

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each LICENSED HEALTHCARE PROFESSIONAL. Then any duplicate values shall be sorted in descending order by the LICENSED HEALTHCARE PROFESSIONAL'S license numbers (last 6 digits only).

(iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of LICENSED HEALTHCARE PROFESSIONALS necessary to reach the 75 percent level.

(v) For the LICENSED HEALTHCARE PROFESSIONALS representing 75 percent of the total available adjusted procedures in (c)(iv) above, sum the available adjusted procedures.

(vi) For the LICENSED HEALTHCARE PROFESSIONALS used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those LICENSED HEALTHCARE PROFESSIONALS identified in (c)(v) above, multiply the result of (c)(vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) ...

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) LICENSED HEALTHCARE PROFESSIONAL commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).

15. Section 19: Revise appearance of "doctor" to "LICENSED HEALTHCARE PROFESSIONAL":

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment on a form provided by the Department in response to the applicant's letter of intent for each LICENSED HEALTHCARE PROFESSIONAL committing available MRI adjusted procedures to that application for a new MRI unit that requires LICENSED HEALTHCARE PROFESSIONAL commitments.

(b) An applicant also shall submit, at the time the application is submitted to the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each LICENSED HEALTHCARE PROFESSIONAL for whom a signed and dated data commitment form is submitted.

(i) ...

(ii) If the LICENSED HEALTHCARE PROFESSIONAL commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding LICENSED HEALTHCARE PROFESSIONAL commitments that were submitted at the time of application.

(c) If the required documentation for the LICENSED HEALTHCARE PROFESSIONAL commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed submitted on the first applicable designated application date after all required documentation is received by the Department.

(4) ...

(a) A committing LICENSED HEALTHCARE PROFESSIONAL certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 18, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A LICENSED HEALTHCARE PROFESSIONAL shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the LICENSED HEALTHCARE PROFESSIONAL in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing LICENSED HEALTHCARE PROFESSIONAL certifies ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing LICENSED HEALTHCARE PROFESSIONAL is a member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark ii,



and the Code of Federal Regulations, 42 cfr, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(c) A committing LICENSED HEALTHCARE PROFESSIONAL certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(5)(a) The Department shall not consider a data commitment from a LICENSED HEALTHCARE PROFESSIONAL for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new MRI unit, pursuant to Section 3, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) ...

(ii) ...

(b) The Department shall not consider a data commitment from a LICENSED HEALTHCARE PROFESSIONAL for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) ...

(ii) ...

(6) The Department shall not consider a data commitment from a committing LICENSED HEALTHCARE PROFESSIONAL for available MRI adjusted procedures from the same MRI service if that LICENSED HEALTHCARE PROFESSIONAL has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a LICENSED HEALTHCARE PROFESSIONAL has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, the Department shall,

(a) if the applications were submitted on the same designated application date, notify all applicants, simultaneously and in writing, that one or more LICENSED HEALTHCARE PROFESSIONAL(S) have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the LICENSED HEALTHCARE PROFESSIONALS' data from the same MRI service shall not be considered in the review of any of the pending applications submitted on the same designated application date until the LICENSED HEALTHCARE PROFESSIONAL notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted on designated application dates subsequent to the earliest date that one or more committing LICENSED HEALTHCARE PROFESSIONAL(S) have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the LICENSED

HEALTHCARE PROFESSIONALS' data shall not be considered in the review of the application(s) submitted on the subsequent designated application date(s).

(7) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed submitted unless an applicant is notified by the Department, pursuant to subsection (6), that one or more committing LICENSED HEALTHCARE PROFESSIONAL(S) submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more LICENSED HEALTHCARE PROFESSIONALS' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (6).

(a) The applicant shall have 30 days to submit replacement of LICENSED HEALTHCARE PROFESSIONAL commitments as identified by the Department in this Section.

(9) The Department shall consider a withdrawal of a signed data commitment if a committing LICENSED HEALTHCARE PROFESSIONAL submits a written notice to the Department before the application is deemed submitted, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn.

16. New Section 19(3): Added exception criteria for Section 19(2) for projects involving mobile MRI host sites approved under Section 3(4)(d):

(3) SUBSECTION 19(2) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A MOBILE MRI HOST SITE UNDER SECTION 3(4)(d) IF THE MOBILE MRI HOST SITE WILL BE AT THE SAME SITE AS A FIXED MRI SERVICE AND THE HOST SITE WILL BE OWNED BY THE SAME APPLICANT ENTITY AS THE FIXED MRI SERVICE.

17. Section 20: Revise appearance of "doctor" to "LICENSED HEALTHCARE PROFESSIONAL":

(1) ...

(a) ...

(b) ...

(ii) The name, address, and license number of each referring LICENSED HEALTHCARE PROFESSIONAL, identified in Section 18(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring LICENSED HEALTHCARE PROFESSIONAL, identified in Section 18(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 18(1). A referring LICENSED HEALTHCARE PROFESSIONAL may have fractional portions of available MRI adjusted procedures.

(c) ...

18. (d) The Department shall not be required to publish a list that sorts MRI database information by referring LICENSED HEALTHCARE PROFESSIONAL, only by MRI service.

19. Other technical edits.



**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR  
MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS**

The proposed language changes include the following:

1. Section 4(2): Modify requirements to replace an MRT service to a new site to allow applicants in rural or micropolitan statistical area counties the same reduced equivalent treatment visits as those approved under Section 3(3):

(2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the following:

(a) The proposed site is within the same planning area as the existing MRT service site.

(b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:

(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit EITHER approved under Section 3(2) or 3(3) OR LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

(ii) HMRT unit(s) AT 8,000 equivalent treatment visits per unit.

(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit

2. Section 10(4): Add language to provide additive factor to visit weight for CT-guided real time tracking radiation without adaptive and CT-guided real time tracking with adaptive:

CT-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE RECEIVES A 1.00 ADDITIVE FACTOR. CT-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED CT/MRT UNIT PROVIDING CT IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY.

CT-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE RECEIVES 3.00 ADDITIVE FACTOR. CT-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED CT/MRT UNIT PROVIDING CT IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY; ALONG WITH CREATION, EVALUATION AND DELIVERY OF A NEW RADIATION THERAPY PLAN WHILE THE PATIENT REMAINS IN THE TREATMENT ROOM.

3. Other technical edits.



Oral comments may be presented during the hearing on Thursday, July 28, 2022, or submitted in writing by sending an email to the following email address: [MDHHS-ConWebTeam@michigan.gov](mailto:MDHHS-ConWebTeam@michigan.gov)

Please submit written comments no later than 5:00 p.m., Thursday, August 4, 2022.

If you have any questions or concerns, please contact Kenny Wirth at [wirthk4@michigan.gov](mailto:wirthk4@michigan.gov).