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, January 11, 2024

Time: 9:30 a.m.

Topic: Public Hearing for Hospital Beds, Hospital Beds Rural Emergency Hospital (REH) Addendum, Open Heart Surgery (OHS), and Megavoltage Radiation Therapy (MRT), Review Standards.

Location: South Grand Building
333 S. Grand Avenue, 1st 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/84160413743?pwd=K2CqGGEr04RyY0VNhRuXop5sBaiGBN.1

Or by Telephone:
USA (216) 706-7005
USA (866) 434-5269 (US Toll Free)
Conference code: 729478

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CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BED

The proposed language changes include the following:

1. Section 2(1): Updated definitions for “Alcohol and substance abuse hospital” and “Obstetrics patient days of care” to reflect updated MSDRGs:

   (c) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by MSDRGs –894 - 897. THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE

STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.

(gg) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 15 AND OVER with MSDRGs LISTED IN APPENDIX E (obstetrical discharges). THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.

2. Modified Section 6: Added language allowing continued operation for an LTAC or IRF hospital after closure of host hospital:

   Section 6. Requirements for approval -- new beds in a hospital, LTAC HOSPITAL OR IRF HOSPITAL OR SUBSTANCE ABUSE HOSPITAL; RELICENSURE OF BEDS BY A HOST HOSPITAL; LTAC OR IRF HOSPITAL SPACE RENEWAL OF LEASE; AND LTAC OR IRF HOSPITAL CONTINUED OPERATION AFTER HOST HOSPITAL CLOSES

   (2) An applicant proposing to begin operation as a new LTAC hospital, IRF hospital, or alcohol and substance abuse hospital within an existing licensed, host hospital, OR AN LTAC OR IRF HOSPITAL CONTINUING OPERATION AFTER A HOST HOSPITAL CLOSES, shall demonstrate that it meets all of the requirements of this subsection:

   (iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements, UPON VOLUNTARY CLOSURE OF THE HOST HOSPITAL, or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

   (D) VOLUNTARY CLOSURE OF THE HOST HOSPITAL. AN LTAC or IRF HOSPITAL PROPOSING TO CONTINUE OPERATION AFTER ITS HOST HOSPITAL VOLUNTARILY CLOSES SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW AND SHALL BE PROCESSED UNDER THE SAME PROCEDURES FOR NON-SUBSTANTIVE REVIEW. THE APPLICANT SHALL ALSO DEMONSTRATE IT MEETS ALL OF THE FOLLOWING:

(1) THE LTAC OR IRF HOSPITAL HAS OR AGREES TO PERMANENTLY ACQUIRE ITS LTAC OR IRF HOSPITAL BEDS FROM THE HOST HOSPITAL AS DEMONSTRATED BY A CURRENT AGREEMENT WITH THE HOST HOSPITAL OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,

(2) THE LTAC OR IRF HOSPITAL HAS OR AGREES THAT IT WILL HAVE CONTINUED CONTROL OF ITS PHYSICAL SPACE AS DEMONSTRATED BY A CURRENT EXECUTED LEASE, PROOF OF OWNERSHIP, AN AGREEMENT TO LEASE OR PURCHASE OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,

(3) THE LTAC OR IRF AGREES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS, AND

(4) THE LTAC OR IRF HOSPITAL APPROVED UNDER THIS SUBSECTION AGREES THAT IF IT CEASES OPERATION AS AN LTAC OR IRF HOSPITAL IT WILL DISPOSE OF ITS LICENSED BEDS BY EITHER (i) RELOCATING THE BEDS TO AN EXISTING, LICENSED HOSPITAL OR (ii) DELICENSING THE BEDS.

3. Section 9: Added project delivery requirements for freestanding LTAC or IRF hospital after closure of host hospital:
   (6) AN LTAC or IRF HOSPITAL APPROVED PURSUANT TO SECTION 6(2) MAY CONTINUE TO OPERATE AFTER ITS HOST HOSPITAL CLOSES AND SHALL BE IN COMPLIANCE WITH ALL OF THE FOLLOWING:

   (a) BE SEPARATELY LICENSED,

   (b) MAINTAIN ITS OWN GOVERNING BODY,

   (c) OWN AND OPERATE ITS APPROVED BEDS, AND

   (d) OPERATIONS MUST CONTINUE WITHOUT INTERRUPTION INCLUDING MAINTAINING ITS OWN STAFF, SUPPLIES, AND SERVICES.

4. Added APPENDIX E to house Obstetrics MSDRGs which will be updated as MIDB data becomes available.

5. Section 9(4): Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:

   (f) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

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CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS RURAL EMERGENCY HOSPITAL (REH) ADDENDUM

The proposed language changes include the following:

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON review standards for hospital beds and shall be used for Rural Emergency Hospitals.

(2) Except as provided in Sections 3, 4, 5, 6 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Hospital Beds.

(3) The definitions which apply to the CON Review Standards for Hospital Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:
(a) “Rural emergency hospital” or “REH” means a hospital that is designated by CMS to offer rural emergency hospital services.

(b) “Rural emergency hospital services” means that term as defined in 42 USC 1395x.

Section 2. Requirements for approval of an applicant proposing to begin operation as a REH, 28 extension of temporary delicensure

Sec. 2. (1) An application proposing to begin operation as a REH shall demonstrate that it meets, and agrees to, all of the following:
(a) Applicant agrees to submit application no later than 6 months after CMS designation as REH.
(b) The applicant agrees to temporarily delicense 100% of its licensed beds for not more than 5 years, pursuant to MCL 333.21551. The applicant also agrees to provide the following information:
(i) The number and location of the specific beds to be delicensed,
(ii) The period of time during which the beds will be delicensed,
(iii) The alternative use proposed for the space occupied by the beds to be delicensed.
(c) Upon approval of REH designation, the REH shall file a LOI for each period of time it seeks temporary delicensure of beds or permanent delicensure of beds pursuant to Section 5(2).

(2) An application proposing to extend the temporary delicensure of beds by up to an additional 5 years shall demonstrate that it meets, and agrees to, all of the following:

(a) The applicant has been approved pursuant to Section 2(1) of this addendum and has abided by all applicable requirements.
(b) There is not a demonstrated need for the temporarily delicensed beds in the hospital group in which the hospital is located, as determined by the Department.
(c) If the applicant is not approved for extension under this section, the applicant shall request relicensure of the beds pursuant to Section 6(1) of this addendum or allow the beds to be permanently delicensed pursuant to Section 6(2) of this addendum.

(3) The applicant shall not relocate temporarily delicensed beds from an REH approved under this section unless requirements of Section 4 of this addendum are met.

(4) The applicant agrees that upon receipt of the REH designation, the hospital shall not be replaced to a new geographical site during the period of designation as an REH by CMS, unless requirements of Section 3 of this addendum are met.

(5) Applications under this section shall not be subject to comparative review and shall be processed under the procedures for non-substantive review.

Section 3. Requirements for approval – replacement of REH beds

Sec. 3. (1) If the application involves the replacing of a portion of the temporarily delicensed beds at the existing licensed REH site, the project shall be reviewed as a covered capital expenditure.

(2) An applicant proposing replacement of a licensed hospital to a new site shall be exempt from the average adjusted occupancy requirements of Section 7(4) of the Hospital Bed Review Standards if all of the following are met:
(a) The applicant is currently:
(i) a licensed hospital that is no longer designated as an REH, or
(ii) a licensed REH proposing to provide acute care hospital services at the new site.
(b) the applicant meets all other criteria under Section 7 of the Hospital Beds Review Standards,
(c) within the previous 3 years as of the date the application is submitted to the Department, the applicant had a designation by CMS as an REH to provide rural emergency hospital services, and
(d) the applicant agrees to operate the licensed hospital at the new replacement site not as an REH and has met the conditions of relicensing the REH beds under MCL 333.21551.

(3) If the application involves the replacement of the REH to a new site, the applicant shall demonstrate that the new licensed site is in the replacement zone. The replacement zone, for this Section 3 of the addendum, means a proposed licensed site that is in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of the Hospital Beds standards and is on a

site within 2 miles 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 of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(4) Applications under this section shall not be subject to comparative review.

Section 4. Requirements for approval – relocation of temporarily delicensed REH beds

Sec. 4. (1) The proposed project to relocate REH beds, under this section, shall constitute a change in bed capacity.

(2) An existing REH may relocate all or a portion of its temporarily delicensed beds to an existing licensed acute care hospital as follows:
(a) The REH and existing licensed acute care hospital are located within the same hospital group,
(b) the REH and the existing licensed acute care hospital shall not require any ownership relationship, or
(c) the REH and the existing licensed acute care hospital are located within the same HSA and the licensed acute care hospital receiving the licensed beds is owned by, under common control of, or has a common parent with the REH.

(3) An existing REH may relocate all or a portion of its temporarily delicensed beds to another existing licensed acute care hospital if it meets all of the following:
(a) The existing REH is unable to extend their period of temporary delicensure pursuant to Section 2(2) of this addendum, or proposed to close as a REH, or wishes to permanently delicense all of its hospital beds,

(b) the REH and the receiving hospital have filed CON applications for relocation of the REH beds at least 90 days prior to the last day of the time period for which the Department granted temporary delicensure of the REH beds, and
(c) in the hospital group in which the REH is located, the number of existing hospital beds in the hospital group is equal to or exceeds the bed need.

(4) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable hospital group.

(5) The relocation of beds under this section shall not be subject to a mileage limitation.

Section 5. Requirements for approval – acquisition of REH, lease renewal for REH

Sec. 5. An applicant proposing to acquire an existing REH or renew the lease of an existing REH must meet the following as applicable:

(1) An applicant proposing to acquire an existing REH shall not be required to be in compliance with the needed hospital bed supply for the hospital group in which the REH subject to the proposed acquisition is assigned if the applicant demonstrates that it meets all of the following:

(a) the acquisition will not result in a change in bed capacity,
(b) the licensed site does not change as a result of the acquisition, and
(c) the project is limited solely to the acquisition of a hospital with a valid license.

(2) An applicant proposing to renew the lease of an existing REH shall not be required to be in compliance with the needed hospital bed supply for the hospital group in which the hospital is located if all of the following requirements are met:
(a) The lease renewal will not result in a change in bed capacity.
(b) The licensed site does not change as a result of the lease renewal.

(3) Applications under this section shall not be subject to comparative review and shall be processed under the procedures for non-substantive review.

Section 6. Requirements for approval – change in REH designation, permanent delicensure of beds

Sec. 6. (1) An application proposing to stop rural emergency hospital services, to initiate services as a licensed acute care hospital, and to relicense their temporarily delicensed hospital beds shall not be required to be in compliance with the needed hospital bed supply for the hospital group in which the hospital is located if all of the following requirements are met:
(a) The applicant was approved pursuant to Section 2 of this addendum.
(b) The hospital has filed an LOI at least 90 days before the earlier of the following:
(i) The expiration of the period for which delicensure was granted.
(ii) The date upon which the hospital is requesting relicensure.
(iii) The last hospital license renewal date in the delicensure period.
(c) The applicant is in compliance with Section 21551 of the Code.

(2) If a hospital does not meet the requirements of Section 6(1) of this addendum, is unable to extend their period of temporary delicensure pursuant to Section 2(2) of this addendum, closes as a hospital, or wishes to permanently delicense its hospital beds, the hospital must file an LOI notifying the Department that the beds must be automatically and permanently delicensed effective on the last day of the period for which the Department granted temporary delicensure.

(3) Applications under this section shall not be subject to comparative review and shall be processed under the procedures for non-substantive review.

Section 7. Project delivery requirements – terms of approval for all applicants seeking approval under section 2(1) of this addendum

Sec. 7. An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:
(a) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.
(b) The applicant REH 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 REH to a hospital that is capable of providing the necessary inpatient services.

(3) Compliance with the following access to care requirements:
(a) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
(b) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
(i) Not deny services to any individual based on ability to pay or source of payment.
(ii) Maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.
(iii) Provide services to any individual based on clinical indications of need for the services.

(4) Compliance with the following monitoring and reporting requirements:
(a) The applicant shall participate in a data collection system 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, through-put schedules, and demographic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each 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.
(i) The applicant must also include in this data the number of patients whose stay was longer than 23 hours and 59 minutes, and the purpose for the stay of more than 23 hours and 59 minutes.
(b) The applicant shall provide the Department with timely notice of proposed project implementation consistent with applicable statute and promulgated rules.

(5) The applicant agrees that all temporarily delicensed beds must be automatically and permanently delicensed effective on the last day of the period for which the Department granted temporary delicensure if the applicant has already temporarily delicensed its hospital beds for the maximum amount of time allowed under MCL 333.21551 and at least one of the following happen:

(a) The applicant does not meet the requirements for relicensure of beds pursuant to Section 6(1) of this addendum.
(b) The hospital decides to allow beds to become permanently delicensed as described in Section 6(2).

(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 8. Continued provision of other previously approved CON covered services

Sec. 8. (1) An applicant approved pursuant to Section 2(1) of this addendum and proposing to continue providing an existing CON covered service(s) shall demonstrate the following:
(a) The applicant agrees to abide by the Project Delivery Requirements in the respective CON Review Standard(s), as applicable to the REH.
(b) The applicant will not experience a disruption in services.
(c) If the applicant plans to discontinue any operational CON services, the applicant shall provide notice to the Department of any planned decrease or discontinuation of service(s) no later than 30 days after the planned decrease or discontinuation of the service(s).

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CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT)

The proposed language changes include the following:

1. 1. Section 3(3)(c): Reduced distance requirement between MRT services in HSA 8:

(c) The site of the proposed MRT service is 90 45 driving miles or more, verifiable by the department, from the nearest MRT service.

2. Section 10(4): Modified Table 1 equivalent treatment visits and associated definitions:

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	.66	
Intermediate	1.00	
Complex	2.00	
IMRT	1.66	
Total Body Irradiation	5.00	5.00
HMRT Therapy		3.33

Stereotactic radiosurgery/radiotherapy*	4.00	4.00
IORT		20.00
VIRTUAL OR ELECTRON SIMULATION	1.00	1.00
*ADDITIONAL ISOCENTER	1.33	1.33

ADDITIVE FACTOR CATEGORY	NON SRS-SBRT VISIT	SRS/SBRT VISIT
GATING OR INTERNAL TRACKING W/ BEAM HOLD	1.00	1.00
NON-STANDARD IMAGE GUIDANCE	0.50	0.50
IN-ROOM CONTRAST OR TRACER INJECTION	0.25	0.25
IN-ROOM ADAPTIVE TREATMENT PLAN	0.50	0.50

All patients under 5 years of age receive a 2.00 additive factor.

GATING OR INTERNAL TRACKING WITH BEAM HOLD IS THE CONTINUOUS CAPTURING AND MONITORING OF A TARGET, FIDUCIAL, OR A SURROGATE THAT IS SYNCHRONIZED WITH THE PATIENT'S RESPIRATORY OR ORGAN MOTION DURING RADIATION TREATMENT WITH MODULATION OF THE RADIATION BEAM TO DELIVER RADIATION MORE PRECISELY TO THE TARGET AND/OR DECREASE THE RADIATION DOSE TO THE SURROUNDING NORMAL TISSUE.

GATING OR INTERNAL TRACKING WITH BEAM HOLD IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

Gating receives a 1.00 additive factor. Gating is the capturing and monitoring of the target's or fiducial's motion during radiation treatment and the modulation of the radiation beam in order to more precisely deliver radiation to the target and/or decrease the radiation dose to the surrounding normal tissue.

NON-STANDARD IMAGE GUIDANCE IS THE PROCESS OF ACQUIRING AND UTILIZING AN INTERNAL ANATOMICAL IMAGING MODALITY WITH THE OBJECTIVE OF GUIDING IMAGES, TAKING PLACE EXCLUSIVELY WITHIN THE DESIGNATED MRT TREATMENT ROOM, AS DELINEATED BELOW. THE FOLLOWING TECHNIQUES SHALL BE CLASSIFIED AS NON-STANDARD IMAGE GUIDANCE: 1) 4DCT, 2) 3D MR IMAGING, AND 3) 3D GAMMA-RAY IMAGING. THESE AFOREMENTIONED IMAGING TECHNIQUES ARE DEEMED TO FALL WITHIN THE SCOPE OF NON-STANDARD IMAGE GUIDANCE. THIS SHOULD TAKE PLACE DURING AN MRT TREATMENT VISIT.

NON-STANDARD IMAGE GUIDANCE IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

MR-guided real time tracking radiation w/o adaptive receives a 2.00 additive factor. MR-guided real time tracking radiation w/o adaptive means a visit involving an integrated MRI/MRT unit providing MR images in the treatment room before and during an MRT treatment of any complexity.

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.

IN-ROOM CONTRAST OR TRACER INJECTION IS THE INTRAVENOUS INJECTION OF A CONTRAST AGENT OR TRACER WHILE THE PATIENT IS IN THE MRT TREATMENT ROOM AND DURING AN MRT TREATMENT VISIT.

IN-ROOM CONTRAST OR TRACER INJECTION IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

IN-ROOM ADAPTIVE TREATMENT PLAN SIGNIFIES A DISTINCT VISIT WHEREIN A THREE-DIMENSIONAL (3D) DATASET IS ACQUIRED WITHIN THE MRT TREATMENT ROOM JUST PRIOR TO THE COMMENCEMENT OF AN MRT VISIT. SAID ACQUIRED IMAGES ARE SUBSEQUENTLY UTILIZED TO GENERATE AND EVALUATE AN ORIGINAL RADIATION THERAPY PLAN, WHILE THE PATIENT REMAINS PRESENT WITHIN THE TREATMENT ROOM. THE RESULTANT ADAPTIVE TREATMENT PLAN, REGARDLESS OF ITS CLINICAL IMPLEMENTATION OR THE UTILIZATION OF THE STANDARD PLAN, IS REQUIRED TO UNDERGO A DOCUMENTED ASSESSMENT BY A PHYSICIAN PRIOR TO THE INITIATION OF MRT TREATMENT, FOR IT TO BE CONSIDERED AND ACCOUNTED FOR.

IN-ROOM ADAPTIVE TREATMENT PLAN IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

MR-guided real time tracking radiation with adaptive receives a 3.00 additive factor. MR-guided real time tracking radiation with adaptive means a visit involving an integrated MRI/MRT unit providing MR 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.

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.

VIRTUAL OR ELECTRON SIMULATION REFERS TO A SESSION PRIOR TO THE COMMENCEMENT OF AN MRT COURSE, WHEREIN A PATIENT IS POSITIONED WITHIN AN MRT TREATMENT ROOM IN ACCORDANCE WITH PREDETERMINED TREATMENT PARAMETERS, SIMULATING THE CONDITIONS AS IF THE PATIENT WERE TO UNDERGO A PLANNED TREATMENT, WITHOUT THE ACTUAL ADMINISTRATION OF TREATMENT.

VIRTUAL OR ELECTRON SIMULATION IS NOT TO EXCEED TWICE PER COURSE OF TREATMENT.

*ADDITIONAL ISOCENTER IS DEFINED AS EACH ADDITIONAL UNIQUE SET OF TREATMENT BEAMS DESIGNED TO TARGET ONE OR MORE ADDITIONAL LESIONS. THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF TREATMENT. AFTER THE FIRST ISOCENTER, EACH ADDITIONAL ISOCENTER RECEIVES 1.33 EQUIVALENT TREATMENT VISITS.

Patient specific QA for IMRT receives a 2.0 additive factor, not to exceed twice per course of treatment. Patient specific QA for IMRT means verification of radiation delivered dose and/or fluence through physical measurement with a dosimetry phantom and/or detector array in the treatment room. Prior to the start of treatment and using all of the parameters of the patient's treatment plan, one or more points in the delivered distribution should be compared against the planned distribution.

Patient specific QA for SRS/SBRT receives a 3.0 additive factor, not to exceed twice per course of treatment. Patient specific QA for SRS/SBRT means verification of radiation delivered dose and/or fluence through physical measurement with a dosimetry phantom and/or detector array in the treatment room. Prior to the start of treatment and using all of the parameters of the patient's treatment plan, one or more points in the delivered distribution should be compared against the planned distribution.

* After the first isocenter, each additional isocenter receives 1.33 equivalent treatment visits. There is a maximum of five visits per course of therapy.

3. Section 11(4): Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:

(f) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

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CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY (OHS)

The proposed language changes include the following:

1. Section 8(4)(d): Revised monitoring and reporting requirements for STS star ratings:

   (d) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within OHS programs. The Department shall use ALL COMPOSITES IN the STS Composite Star Rating System, INCLUDING BUT NOT LIMITED TO: which currently includes coronary artery bypass graft composite (CABG), aortic valve replacement (AVR), AND THE MULTIPROCEDURAL composite MEASURE., and plans to add additional cardiac surgical composites each year. The Department or its designee shall require that the applicant hospital submit a summary report as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. The outcomes database must undergo statewide auditing.

2. Section 8(4): Revised reporting procedure for STS Composite Star Ratings:

   (e) The applicant hospital shall utilize and report the STS Composite Star Rating System for all procedures as follows:

   (i) IF THE PROGRAM DOES NOT QUALIFY TO RECEIVE A STAR RATING IN ONE OR MORE COMPOSITE METRICS BUT RECEIVES A TWO-STAR OR HIGHER RATING IN AT LEAST ONE COMPOSITE METRIC FOR THE SAME TIME PERIOD, THE PROGRAM SHALL BE CONSIDERED IN COMPLIANCE.

   (ii) If the program receives a one-star rating in any composite metric, they shall submit a report to the Department explaining the reason(s) for the unsatisfactory rating.

   (iii) If the program receives two one-star ratings in a row in the same composite metric, they shall submit an action plan to the Department detailing specific actions to rectify the program deficiencies.

   (iv) If the program receives two one-star ratings within the same composite metric, the program may have two years to obtain a minimum two-star rating within that composite metric. Upon receipt of a two-star or higher rating, the program SHALL be considered in compliance.

   (f) IF THE PROGRAM PARTICIPATES IN THE STS COMPOSITE STAR RATING SYSTEM AND DOES NOT RECEIVE A STAR RATING FOR ANY REASON, THEY SHALL SUBMIT A REPORT TO THE DEPARTMENT EXPLAINING THE REASON(S) FOR NOT RECEIVING A STAR RATING.

3. Section 8(4): Added subsection to require a notification to the Department at least 30 days prior to a planned decrease or discontinuation of services:

   (h) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

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Oral comments may be presented during the hearing on Thursday, January 11, 2024, or submitted in writing by sending an email to the following email address: MDHHS-ConWebTeam@michigan.gov. If your comment is in written form, please provide a copy to Tiffani Stanton at the conclusion of your testimony.

Please submit written comments no later than 5:00 p.m., Friday, January 19, 2024

If you have any questions or concerns, please contact or Tiffani Stanton at StantonT4@michigan.gov.