

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

Thursday, September 19, 2019

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

APPROVED MEETING MINUTES

I. Call to Order

Chairperson Falahee called the meeting to order at 9:30 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams
Lindsey Dood
Tressa Gardner, DO
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde
Amy McKenzie, MD
Stewart Wang, MD

B. Members Absent:

Melisa Oca, MD

C. Department of Attorney General Staff:

Carl Hammaker

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

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Mittelbrun, seconded by Commissioner Hughes to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of June 13, 2019

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

V. Immune Effector Cell Therapy (IECT) – Public Hearing Summary

Ms. Rogers gave an overview of the public hearing and the Department's recommendations (Attachment A).

A. Public Comment

1. Senator Kurt Vanderwall, Chairman, Senate Health Policy and Human Services Committee
2. Brett Jackson, Economic Alliance of Michigan (EAM)
3. Greg Yanik, MD, University of Michigan (U of M) – (Attachment B - REMs application)
4. Phil Stella, MD, St. Joseph Mercy Hospital

B. Commission Discussion

Discussion followed.

C. Commission Action

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

VI. Psychiatric Beds and Services – Public Hearing Summary and Set Effective Date of the New Bed Need Numbers

Ms. Rogers gave an overview of the public hearing and the Department's recommendations (Attachment D).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Gardner to take final action on the language (Attachment E) as presented and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period and to set the effective date of the bed need to be the same as the effective date of the standards. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VII. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Services – Public Hearing Summary

Ms. Rogers gave an overview of the public hearing and the Department's recommendations (Attachment F).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

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

VIII. Hospital Beds – Limited Access Areas (LAAs)

Ms. Nagel provided a PowerPoint presentation (Attachment H).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittelbrun, seconded by Commissioner Hughes to ask the Department to work with MSU and Paul Delamater, Ph.D. to develop a solution to accurately identify the LAAs and review progress at the December Commission meeting. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

IX. Nursing Home/Hospital Long-Term Care Unit Beds (NH/HLTC) Standard Advisory Committee (SAC) Update

Chairperson Falahee provided an update.

Motion by Commissioner Dood, seconded by Commissioner Mittlebrun to suspend discussion until after item X of the agenda. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

X. NH-HLTC - Set Effective Date of New Bed Need Numbers (*Written Report from Paul Delamater, et al.*)

Chairperson Falahee provided an overview (Attachment I).

Public Comment

1. Henry Boutros, Health Care Association of Michigan (HCAM)
2. Pat Anderson, HCAM

Motion by Commissioner Dood, to postpone indefinitely. Motion failed due to lack of a second.

Motion by Commissioner Mittlebrun, seconded by Commissioner Lalonde to set an effective date of November 1, 2019 for the new bed need numbers. Motion carried in a vote of 9 - Yes, 1 - No, and 0 - Abstained.

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to go back and review item IX. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Mittlebrun, seconded by Commissioner Gardner to seat a SAC and have the chairperson develop the charge working with the Department. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Recessed at 11:40 a.m. and reconvened at 11:45a.m.

Motion by Dood, seconded by Mittlebrun to reconsider the prior motion to develop a new charge and seat a SAC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Dood, seconded by LaLonde, to seat a SAC and use the previously approved charge and previous nominees will still be considered and don't need to resubmit. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XI. Computed Tomography (CT) Scanner Services (*Written Report Only*)

Chairperson Falahee mentioned the report (Attachment J).

XII. Legislative Update

Chairperson Falahee provided an update.

XIII. Administrative Update

A. Planning & Access to Care Section Update

1. Open Heart Surgery (OHS) – Effective Date for Revised Utilization Weights for Adults & Pediatrics Numbers (*Written Report from Paul Delamater, et al.*)

Ms. Nagel mentioned the report (Attachment K) and stated the effective date of the revised weights is October 1, 2019.

Ms. Nagel provided an update on the Public Comment period for those standards up for review in 2020.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment L)
2. Quarterly Performance Measures (Attachment M)
3. Application Process Update

XIV. Legal Activity Report

Mr. Hammaker provided an update on the CON legal activity (Attachment N).

XV. Future Meeting Dates: December 5, 2019, January 30, 2020 (Special Commission Meeting), March 19, 2020, June 18, 2020, September 17, 2020, and December 10, 2020

XVI. Public Comment

None.

XVII. Review of Commission Work Plan

Ms. Rogers provided an overview of the changes to the Work Plan including actions taken at today's meeting (Attachment O).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner McKenzie 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.

XVIII. Adjournment

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to adjourn the meeting at 12:01 p.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 8, 2019

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 Immune Effector Cell Therapy (IECT) Services Standards

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 IECT Services Standards at its June 13, 2019 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed IECT Services Standards on July 25, 2019. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from several organizations.

Written Testimony:

- 1.) *Robert Falb, Director, U.S. Policy and Advocacy – Alliance for Regenerative Medicine*
 - Does not support the new standards.
- 2.) *Nancy Susick, MSN, RN – Beaumont Health*
 - Supports the proposed language.
- 3.) *Andy Cosgrove, Senior Director, Health Policy; Crystal Kuntz, Vice President, Healthcare Policy & Research – Biotechnology Innovation Organization (BIO)*
 - Does not support the new standards.
- 4.) *Mark Campbell, MD, MHA, President – Cancer & Hematology Centers of Western Michigan, P.C.*
 - Does not support the new standards.
- 5.) *Richard H. Bagger, Executive Vice President, Corporate Affairs and Market Access - Celgene*
 - Does not support the new standards.

- 6.) *Dr. Steven Kalkanis, Medical Director, Henry Ford Cancer Institute, Henry Ford Hospital; Robert G. Riney, President, Healthcare Operations and Chief Operating Officer, Henry Ford Health System*
- Supports the new standards.
- 7.) *American Cancer Society Cancer Action Network; Blood & Marrow Transplant Information Network; Cutaneous Lymphoma Foundation; International Myeloma Foundation; Lymphoma Research Foundation*
- Does not support the new standards.
- 8.) *Stephen Rapundalo, PhD, President and CEO – Michigan Biosciences Industry Association (MichBio)*
- Does not support the new standards.
- 9.) *Senator Mike Shirkey, District 16, Senate Majority Leader; Senator Curtis S. VanderWall, District 35, Chairman, Senate Health Policy and Human Services Committee; Senator John Bizon, District 19, Vice Chair, Senate Health Policy and Human Services Committee – Michigan Biosciences Industry Association (MichBio)*
- Does not support the new standards.
- 10.) *Mary Kay VanDriel, FACHE – Spectrum Health*
- Supports the new standards.
- 11.) *James Essell, Chair Cellular Therapy – The US Oncology Network*
- Supports consideration of patient access to care as a primary factor.
- 12.) *David Spahlinger, MD, President, University of Michigan Health System (U of M) and Executive Vice Dean for Clinical Affairs, U of M Medical School; T. Anthony Denton, MHA, JD, Senior Vice-President and Chief Operating Officer, U of M Health System; Gregory Yanik, MD, Leland and Elaine Blatt Family Professor of Pediatric Hematology/Oncology*
- Supports the new standards.
- 13.) *Rosalie Tocco-Bradley, MD, PhD, Chief Clinical Officer – Trinity Health Michigan*
- Supports the new standards.

Department Recommendation:

The Department encourages the Commission to consider all testimony received during the public hearing and to investigate the new information presented.



To become an authorized representative for your hospital and its associated clinics in the YESCARTA™ REMS Program, you will need to answer all questions below correctly.

Responses to the YESCARTA™ REMS Program Knowledge Assessment questions and the YESCARTA™ REMS Program Hospital Enrollment Form must be emailed to YESCARTAREMS@kitepharma.com or faxed to **1-310-496-0397**.

Questions

1. What is the approved indication for YESCARTA™?

- A. Patients with relapsing multiple sclerosis
- B. Patients with lung cancer
- C. Patients with bladder cancer
- D. Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

2. A YESCARTA™ Patient Wallet Card must be given to patients who have been infused with YESCARTA™.

True ____ False ____

3. Every certified hospital and its associated clinics are required to have a minimum of 2 doses of tocilizumab on-site for each patient and available for administration, for treatment of CRS, within 2 hours of YESCARTA™ infusion.

True ____ False ____

4. After YESCARTA™ infusion, patients should be advised to:

- A. Refrain from driving or operating heavy or potentially dangerous machinery after YESCARTA™ administration until at least 8 weeks after infusion
- B. Remain within close proximity (within 2 hours) of the certified treating hospital and its associated clinics for at least 4 weeks following infusion
- C. Seek immediate attention if they experience signs and symptoms of CRS and/or neurologic toxicities
- D. All of the above

5. Which of the following is true regarding the time to onset of CRS? It typically occurs:

- A. With a median time to onset of 7 days
- B. With a median time to onset of 5 days
- C. With a median time to onset of 2 days
- D. Rarely starts during the first week following YESCARTA™ infusion

Continued on Back



6. All of the following regarding neurologic toxicity related to YESCARTA™ are correct except:
- A. Neurologic toxicity always occurs concurrently with CRS
- B. Continuous cardiac telemetry and pulse oximetry are recommended for Grade 2 or higher neurologic toxicity
- C. The median time to onset of neurologic toxicity is 4 days
- D. The most common signs or symptoms of neurologic toxicity include encephalopathy, headache, tremor, dizziness, aphasia, delirium, insomnia, and anxiety
7. Four days after infusion with YESCARTA™, a 49-year-old woman with relapsed diffuse large B-cell lymphoma (DLBCL) fully recovers from a Grade 3 CRS that started the day after infusion of YESCARTA™. The next day, she develops a Grade 2 dysphasia. She has no signs or symptoms of CRS. Appropriate management for this patient would include:
- A. Consider nonsedating, antiseizure medicines (eg, levetiracetam) for seizure prophylaxis
- B. Start tocilizumab 8 mg/kg intravenous over 1 hour (not to exceed 800 mg)
- C. Start dexamethasone at 10 mg intravenous every 6 hours
- D. A and C
8. One day after infusion of YESCARTA™, a 60-year-old man with relapsed diffuse large B-cell lymphoma (DLBCL) develops the following signs and symptoms of CRS: high fevers (39°C-40°C), hypoxia requiring < 40% FiO₂, and hypotension requiring intravenous fluids. This patient's CRS grade would be most consistent with:
- A. Grade 1 CRS
- B. Grade 2 CRS
- C. Grade 3 CRS
- D. Grade 4 CRS

Authorized Representative Name

Title

Credentials ___DO ___MD ___RPh ___NP/PA Other _____

C.S. MOTT Children's Hospital/ University of Michigan Medicine

Hospital/Associated Clinic Name

1500 E Medical Ctr Dr.

Address

Ann Arbor

MI

48109

City

State

ZIP Code

Signature

Date

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR IMMUNE EFFECTOR CELL THERAPY (IECT) 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 TO INITIATE, REPLACE OR ACQUIRE IECT SERVICES UNDER PART 222 OF THE CODE. THE CON COMMISSION ADDED IECT SERVICES AS A COVERED CLINICAL SERVICE PURSUANT TO MCL 333.22215. 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(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

SECTION 2. DEFINITIONS

Sec. 2. (1) AS USED IN THESE STANDARDS:

(a) "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.

(b) "CHIMERIC ANTIGEN RECEPTOR (CAR) T CELLS" MEANS A GENETICALLY MODIFIED T CELL USED IN IMMUNE EFFECTOR CELL THERAPY (IECT).

(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) "DEPARTMENT" MEANS THE MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS).

(e) "DEPARTMENT INVENTORY OF IECT SERVICES" MEANS THE LIST MAINTAINED BY THE DEPARTMENT OF: (i) THE IECT SERVICES OPERATING PURSUANT TO A VALID CON ISSUED UNDER PART 222; AND (ii) IECT SERVICES THAT ARE NOT YET OPERATIONAL BUT HAVE A VALID CON ISSUED UNDER PART 222. THE LIST SHALL SPECIFY THE SITE AT WHICH THE IECT SERVICE IS AUTHORIZED.

(f) "EXISTING IECT SERVICE," MEANS ANY OF THE FOLLOWING: (I) AN IECT SERVICE LISTED ON THE DEPARTMENT INVENTORY, (II) A PROPOSED IECT SERVICE UNDER APPEAL FROM A FINAL DECISION OF THE DEPARTMENT, OR (III) A PROPOSED IECT SERVICE THAT IS PART OF A COMPLETED APPLICATION UNDER PART 222 (OTHER THAN THE APPLICATION UNDER REVIEW) FOR WHICH A PROPOSED DECISION HAS BEEN ISSUED AND WHICH IS PENDING FINAL DECISION.

(g) "IMMUNE EFFECTOR CELL THERAPY (IECT)" OR "CELLULAR THERAPY" MEANS CELLULAR IMMUNOTHERAPIES, AND OTHER TYPES OF BOTH AUTOLOGOUS AND ALLOGENEIC CELLS DERIVED FROM IMMUNE EFFECTOR CELLS TO TREAT CERTAIN THERAPEUTIC INDICATIONS. FOR PURPOSES OF CON, THIS TERM DOES NOT INCLUDE THERAPEUTIC CANCER VACCINES REGULATED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) OR ADOPTIVE IMMUNOTHERAPEUTIC PRODUCTS THAT ARE CURRENTLY FDA APPROVED AND ARE GIVEN TO PATIENTS IN THE OUTPATIENT SETTING, AS THESE STANDARDS PRODUCTS HAVE DIFFERENT MECHANISMS OF ACTION AND THEREFORE THESE STANDARDS SHALL NOT APPLY.

(h) "IMMUNE EFFECTOR CELL THERAPY SERVICE" OR "IECT SERVICE" MEANS THE INFUSION OR TRANSFER OF IMMUNE EFFECTOR CELLS AND/OR IMMUNE EFFECTOR CELL

54 THERAPIES INTO PATIENTS. THIS DEFINITION DOES NOT INCLUDE BONE MARROW OR STEM
55 CELL TRANSPLANTATION.

56 (i) "IMMUNE EFFECTOR CELLS" MEANS CELLS FROM THE HUMAN BODY THAT HAVE
57 DIFFERENTIATED INTO A FORM CAPABLE OF MODULATING OR EFFECTING AN IMMUNE
58 RESPONSE SUCH AS, BUT NOT LIMITED TO, B CELLS, DENDRITIC CELLS, NATURAL KILLER
59 CELLS, AND T CELLS. THIS DEFINITION INCLUDES CAR T CELLS. FOR PURPOSES OF THESE
60 STANDARDS, IMMUNE EFFECTOR CELLS TO BE USED IN IECT SERVICES MUST BE COLLECTED
61 AND PROCESSED AT A FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
62 (FACT) ACCREDITED FACILITY.

63 (j) "INSTITUTIONAL REVIEW BOARD" OR "IRB" MEANS AN INSTITUTIONAL REVIEW
64 BOARD AS DEFINED BY PUBLIC LAW 93-348 WHICH IS REGULATED BY TITLE 45 CFR 46.

65 (k) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT.
66 620, 42 U.S.C. 1396 TO 1396G AND 1396I TO 1396U.

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68 (2) THE DEFINITIONS OF PART 222 SHALL APPLY TO THESE STANDARDS.
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70 **SECTION 3. REQUIREMENTS TO INITIATE AN IECT SERVICE**

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72 Sec. 3. INITIATE AN IECT SERVICE MEANS TO BEGIN OPERATION OF AN IECT SERVICE AT
73 A SITE THAT DOES NOT PROVIDE IECT SERVICES AND IS NOT LISTED ON THE DEPARTMENT
74 INVENTORY AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN
75 APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING
76 REQUIREMENTS.
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78 (1) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL AGREE TO OBTAIN
79 FACT ACCREDITATION FOR IECT WITHIN 3 YEARS OF CON APPROVAL. THE APPLICANT SHALL
80 ALSO AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF
81 THE SERVICE.
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83 (2) AN APPLICANT SHALL SPECIFY THE FACT ACCREDITED SITE AT WHICH THE IECT
84 SERVICE WILL BE PROVIDED.
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86 (3) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL CERTIFY THAT IT
87 WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FOOD AND DRUG ADMINISTRATION
88 (FDA) APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE
89 CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS
90 OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL
91 OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED
92 PROTOCOLS.
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94 **SECTION 4. REQUIREMENTS FOR APPROVAL – ACQUISITION OF AN IECT SERVICE**

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96 SEC 4. ACQUISITION OF AN IECT SERVICE MEANS THE ACQUISITION (INCLUDING
97 PURCHASE, LEASE, DONATION, OR OTHER ARRANGEMENT) OF AN EXISTING IECT SERVICE.
98 AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING IECT SERVICE SHALL DEMONSTRATE
99 THE FOLLOWING:
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101 (1) THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE
102 TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE
103 SERVICE.
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105 (2) THE APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE
106 PROJECT DELIVERY REQUIREMENTS.

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SECTION 5. REQUIREMENTS TO REPLACE IECT SERVICES

SEC. 5. REPLACEMENT OF AN IECT SERVICE MEANS RELOCATING AN EXISTING IECT SERVICE TO A NEW GEOGRAPHIC LOCATION. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING IECT SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING.

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE THAT THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE TO OBTAIN FACT ACCREDITATION, AND THE NEW SERVICE SHALL MEET THE REQUIREMENTS OF SECTION 3.

(2) THE EXISTING IECT SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE IECT SERVICE SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.

SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION

SEC. 6. 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 7. PROJECT DELIVERY REQUIREMENTS TERMS OF APPROVAL FOR ALL APPLICANTS

SEC. 7. AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE IECT SERVICE SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL:

(1) COMPLIANCE WITH THESE STANDARDS. AN APPLICANT SHALL IMMEDIATELY REPORT TO THE DEPARTMENT ANY CHANGES IN THE IECT SERVICE THAT MAY AFFECT ITS ABILITY TO COMPLY WITH THESE STANDARDS.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

(a) THE APPLICANT SHALL OBTAIN FACT ACCREDITATION WITHIN 3 YEARS OF CON APPROVAL AND SHALL MAINTAIN FACT ACCREDITATION THROUGHOUT THE LIFE OF THE SERVICE AS LONG AS THE SERVICE PROVIDES CELLULAR THERAPIES FOR WHICH FACT ACCREDITATION IS REQUIRED OR RECOMMENDED. THE APPLICANT SHALL IMMEDIATELY NOTIFY THE DEPARTMENT IF IT'S FACT ACCREDITATION IS SUSPENDED, REVOKED, EXPIRED OR OTHERWISE LIMITED.

(b) AN APPLICANT SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FDA APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED PROTOCOLS.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

159 (A) THE IECT SERVICE SHALL ACCEPT REFERRALS FOR IECT SERVICES FROM ALL
160 APPROPRIATELY LICENSED HEALTH CARE PRACTITIONERS.

161 (B) THE IECT SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE
162 MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE
163 ANNUALLY THEREAFTER.

164 (C) THE IECT SERVICE SHALL NOT DENY IECT SERVICES TO ANY INDIVIDUAL BASED ON
165 ABILITY TO PAY OR SOURCE OF PAYMENT.

166 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE IECT SERVICE SHALL BE IN
167 CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.16221;
168 MSA 14.15 (16221).

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170 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

171 (a) THE APPLICANT SHALL PARTICIPATE IN A DATA COLLECTION NETWORK
172 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY
173 INCLUDE, BUT IS NOT LIMITED TO, ANNUAL BUDGET AND COST INFORMATION, DEMOGRAPHIC
174 AND DIAGNOSTIC INFORMATION, PRIMARY AND SECONDARY DIAGNOSES, LENGTH OF STAY,
175 THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES, AND OTHER
176 DATA REQUESTED BY THE DEPARTMENT AND APPROVED BY THE CON COMMISSION. THE
177 APPLICANT SHALL PROVIDE THE REQUIRED DATA ON AN INDIVIDUAL BASIS FOR EACH
178 DESIGNATED FACT ACCREDITED SITE; IN A FORMAT ESTABLISHED BY THE DEPARTMENT; AND
179 IN A MUTUALLY AGREED UPON MEDIA. THE DEPARTMENT MAY ELECT TO VERIFY THE DATA
180 THROUGH ON-SITE REVIEW OF APPROPRIATE RECORDS.

181 (b) THE IECT SERVICE SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF THE
182 PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND
183 PROMULGATED RULES.

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185 (5) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
186 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

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188 **SECTION 8. DEPARTMENT INVENTORY OF IECT SERVICES**

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190 SEC. 8. THE DEPARTMENT SHALL MAINTAIN, AND PROVIDE ON REQUEST, A LISTING OF
191 THE DEPARTMENT INVENTORY OF IECT SERVICES.

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193 **SECTION 9. EFFECT ON PRIOR POLICIES; COMPARATIVE REVIEWS**

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195 SEC. 10. (1) PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT
196 TO COMPARATIVE REVIEW.

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

Date: August 8, 2019

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 Psychiatric Beds and Services Standards

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 Psychiatric Beds and Services Standards at its June 13, 2019 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Psychiatric Beds and Services Standards on July 25, 2019. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from five organizations.

Written Testimony:

- 1.) *Jarrett M. Schroeder, MD, Chief of Behavioral Health Services; Selena Schmidt, PMHNP-BC, Director, Behavioral Health Service Line – Ascension MI*
 - Ascension would like clarity on the special pool for high acuity psychiatric beds regarding "what the defined procedure is when a patient no longer meets the criteria set forth in the standards. Is the expectation that the patient would need to go to a General Psych area? Furthermore, we request clarity in the standards language as to what is the expected procedure if there is not a general psych unit available (i.e. transfer within 25 miles, a lateral transfer, etc.)?"
- 2.) *Lee Ann Odom, President, Shared Services, Beaumont Health*
 - Supports the proposed language.
- 3.) *Geri Souve, Member, SEIU Healthcare Michigan*
 - SEIU believes that there should be "specific rules preventing providers who are under federal or state investigation for alleged fraudulent activities from obtaining CON approval."

4.) *Universal Health Services, Inc. (UHS)*

- UHS disagrees with SEIUs recommendation that there should be “specific rules preventing providers who are under federal or state investigation for alleged fraudulent activities from obtaining CON approval.”

5.) *Rosalie Tocco-Bradley, MD, PhD, Chief Clinical Officer, Trinity Health*

- Supports the proposed language.

Department Recommendation:

The Department supports the language as presented at the June 13, 2019 CON Commission meeting.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR PSYCHIATRIC BEDS AND 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 under Part 222 of the Code that involve (a) beginning operation of a new psychiatric service, (b) replacing licensed psychiatric beds or physically relocating licensed psychiatric beds from one licensed site to another geographic location, or (c) increasing licensed psychiatric beds within a psychiatric hospital or unit licensed under the Mental Health Code, 1974 PA 258, or (d) acquiring a psychiatric service pursuant to Part 222 of the Code. A psychiatric hospital or unit is a covered health facility. 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.

(2) An increase in licensed hospital beds is a change in bed capacity for purposes of Part 222 of the Code.

(3) The physical relocation of hospital beds from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

Section 2. Definitions

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

(a) "Acquisition of a psychiatric hospital or unit" means the issuance of a new license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed psychiatric hospital or unit and which does not involve a change in the number of licensed psychiatric beds at that health facility.

(b) "Adult" means any individual aged 18 years or older.

(c) "Base year" means the most recent year for which verifiable data are collected by the Department and are available separately for the population age cohorts of 0 to 17 and 18 and older. "AVERAGE OCCUPANCY RATE" IS CALCULATED AS FOLLOWS:

(i) CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

(ii) CALCULATE THE TOTAL LICENSED BED DAYS FOR THE SAME 12-MONTH PERIOD AS IN (i) ABOVE BY MULTIPLYING THE TOTAL LICENSED BEDS BY THE NUMBER OF DAYS THEY WERE LICENSED.

(iii) DIVIDE THE NUMBER OF PATIENT DAYS CALCULATED IN (i) ABOVE BY THE TOTAL LICENSED BED DAYS CALCULATED IN (ii) ABOVE, THEN MULTIPLY THE RESULT BY 100.

(d) "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.

(e) "Child/adolescent" means any individual less than 18 years of age.

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

(g) "Community mental health board" or "board" or "CMH" means the board of a county(s) community mental health board as referenced in the provisions of MCL 330.1200 to 330.1246.

54 (h) "Comparative group" means the applications which have been grouped for the same type of
 55 project in the same planning area or statewide special population group and are being reviewed
 56 comparatively in accordance with the CON rules.

57 (i) "Department" means the Michigan Department of Health and Human Services (MDHHS).

58 (j) "Department inventory of beds" means the current list maintained for each planning area on a
 59 continuing basis by the Department which includes:

60 (i) licensed adult and child/adolescent psychiatric beds; and

61 (ii) adult and child/adolescent psychiatric beds approved by a valid CON, which are not yet licensed.
 62 A separate inventory will be maintained for child/adolescent beds and adult beds.

63 (k) "Existing adult inpatient psychiatric beds" or "existing adult beds" means:

64 (i) all adult beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental
 65 Health Code;

66 (ii) all adult beds approved by a valid CON, which are not yet licensed;

67 (iii) proposed adult beds under appeal from a final Department decision, or pending a hearing from a
 68 proposed decision; and

69 (iv) proposed adult beds that are part of a completed application (other than the application or
 70 applications in the comparative group under review) which are pending final Department decision.

71 (l) "Existing child/adolescent inpatient psychiatric beds" or "existing child/adolescent beds" means:

72 (i) all child/adolescent beds in psychiatric hospitals or units licensed by the Department pursuant to
 73 the Mental Health Code;

74 (ii) all child/adolescent beds approved by a valid CON, which are not yet licensed;

75 (iii) proposed child/adolescent beds under appeal from a final Department decision, or pending a
 76 hearing from a proposed decision; and

77 (iv) proposed child/adolescent beds that are part of a completed application (other than the
 78 application or applications in the comparative group under review) which are pending final Department
 79 decision.

80 (m) "Flex bed" means an existing adult psychiatric bed converted to a child/adolescent psychiatric
 81 bed in an existing child/adolescent psychiatric service to accommodate during peak periods and meet
 82 patient demand.

83 (n) "Initiation of service" means the establishment of an inpatient psychiatric unit with a specified
 84 number of beds at a site not currently providing psychiatric services.

85 (o) "Involuntary commitment status" means a hospital admission effected pursuant to the provisions
 86 of MCL 330.1423 to 330.1429.

87 (p) "Licensed site" means the location of the facility authorized by license and listed on that
 88 licensee's certificate of licensure.

89 (q) "Medicaid" means title XIX of the Social Security Act, chapter 531, 49 Stat. 620, 1396 to 1396g
 90 and 1396i to 1396u.

91 (r) "Mental Health Code" means Act 258 of the Public Acts of 1974, as amended, being Sections
 92 330.1001 to 330.2106 of the Michigan Compiled Laws.

93 (s) "Mental health professional" means an individual who is trained and experienced in the area of
 94 mental illness or developmental disabilities and who is any 1 of the following:

95 (i) a physician who is licensed to practice medicine or osteopathic medicine and surgery in Michigan
 96 and who has had substantial experience with mentally ill, mentally retarded, or developmentally disabled
 97 clients for 1 year immediately preceding his or her involvement with a client under administrative rules
 98 promulgated pursuant to the Mental Health Code;

99 (ii) a psychologist who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to
 100 333.18838;

101 (iii) a licensed master's social worker licensed in Michigan Pursuant to the provisions of MCL
 102 333.16101 to 333.18838;

103 (iv) a registered nurse who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to
 104 333.18838;

105 (v) a licensed professional counsel or licensed in Michigan pursuant to the provisions of MCL
 106 333.16101 to 333.18838;

- 107 (vi) a marriage and family therapist licensed in Michigan pursuant to the provisions of MCL
108 333.16101 to 333.18838;
- 109 (vii) a professional person, other than those defined in the administrative rules promulgated pursuant
110 to the Mental Health Code, who is designated by the Director of the Department or a director of a facility
111 operated by the Department in written policies and procedures. This mental health professional shall
112 have a degree in his or her profession and shall be recognized by his or her respective professional
113 association as being trained and experienced in the field of mental health. The term does not include
114 non-clinical staff, such as clerical, fiscal or administrative personnel.
- 115 (t) "Mental health service" means the provision of mental health care in a protective environment
116 with mental illness or mental retardation, including, but not limited to, chemotherapy and individual and
117 group therapies pursuant to MCL 330.2001.
- 118 (u) "Non-renewal or revocation of license" means the Department did not renew or revoked the
119 psychiatric hospital's or unit's license based on the hospital's or unit's failure to comply with state licensing
120 standards.
- 121 (v) "Non-renewal or termination of certification" means the psychiatric hospital's or unit's Medicare
122 and/or Medicaid certification was terminated or not renewed based on the hospital's or unit's failure to
123 comply with Medicare and/or Medicaid participation requirements.
- 124 (w) "Offer" means to provide inpatient psychiatric services to patients.
- 125 (x) "Physician" means an individual licensed in Michigan to engage in the practice of medicine or
126 osteopathic medicine and surgery pursuant to MCL 333.16101 to 333.18838.
- 127 (y) "Planning area" means the geographic boundaries of the groups of counties shown in Section
128 4716.
- 129 (z) "Planning year" means a year in the future, at least 3 years but no more than 7 years, for which
130 inpatient psychiatric bed needs are developed. The planning year shall be a year for which official
131 population projections from the Department of Technology, Management and Budget or its designee are
132 available.
- 133 (aa) "Psychiatric hospital" means an inpatient program operated by the Department for the treatment
134 of individuals with serious mental illness or serious emotional disturbance or a psychiatric hospital or
135 psychiatric unit licensed under pursuant to MCL 330.1137.
- 136 (bb) "Psychiatrist" means 1 or more of the following, pursuant to MCL 330.1100c:
- 137 (i) a physician who has completed a residency program in psychiatry approved by the Accreditation
138 Council for Graduate Medical Education or The American Osteopathic Association, or who has completed
139 12 months of psychiatric rotation and is enrolled in an approved residency program;
- 140 (ii) a psychiatrist employed by or under contract with the Department or a community health services
141 program on March 28, 1996;
- 142 (iii) a physician who devotes a substantial portion of his or her time to the practice of psychiatry and
143 is approved by the Director.
- 144 (cc) "Psychiatric unit" means a unit of a general hospital that provides inpatient services for individuals
145 with serious mental illness or serious emotional disturbances pursuant to MCL 330.1100c.
- 146 (dd) "Psychologist" means an individual licensed to engage in the practice of psychology, who devotes
147 a substantial portion of his or her time to the diagnosis and treatment of individuals with serious mental
148 illness, serious emotional disturbance, or developmental disability, pursuant to MCL 333.16101 to
149 333.18838.
- 150 (ee) "Public patient" means an individual approved for mental health services by a CMH or an
151 individual who is admitted as a patient under the Mental Health Code, Act No. 258 of the Public Acts of
152 1974, being Sections 330.1423, 330.1429, and 330.1438 of the Michigan Compiled Laws.
- 153 (ff) "Qualifying project" means each application in a comparative group which has been reviewed
154 individually and has been determined by the Department to have satisfied all of the requirements of
155 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
156 applicable requirements for approval in the Code and these standards.
- 157 (gg) "Registered professional nurse" or "R.N." means an individual licensed in Michigan pursuant to
158 the provisions of MCL 333.16101 to 333.18838.

159 (hh) "Relocate existing licensed inpatient psychiatric beds" means a change in the location of existing
 160 inpatient psychiatric beds from the existing licensed psychiatric hospital site to a different existing
 161 licensed psychiatric hospital site within the same planning area. This definition does not apply to projects
 162 involving replacement beds in a psychiatric hospital or unit governed by Section 7-6 of these standards.

163 (ii) "Replace beds" means a change in the location of the licensed psychiatric hospital or unit, or the
 164 replacement of a portion of the licensed beds at the same licensed site. The beds will be in new physical
 165 plant space being developed in new construction or in newly acquired space (purchase, lease, donation,
 166 etc.) within the replacement zone.

167 (jj) "Replacement zone" means a proposed licensed site that is:

168 (i) in the same planning area as the existing licensed site; and

169 (ii) on the same site, on a contiguous site, or on a site within 15 miles of the existing licensed site.

170 (kk) "Social worker" means an individual registered in Michigan to engage in social work under the
 171 provisions of MCL 333.18501.

172
 173 (2) The terms defined in the Code have the same meanings when used in these standards.
 174

175 Section 3. Determination of needed inpatient psychiatric bed supply

176
 177 ~~Sec. 3. (1) Until changed by the Commission in accordance with Section 5, the use rate for the base~~
 178 ~~year for the population age 0-17 is set forth in Appendix B.~~

179
 180 ~~—(2)The number of child/adolescent inpatient psychiatric beds needed in a planning area shall be~~
 181 ~~determined by the following formula:~~

182 ~~—(a)Determine the population for the planning year for each separate planning area for the population~~
 183 ~~age 0-17.~~

184 ~~—(b)Multiply the population by the use rate established in Appendix B. The resultant figure is the total~~
 185 ~~patient days.~~

186 ~~—(c)Divide the total patient days obtained in subsection (b) by 365 (or 366 for leap years) to obtain the~~
 187 ~~projected average daily census (ADC).~~

188 ~~—(d)Divide the ADC by 0.75.~~

189 ~~—(e)For each planning area, all psychiatric hospitals or units with an average occupancy of 60% or less~~
 190 ~~for the previous 24 months will have the ADC, for the previous 24 months, multiplied by 1.7. The net~~
 191 ~~decrease from the current licensed beds will give the number to be added to the bed need.~~

192 ~~—(f)The adjusted bed need for the planning area is the sum of the results of subsections (d) and (e).~~
 193 ~~round up to the nearest whole number.~~

194
 195 ~~—(3)The number of needed adult inpatient psychiatric beds shall be determined by multiplying the~~
 196 ~~population aged 18 years and older for the planning year for each planning area by either:~~

197 ~~—(a)The ratio of adult beds per 10,000 adult population set forth in Appendix A; or~~

198 ~~—(b)The statewide ratio of adult beds per 10,000 adult population set forth in Appendix A, whichever is~~
 199 ~~lower; and dividing the result by 10,000. If the ratio set forth in Appendix A for a specific planning area is~~
 200 ~~"0", the statewide ratio of adult beds per 10,000 adult population shall be used to determine the number of~~
 201 ~~needed adult inpatient psychiatric beds.~~

202 ~~—(c)For each planning area, an addition to the bed need will be made for low occupancy facilities. All~~
 203 ~~psychiatric hospitals or units with an average occupancy of 60% or less for the previous 24 months will~~
 204 ~~have the ADC, for the previous 24 months, multiplied by 1.5. The net decrease from the current licensed~~
 205 ~~beds will give the number to be added to the bed need.~~

206 ~~—(d) — The adjusted bed need for the planning area is the sum of the results of subsections (b)~~
 207 ~~and (c). THE NUMBER OF CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS NEEDED IN A~~
 208 ~~PLANNING AREA SHALL BE DETERMINED BY THE FOLLOWING FORMULA:~~

209 ~~(a) TABULATE THE YEARLY NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR THE~~
 210 ~~MOST RECENT FIVE YEARS OF DATA FROM THE CON ANNUAL SURVEY.~~

211 ~~(b) CONSTRUCT A LINEAR REGRESSION MODEL WITH YEAR AS THE INDEPENDENT~~

VARIABLE AND YEARLY PATIENT DAYS AS THE DEPENDENT VARIABLE. IF THE COEFFICIENT OF DETERMINATION (R^2) OF THE LINEAR MODEL IS 0.5 OR GREATER, USE THE REGRESSION PARAMETERS TO PREDICT THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR. IF THE COEFFICIENT OF DETERMINATION OF THE LINEAR MODEL IS LESS THAN 0.5, CALCULATE THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR BY TAKING THE MEAN OF THE MOST RECENT THREE YEARS OF DATA.

(c) DIVIDE THE TOTAL PATIENT DAYS OBTAINED IN SUBSECTION (B) BY THE STATEWIDE PLANNING YEAR POPULATION AGE 0-17. THE RESULT IS THE UTILIZATION RATE FOR THE POPULATION AGE 0-17 IN THE PLANNING YEAR.

(d) MULTIPLY THE UTILIZATION RATE OBTAINED IN SUBSECTION (C) BY THE PLANNING YEAR POPULATION AGE 0-17 IN EACH PLANNING AREA. THE RESULT IS THE UNADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(e) USING THE MOST RECENT DATA FROM THE DEPARTMENT INVENTORY OF BEDS, CALCULATE THE AVERAGE NUMBER OF LICENSED CHILD/ADOLESCENT BEDS PER FACILITY FOR EACH PLANNING AREA.

(f) FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY LESS THAN 20, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.65. FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY OF 20 OR MORE, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.70. THE RESULT IS THE OCCUPANCY-ADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(g) FOR EACH PLANNING AREA, DIVIDE THE OCCUPANCY-ADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FROM (F) BY 365 (OR 366 FOR LEAP YEARS). ROUND THE VALUES UP TO THE NEAREST WHOLE NUMBER. THE RESULT IS CHILD/ADOLESCENT BED NEED IN THE PLANNING YEAR.

(2) THE NUMBER OF ADULT INPATIENT PSYCHIATRIC BEDS NEEDED IN A PLANNING AREA SHALL BE DETERMINED BY THE FOLLOWING FORMULA:

(a) TABULATE THE YEARLY NUMBER OF ADULT PATIENT DAYS FOR THE MOST RECENT FIVE YEARS OF DATA FROM THE CON ANNUAL SURVEY.

(b) CONSTRUCT A LINEAR REGRESSION MODEL WITH YEAR AS THE INDEPENDENT VARIABLE AND YEARLY PATIENT DAYS AS THE DEPENDENT VARIABLE. IF THE COEFFICIENT OF DETERMINATION (R^2) OF THE LINEAR MODEL IS 0.5 OR GREATER, USE THE REGRESSION PARAMETERS TO PREDICT THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR. IF THE COEFFICIENT OF DETERMINATION OF THE LINEAR MODEL IS LESS THAN 0.5, CALCULATE THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR BY TAKING THE MEAN OF THE MOST RECENT THREE YEARS OF DATA.

(c) DIVIDE THE TOTAL PATIENT DAYS OBTAINED IN SUBSECTION (B) BY THE STATEWIDE PLANNING YEAR POPULATION AGE 18+. THE RESULT IS THE UTILIZATION RATE FOR THE POPULATION AGE 18+ IN THE PLANNING YEAR.

(d) MULTIPLY THE UTILIZATION RATE OBTAINED IN SUBSECTION (C) BY THE PLANNING YEAR POPULATION AGE 18+ IN EACH PLANNING AREA. THE RESULT IS THE UNADJUSTED NUMBER OF ADULT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(e) USING THE MOST RECENT DATA FROM THE DEPARTMENT INVENTORY OF BEDS, CALCULATE THE AVERAGE NUMBER OF LICENSED ADULT BEDS PER FACILITY FOR EACH PLANNING AREA.

(f) FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY LESS THAN 20, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.65. FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY OF 20 OR MORE, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.70. THE RESULT IS THE OCCUPANCY-ADJUSTED NUMBER OF ADULT PATENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(g) FOR EACH PLANNING AREA, DIVIDE THE OCCUPANCY-ADJUSTED NUMBER OF ADULT PATIENT DAYS FROM (F) BY 365 (OR 366 FOR LEAP YEARS). ROUND THE VALUES UP TO THE NEAREST WHOLE NUMBER. THE RESULT IS ADULT BED NEED IN THE PLANNING YEAR.

Section 4. Bed need for inpatient psychiatric beds

Sec. 4. (1) The bed need numbers determined pursuant to Section 3 shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Department shall apply the bed need methodologies in Section 3 on a biennial basis.

(3) The effective date of the bed need numbers shall be established by the Commission.

(4) New bed need numbers shall supercede previous bed need numbers and shall be posted on the State of Michigan CON web site as part of the Psychiatric Bed Inventory.

(5) Modifications made by the Commission pursuant to this Section shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. ~~Modification of the child/adolescent use rate by changing the base year~~

~~Sec. 5. (1) The Commission may modify the base year based on data obtained from the Department and presented to the Commission. The Department shall calculate the use rate for the population age 0-17 and biennially present the revised use rate based on the most recent base year information available biennially to the CON Commission.~~

~~(2) The Commission shall establish the effective date of the modifications made pursuant to subsection (1).~~

~~(3) Modifications made by the Commission pursuant to subsection (1) shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.~~

Section 6. Requirements for approval to initiate service

Sec. 65. An applicant proposing the initiation of an adult or child/adolescent psychiatric service shall demonstrate or provide the following:

(1) The number of beds proposed in the CON application shall not result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the bed need. However, an applicant may request and be approved for up to a maximum of 10 beds if, when the total number of existing adult beds or existing child/adolescent beds is subtracted from the bed need for the planning area, the difference is equal to or more than 1 or less than 10.

(2) A written recommendation, from the Department or the CMH that serves the county in which the proposed beds or service will be located, shall include an agreement to enter into a contract to meet the needs of the public patient. At a minimum, the letter of agreement shall specify the number of beds to be allocated to the public patient and the applicant's intention to serve patients with an involuntary commitment status.

(3) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct

318 response to a Department plan pursuant to subsection (5) shall allocate not less than 80% of the beds
 319 proposed in the CON application.

320

321 (4) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit
 322 has or proposes to operate both adult and child/adolescent beds, each unit shall have a minimum of 10
 323 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant
 324 demonstrates to the satisfaction of the Department, that travel time to existing units would significantly
 325 limit access to care.

326

327 (5) An applicant shall not be required to be in compliance with subsection (1) if the applicant
 328 demonstrates that the application meets both of the following:

329 (a) The Director of the Department determines that an exception to subsection (1) should be made
 330 and certifies in writing that the proposed project is a direct response to a Department plan for reducing the
 331 use of public institutions for acute mental health care through the closure of a state-owned psychiatric
 332 hospital; and

333 (b) The proposed beds will be located in the area currently served by the public institution that will be
 334 closed, as determined by the Department.

335

336 **Section 76. Requirements for approval to replace beds**

337

338 **Sec. 76. An applicant proposing to replace beds shall not be required to be in compliance with the**
 339 **needed bed supply if the applicant demonstrates all of the following:**

340

341 (1) The applicant shall specify whether the proposed project is to replace the existing licensed
 342 psychiatric hospital or unit to a new site or to replace a portion of the licensed psychiatric beds at the
 343 existing licensed site.

344

345 (2) The proposed licensed site is in the replacement zone.

346

347 (3) Not less than 50% of the beds proposed to be replaced shall be allocated for use by public
 348 patients.

349

350 (4) Previously made commitments, if any, to the Department or CMH to serve public patients have
 351 been fulfilled.

352

353 (5) Proof of current contract or documentation of contract renewal, if current contract is under
 354 negotiation, with the CMH or its designee that serves the planning area in which the proposed beds or
 355 service will be located.

356

357 **(6) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS**
 358 **APPLICABLE:**

359 **(a) THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE**
 360 **OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT**
 361 **BEDS.**

362 **(b) IF THE AVERAGE OCCUPANCY RATE FOR THE EXISTING PSYCHIATRIC HOSPITAL OR**
 363 **UNIT IS BELOW 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, THEN THE**
 364 **APPLICANT PSYCHIATRIC HOSPITAL OR UNIT SHALL REDUCE THE APPROPRIATE NUMBER OF**
 365 **LICENSED BEDS TO ACHIEVE AN AVERAGE ANNUAL OCCUPANCY RATE OF AT LEAST 60% FOR**
 366 **ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS. THE APPLICANT PSYCHIATRIC**
 367 **HOSPITAL OR UNIT SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS FOLLOWS:**

368 **(i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER**
 369 **OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE**
 370 **VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.**

(ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER REPLACEMENT.

(iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

(iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER REPLACEMENT.

Section 87. Requirements for approval of an applicant proposing to relocate existing licensed inpatient psychiatric beds

Sec. 87. (1) The proposed project to relocate beds, under this section, shall constitute a change in bed capacity under Section 1(3) of these standards.

(2) Any existing licensed inpatient psychiatric hospital or unit may relocate all or a portion of its beds to another existing licensed inpatient psychiatric hospital or unit located within the same planning area.

(3) The inpatient psychiatric hospital or unit from which the beds are being relocated, and the inpatient psychiatric hospital or unit receiving the beds, shall not require any ownership relationship.

(4) The relocated beds shall be licensed to the receiving inpatient psychiatric hospital or unit and will be counted in the inventory for the applicable planning area.

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

(6) The relocation of beds under this section shall not result in initiation of a new adult or child/adolescent service except for an existing adult inpatient psychiatric service requesting to initiate a child/adolescent inpatient psychiatric service in an overbedded child/adolescent planning area pursuant to

Section 98(11).

(7) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(a) THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS.

(b) IF THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT DOES NOT HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS, THEN THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL REDUCE THE APPROPRIATE NUMBER OF LICENSED BEDS TO ACHIEVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS UPON COMPLETION OF THE RELOCATION(S). THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS FOLLOWS:

(i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

(ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER THE RELOCATION.

423 (iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE
 424 THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH
 425 PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

426 (iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH
 427 PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10,
 428 WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT
 429 THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER THE RELOCATION.

430
 431 (4) A SOURCE HOSPITAL SHALL APPLY FOR MULTIPLE RELOCATIONS ON THE SAME
 432 APPLICATION DATE, AND THE APPLICATIONS CAN BE COMBINED TO MEET THE CRITERIA OF
 433 (7)(b) ABOVE. A SEPARATE APPLICATION SHALL BE SUBMITTED FOR EACH PROPOSED
 434 RELOCATION.

435 436 **Section 98. Requirements for approval to increase beds**

437
 438 **Sec. 98.** An applicant proposing an increase in the number of adult or child/adolescent beds shall
 439 demonstrate or provide the following:

440
 441 (1) AN APPLICANT PROPOSING NEW BEDS IN A PSYCHIATRIC HOSPITAL OR UNIT, EXCEPT
 442 AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (3), (9), or (10) SHALL
 443 DEMONSTRATE THAT ~~t~~he number of beds proposed in the CON application will not result in the
 444 number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area
 445 exceeding the bed need. However, an applicant may request and be approved for up to a maximum of
 446 10 beds if, when the total number of existing adult beds or existing child/adolescent beds is subtracted
 447 from the bed need for the planning area, the difference is equal to or more than 1 or less than 10.

448
 449 (2) AN APPLICANT PROPOSING NEW BEDS IN A PSYCHIATRIC HOSPITAL OR UNIT, EXCEPT
 450 AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (3), (9), or (10) SHALL
 451 DEMONSTRATE THAT ~~t~~he average occupancy rate for the applicant's facility, where the proposed beds
 452 are to be located, was at least 70% for adult or child/adolescent beds, as applicable, during the most
 453 recent, consecutive 12-month period, as of the date of the submission of the application, for which
 454 verifiable data are available to the Department. **THIS SUBSECTION SHALL NOT APPLY IF ADDING
 455 BEDS FROM A SPECIAL POPULATION GROUP CONTAINED IN THE ADDENDUM TO THESE
 456 STANDARDS.** For purposes of this section, average occupancy rate shall be calculated as follows:

457 (a) Divide the number of patient days of care provided by the total number of patient days, then
 458 multiply the result by 100.

459
 460 (3) ~~Subsections (1) and (2) shall not apply.~~ AN APPLICANT MAY APPLY FOR THE ADDITION OF
 461 NEW BEDS if all of the following SUBSECTIONS are met: **FURTHER, AN APPLICANT PROPOSING
 462 NEW BEDS AT AN EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE SHALL NOT BE
 463 REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED PSYCHIATRIC HOSPITAL BED SUPPLY IF
 464 THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES
 465 AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.**

466 (a) The number of existing adult or child/adolescent psychiatric beds in the planning area is equal to
 467 or exceeds the bed need.

468 (b) The beds are being added at the existing licensed site.

469 (c) The average occupancy rate for the applicant's facility was at least 75% for facilities with 19 beds
 470 or less and 80% for facilities with 20 beds or more, as applicable, during the most recent, consecutive 12-
 471 month period, as of the date of the submission of the application, for which verifiable data are available to
 472 the Department.

473 (i) For a facility with flex beds,

474 (A) calculate the average occupancy rate as follows:

475 (1) For adult beds:

- 476 (a) Adult bed days are the number of licensed adult beds multiplied by the number of days they were
477 licensed during the most recent consecutive 12-month period.
- 478 (b) Flex bed days are the number of licensed flex beds multiplied by the number of days the beds
479 were used to serve a child/ adolescent patient.
- 480 (c) Subtract the flex bed days from the adult bed days and divide the adult patient days of care by
481 this number, then multiply the result by 100.
- 482
- 483 (2) For child/adolescent beds:
- 484 (a) Child/adolescent bed days are the number of licensed child/adolescent beds multiplied by the
485 number of days they were licensed during the most recent 12-month period.
- 486 (b) Flex bed days are the number of licensed flex beds multiplied by the number of days the beds
487 were used to serve a child/ adolescent patient.
- 488 (c) Add the flex bed days to the child/adolescent bed days and divide the child/adolescent patient
489 days of care by this number, then multiply the result by 100.
- 490 (d) The number of beds to be added shall not exceed the results of the following formula:
- 491 (ii) Multiply the facility's average daily census for the most recent, consecutive 12-month period, as
492 of the date of the submission of the application, for which verifiable data are available to the Department
493 by 1.5 for adult beds and 1.7 for child/adolescent beds.
- 494 (iii) Subtract the number of currently licensed beds from the number calculated in (ii) above. This is
495 the maximum number of beds that may be approved pursuant to this subsection.
- 496
- 497 (4) Proof of current contract or documentation of contract renewal, if current contract is under
498 negotiation, with at least one CMH or its designee that serves the planning area in which the proposed
499 beds or service will be located.
- 500
- 501 (5) Previously made commitments, if any, to the Department or CMH to serve public patients have
502 been fulfilled.
- 503
- 504 (6) The number of beds proposed in the CON application to be allocated for use by public patients
505 shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct
506 response to a Department plan pursuant to subsection (9) shall allocate not less than 80% of the beds
507 proposed in the CON application.
- 508
- 509 (7) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit
510 has or proposes to operate both adult and child/adolescent beds, then each unit shall have a minimum of
511 10 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant
512 demonstrates, to the satisfaction of the Department, that travel time to existing units would significantly
513 impair access to care. **THIS SUBSECTION SHALL NOT APPLY IF ADDING BEDS FROM A SPECIAL**
514 **POPULATION GROUP CONTAINED IN THE ADDENDUM TO THESE STANDARDS.**
- 515
- 516 (8) Subsection (2) shall not apply if the Director of the Department has certified in writing that the
517 proposed project is a direct response to a Department plan for reducing the use of public institutions for
518 acute mental health care through the closure of a state-owned psychiatric hospital.
- 519
- 520 (9) An applicant shall not be required to be in compliance with subsection (1) if the applicant
521 demonstrates that the application meets both of the following:
- 522 (a) The Director of the Department determines that an exception to subsection (1) should be made
523 and certifies in writing that the proposed project is a direct response to a Department plan for reducing the
524 use of public institutions for acute mental health care through the closure of a state-owned psychiatric
525 hospital; and
- 526 (b) The proposed beds will be located in the area currently served by the public institution that will be
527 closed as determined by the Department.
- 528

529 (10) An applicant proposing to add new adult and/or child/adolescent psychiatric beds, as the
 530 receiving licensed inpatient psychiatric hospital or unit under Section 87, shall demonstrate that it meets
 531 all of the requirements of this subsection and shall not be required to be in compliance with the bed need
 532 if the application meets all other applicable CON review standards and agrees and assures to comply
 533 with all applicable project delivery requirements.

534 (a) The approval of the proposed new inpatient psychiatric beds shall not result in an increase in the
 535 number of licensed inpatient psychiatric beds in the planning area.

536 (b) The applicant meets the requirements of subsections (4), (5), (6), and (7) above.

537 (c) The proposed project to add new adult and/or child adolescent psychiatric beds, under this
 538 subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.

539 (d) Applicants proposing to add new adult and/or child/adolescent psychiatric beds under this
 540 subsection shall not be subject to comparative review.

541
 542 (11) An applicant proposing to initiate a new child/adolescent psychiatric service, as the receiving
 543 licensed inpatient psychiatric hospital or unit under Section 87(6), shall demonstrate that it meets all of
 544 the requirements of this subsection and shall not be required to be in compliance with the bed need if the
 545 application meets all other applicable CON review standards and agrees and assures to comply with all
 546 applicable project delivery requirements.

547 (a) The approval of the proposed new inpatient psychiatric beds shall not result in an increase in the
 548 number of licensed inpatient psychiatric beds in the planning area.

549 (b) The applicant meets the requirements of subsections (4), (5), and (6) above.

550 (c) The applicant is requesting a minimum of 10 child/adolescent psychiatric beds to a maximum of
 551 20 beds.

552 (d) The applicant:

553 (i) is related through common ownership, in whole or in part, or through common control, with an
 554 acute-care hospital that has an emergency department that provides 24-hour emergency care services
 555 and where child/adolescent patients with a psychiatric and/or developmental disability diagnosis present
 556 at an average of at least 100 visits per year for each of the three most recent years in which there is data
 557 verifiable by the Department; and

558 (ii) has an agreement with the acute-care hospital to give primary consideration for admission of
 559 child/adolescent patients from the acute-care hospital's emergency department in need of an inpatient
 560 psychiatric hospital admission.

561 (iii) has a collaborative agreement with an existing child/adolescent psychiatric hospital or unit for
 562 consultation and supportive services with a proposed term of not less than twelve months after
 563 implementation.

564 (e) The proposed site for the new child/adolescent beds has not previously been approved for beds
 565 under this sub-section.

566 (f) The proposed project to add new child adolescent psychiatric beds, under this subsection, shall
 567 constitute a change in bed capacity under Section 1(2) of these standards.

568 (g) Applicants proposing to add new child/adolescent psychiatric beds under this subsection shall not
 569 be subject to comparative review.

570
 571 **Section 409. Requirements for approval for flex beds**

572
 573 **Sec. 409.** An applicant proposing flex beds shall demonstrate the following as applicable to the
 574 proposed project:

575
 576 (1) The applicant has existing adult psychiatric beds and existing child/adolescent psychiatric beds.

577
 578 (2) The number of flex beds proposed in the CON application shall not result in the existing adult
 579 psychiatric unit to become non-compliant with the minimum size requirements within Section 65(4).

580
 581 (3) The applicant shall meet all applicable sections of the standards.

582
583 (4) The facility shall be in compliance and meet all design standards of the most recent Minimum
584 Design Standards for Health Care Facilities in Michigan.

585
586 (5) The applicant shall convert the beds back to adult inpatient psychiatric beds if the bed has not
587 been used as a flex bed serving a child/adolescent patient for a continuous 12-month period or if the CON
588 application is withdrawn.

589
590 **Section 4410. Requirements for approval for acquisition of a psychiatric hospital or unit**

591
592 **Sec. 4410.** An applicant proposing to acquire a psychiatric hospital or unit shall not be required to be
593 in compliance with the needed bed supply, for the planning area in which the psychiatric hospital or unit
594 subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are
595 met:

596
597 (1) The acquisition will not result in a change in the number of licensed beds or beds designated for a
598 child/adolescent specialized psychiatric program.

599
600 (2) The licensed site does not change as a result of the acquisition.

601
602 **(3) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS**
603 **APPLICABLE:**

604 **(a) THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE**
605 **OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT**
606 **BEDS.**

607 **(b) IF THE AVERAGE OCCUPANCY RATE FOR THE EXISTING PSYCHIATRIC HOSPITAL OR**
608 **UNIT IS BELOW 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, THE**
609 **APPLICANT SHALL AGREE TO ALL OF THE FOLLOWING:**

610 **(i) THE PSYCHIATRIC HOSPITAL OR UNIT TO BE ACQUIRED WILL ACHIEVE AN AVERAGE**
611 **OCCUPANCY RATE OF AT LEAST 60% AVERAGE ANNUAL OCCUPANCY FOR ADULT BEDS OR**
612 **40% ANNUAL AVERAGE OCCUPANCY FOR CHILD/ADOLESCENT BEDS FOR THE REVISED**
613 **LICENSED BED COMPLEMENT DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END OF**
614 **THE SECOND YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION.**

615 **(A) CALCULATE AVERAGE OCCUPANCY RATE FOR ADULT BEDS AS FOLLOWS:**

616 **(1) ADD THE NUMBER OF ADULT PATIENT DAYS OF CARE TO THE NUMBER OF**
617 **CHILD/ADOLESCENT PATIENT DAYS OF CARE PROVIDED IN THE FLEX BEDS; DIVIDE THIS**
618 **NUMBER BY THE ADULT BED DAYS, THEN MULTIPLY THE RESULT BY 100.**

619 **(B) CALCULATE AVERAGE OCCUPANCY RATE FOR CHILD/ADOLESCENT BEDS AS**
620 **FOLLOWS:**

621 **(1) SUBTRACT THE NUMBER OF CHILD/ADOLESCENT PATIENT DAYS OF CARE PROVIDED**
622 **IN THE FLEX BEDS FROM THE NUMBER OF CHILD ADOLESCENT PATIENT DAYS OF CARE;**
623 **DIVIDE THIS NUMBER BY THE CHILD/ADOLESCENT BED DAYS, THEN MULTIPLY THE RESULT BY**
624 **100.**

625 **(C) FLEX BEDS APPROVED UNDER SECTION 9 SHALL BE COUNTED AS EXISTING ADULT**
626 **INPATIENT PSYCHIATRIC BEDS.**

627 **(c) IF THE PSYCHIATRIC HOSPITAL OR UNIT TO BE ACQUIRED DOES NOT ACHIEVE AN**
628 **AVERAGE ANNUAL OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS OR 40% FOR**
629 **CHILD/ADOLESCENT BEDS, AS CALCULATED ABOVE, DURING ANY CONSECUTIVE 12-MONTH**
630 **PERIOD BY THE END OF THE SECOND YEAR OF OPERATION AFTER COMPLETION OF THE**
631 **ACQUISITION, THE APPLICANT SHALL RELINQUISH SUFFICIENT BEDS AT THE EXISTING**
632 **PSYCHIATRIC HOSPITAL OR UNIT TO RAISE ITS AVERAGE OCCUPANCY TO 60% FOR ADULT**
633 **BEDS OR 40% FOR CHILD/ADOLESCENT BEDS. THE REVISED NUMBER OF LICENSED BEDS AT**

634 THE PSYCHIATRIC HOSPITAL OR UNIT SHALL BE CALCULATED AS FOLLOWS. HOWEVER, THE
635 PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT BE REDUCED TO LESS THAN 10 BEDS.

636 (i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER
637 OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD WHERE
638 VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

639 (ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 365 (OR 366 IF THE 12-MONTH
640 PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10,
641 WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT
642 THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER ACQUISITION.

643 (iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE
644 THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH
645 PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

646 (iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 365 (OR 366 IF THE 12-MONTH
647 PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10,
648 WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT
649 THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER ACQUISITION.

650
651 **Section 4211. Additional requirements for applications included in comparative review**

652
653 **Sec. 4211.** (1) Any application subject to comparative review under Section 22229 of the Code, being
654 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and
655 reviewed comparatively with other applications in accordance with the CON rules.

656
657 (2) Each application in a comparative group shall be individually reviewed to determine whether the
658 application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of
659 the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these
660 standards. If the Department determines that two or more competing applications satisfy all of the
661 requirements for approval, these projects shall be considered qualifying projects. The Department shall
662 approve those qualifying projects which, when taken together, do not exceed the need, as defined in
663 Section 22225(1) of the Code, and which have the highest number of points when the results of
664 subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number
665 of points, then the Department shall approve those qualifying projects which, when taken together, do not
666 exceed the need, in the order in which the applications were received by the Department, based on the
667 date and time stamp placed on the applications by the Department in accordance with rule 325.9123.

668
669 (3)(a) A qualifying project application will be awarded 5 points if, within six months of beginning
670 operation and annually thereafter, 100% of the licensed psychiatric beds (both existing and proposed) at
671 the facility will be Medicaid certified.

672 (b) A qualifying project will have 4 points deducted if, on or after November 26, 1995, the records
673 maintained by the Department document that the applicant was required to enter into a contract with
674 either the Department or a CMH to serve the public patient and did not do so.

675 (c) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records
676 maintained by the Department document that the applicant entered into a contract with MDCH or CMH
677 but never admitted any public patients referred pursuant to that contract.

678 (d) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records
679 maintained by the Department document that an applicant agreed to serve patients with an involuntary
680 commitment status but has not admitted any patients referred with an involuntary commitment status.

681 (e) A qualifying project will be awarded 3 points if the applicant presents, in its application, a plan,
682 acceptable to the Department, for the treatment of patients requiring long-term treatment. For purposes
683 of this subsection, long-term treatment is defined to mean an inpatient length of stay in excess of 45 days.

684 (f) A qualifying project will be awarded 3 points if the applicant currently provides a partial
685 hospitalization psychiatric program, outpatient psychiatric services, or psychiatric aftercare services, or
686 the applicant includes any of these services as part of their proposed project, as demonstrated by site

687 ~~plans and service contracts~~TRANSPORTATION ASSISTANCE TO PATIENTS WHO REQUIRE THESE
 688 SERVICES. AN APPLICANT PROPOSING A NEW FACILITY WILL BE AWARDED 3 POINTS IF IT
 689 SUBMITS SITE PLANS OR SERVICE CONTRACTS TO DEMONSTRATE IT WILL INLCUDE ANY OF
 690 THESE SERVICES AS PART OF ITS PROPOSED PROJECT.

691 (gc) A qualifying project will have 4 points deducted if the Department has issued, within three years
 692 prior to the date on which the CON application was deemed submitted, a ~~temporary permit or provisional~~
 693 license ~~FOR due to a pattern of licensure deficiencies at~~ any psychiatric hospital or unit owned or
 694 operated by the applicant in this state.

695 (hd) A qualifying project will have points awarded based on the ~~percentage of the hospital's indigent~~
 696 ~~volume as set forth in the following table~~ RANKING OF THE APPLICANT'S MEDICAID DAYS AS
 697 MEASURED AS A PERCENTAGE OF TOTAL DAYS AS SET FORTH IN THE FOLLOWING TABLE.
 698 FOR PURPOSES OF SCORING, THE APPLICANT'S MEDICAID PERCENTAGE WILL BE THE
 699 CUMULATIVE OF ALL TITLE XIX AND HEALTH MICHIGAN INPATIENT PSYCHIATRIC DAYS DIVIDED
 700 BY THE CUMULATIVE OF ALL INPATIENT PSYCHIATRIC DAYS AT ALL CURRENTLY LICENSED
 701 MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP OR CONTROL WITH THE APPLICANT.
 702 FOR PURPOSES OF EVALUATING THIS CRITERION, AN APPLICANT SHALL SUBMIT THE MOST
 703 RECENT REVIEWED AND ACCEPTED MEDICAID COST REPORT FOR EACH CURRENTLY
 704 LICENSED HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL IN MICHIGAN.

Hospital Indigent Volume	Points Awarded
0 - <6%	1
6 - <11%	2
11 - <16%	3
16 - <21%	4
21 - <26%	5
26 - <31%	6
31 - <36%	7
36 - <41%	8
41 - <46%	9
46% +	10

721 For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its
 722 total charges expressed as a percentage as determined by the Department pursuant to Chapter VIII of
 723 the Medical Assistance Program manual. The indigent volume data being used for rates in effect at the
 724 time the application is deemed submitted will be used by the Department in determining the number of
 725 points awarded to each qualifying project.

MEDICAID DAYS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENT OF MEDICAID DAYS	10 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF MEDICAID DAYS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF MEDICAID DAYS, THEN MULTIPLIED BY 10
EXAMPLE BELOW	
THE HIGHEST APPLICANT HAS 58.3% MEDICAID DAYS	10 POINTS
APPLICANT WITH 55.3% MEDICAID DAYS	$(.553 / .583) \times 10 = 9$ POINTS
APPLICANT WITH 51.3% MEDICAID DAYS	$(.513 / .583) \times 10 = 9$ POINTS

PERCENTAGES OF DAYS SHALL BE ROUNDED TO THE NEAREST 1/1000 AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(e) A qualifying project will have points deducted based on the applicant's record of compliance with applicable safety and operating standards for any psychiatric hospital or unit owned and/or operated by the applicant in this state. Points shall be deducted in accordance with the following schedule if, on or after November 26, 1995, the Department records document any non-renewal or revocation of license for cause or non-renewal or termination of certification for cause of any psychiatric hospital or unit owned or operated by the applicant in this state.

Psychiatric Hospital/Unit Compliance Action	Points Deducted
Non-renewal or revocation of license	4
Non-renewal or termination of:	
Certification - Medicare	4
Certification - Medicaid	4

(f) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE APPLICANT'S TOTAL PROJECT COSTS PER BED. FOR PURPOSES OF THIS CRITERION, TOTAL PROJECT COSTS SHALL BE DEFINED AS THE TOTAL COSTS FOR CONSTRUCTION AND RENOVATION, SITE WORK, ARCHITECTURAL/ ENGINEERING AND CONSULTING FEES, CONTINGENCIES, FIXED EQUIPMENT, CONSTRUCTION MANAGEMENT AND PERMITS. POINTS SHALL BE AWARDED IN ACCORDANCE WITH THE TABLE BELOW:

COST PER BED	POINTS AWARDED
APPLICANT WITH THE LOWEST COST PER BED	10 POINTS
ALL OTHER APPLICANTS	APPLICANT'S COST PER BED DIVIDED BY THE LOWEST APPLICANT'S COST PER BED, THEN MULTIPLIED BY 7
EXAMPLE BELOW	
THE LOWEST COST APPLICANT IS \$698,000 PER BED	7 POINTS
APPLICANT WITH \$710,000 PER BED	$(\$698,000 / \$710,000) \times 7 = 7$ POINTS
APPLICANT WITH \$975,000 PER BED	$(\$698,000 / \$975,000) \times 7 = 5$ POINTS

POINTS SHALL NOT BE AWARDED UNDER THIS SECTION FOR ANY PROJECT THAT PROPOSES TO ADD BEDS AT A LEASED FACILITY. COSTS SHALL BE ROUNDED TO THE NEAREST WHOLE DOLLAR AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(g) A QUALIFYING PROJECT WILL BE AWARDED 1 POINT FOR EACH DESIGN FEATURE IN THIS SUBSECTION (MAXIMUM OF 3 POINTS) THAT APPLICANT PROPOSES TO INCLUDE IN THE PROPOSED PROJECT TO REDUCE STRESS, FOSTER DIMINISHED AGGRESSION, AND REDUCE PATIENT RISK:

(i) DESIGN FEATURES AS SHOWN ON THE FLOOR PLAN SUBMITTED WITH THE CON APPLICATION TO ALLOW THE APPLICANT TO CREATE ONE OR MORE SUBUNITS WITHIN A

768 LARGER UNIT FOR CLINICAL OR PROGRAMMATIC PURPOSES, INCLUDING DOOR OR WALL
 769 SYSTEMS PERMITTED UNDER THE MINIMUM DESIGN STANDARDS FOR HEALTHCARE
 770 FACILITIES IN MICHIGAN TO SUBDIVIDE INPATIENT PSYCHIATRIC SPACE ON A TEMPORARY OR
 771 FLEXIBLE BASIS;

772 (ii) GARDENS OR OTHER OUTDOOR AREAS TO ALLOW INPATIENTS DIRECT DAILY ACCESS
 773 TO OUTDOOR SPACE AND DAYLIGHT; AND

774 (iii) A FLOOR PLAN DESIGNED TO HELP REDUCE PATIENT RISK BY OPTIMIZING
 775 OBSERVATION OF PATIENTS IN THE FACILITY IN COMMUNAL AREAS, HALLWAYS, AND PATIENT
 776 ROOMS. FOR PURPOSES OF THIS CRITERIA, APPLICANTS SHALL SUBMIT PROPOSED FLOOR
 777 PLANS THAT SHOW UNOBSTRUCTED SIGHT LINES FROM NURSE STATIONS OR THE
 778 EQUIVALENT TO ALL PATIENT ROOM CORRIDORS AND ALL COMMON AREAS UTILIZED FOR
 779 PATIENT CARE.

780
 781 (h) A QUALIFYING PROJECT WILL BE AWARDED 3 POINTS IF THE APPLICANT HAS OR
 782 PROPOSES TO DEVELOP, WITH CREDIBLE DOCUMENTATION ACCEPTABLE TO THE
 783 DEPARTMENT, A TELEHEALTH AND/OR TELEMEDICINE PROGRAM TO FACILITATE INPATIENT
 784 ADMISSION OF PSYCHIATRIC PATIENTS OR TO ASSIST IN THE DIAGNOSIS, TREATMENT OR
 785 PROVISION OF OTHER INPATIENT SUPPORT AND SERVICES NECESSARY AND APPROPRIATE
 786 FOR THE ADMISSION OR RETENTION OF A PSYCHIATRIC HOSPITAL INPATIENT WITH THE
 787 FOLLOWING FEATURES:

788 (i) THE EXISTING OR PROPOSED TELEHEALTH AND/OR TELEMEDICINE PROGRAM
 789 COMPLIES OR WILL COMPLY WITH MICHIGAN COMPILED LAWS SECTION 333.16283 TO
 790 333.16288;

791 (ii) THE PROPOSED PROJECT INCLUDES INFRASTRUCTURE NECESSARY OR
 792 APPROPRIATE FOR THE PSYCHIATRIC TELEHEALTH AND/OR TELEMEDICINE SERVICES
 793 INCLUDING HIGH-SPEED INTERNET CONNECTIONS, INTEGRATION OF THE TELEHEALTH
 794 AND/OR TELEMEDICINE SERVICES WITH THE ELECTRONIC HEALTH RECORD OF THE
 795 PSYCHIATRIC INPATIENT, AND PHYSICAL PLANT DESIGN ELEMENTS NECESSARY OR
 796 APPROPRIATE FOR COMPLIANCE WITH APPLICABLE STATE AND FEDERAL PRIVACY LAWS;
 797 AND

798 (iii) THE APPLICANT HAS OR PROPOSES A PLAN TO FACILITATE WORKFORCE TRAINING
 799 AND TECHNICAL ASSISTANCE TO SUPPORT OPERATION OF THE TELEHEALTH AND/OR
 800 TELEMEDICINE PROGRAM.

801
 802 (i) A QUALIFYING PROJECT WILL BE AWARDED 3 POINTS IF THE APPLICANT ALREADY
 803 HAS, OR THE PROPOSED PROJECT WILL HAVE COMPREHENSIVE PSYCHIATRIC CRISIS
 804 SERVICES FOR THE PURPOSE OF DIVERTING PATIENTS TO A LOWER ACUITY SETTING
 805 INCLUDING ANY OF THE FOLLOWING: 24-HOUR PATIENT/FAMILY CRISIS TELEPHONE LINES,
 806 WALK-IN CRISIS SERVICES, OR A CRISIS STABILIZATION UNIT. AN APPLICANT SHALL SUBMIT
 807 SITE PLANS OR CONTRACTS TO DEMONSTRATE IT CURRENTLY HAS OR WILL INCLUDE ANY OF
 808 THESE SERVICES AS PART OF ITS PROPOSED PROJECT.

809 (j) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE GEOGRAPHIC
 810 LOCATION OF THE PROJECT IN ACCORDANCE WITH THE FOLLOWING TABLE. FOR PURPOSES
 811 OF EVALUATION, THIS CRITERIA WILL CONSIDER THE PROXIMITY OF THE PROPOSED
 812 PROJECT TO EXISTING BEDS OF THE SAME TYPE AS THOSE PROPOSED IN THE APPLICATION,
 813 INCLUDING BOTH OPERATING AND CON-APPROVED BUT NOT YET OPERATIONAL BEDS ON
 814 THE DATE OF APPLICATION.

PROXIMITY TO EXISTING BEDS OF THE SAME TYPE	POINTS AWARDED
LESS THAN 30 MILES	0
BETWEEN 30 AND 60 MILES	1
BETWEEN 60 AND 90 MILES	2

GREATER THAN 90 MILES

3

FOR PURPOSES OF SCORING THIS CRITERIA, THE APPLICANT SHALL SUBMIT DATA USING THE MICHIGAN STATE UNIVERSITY GEOCODER LOCATED ON THE DEPARTMENT'S WEBSITE AND THE DEPARTMENT'S INVENTORY OF BEDS AT THE TIME THE APPLICATION IS DEEMED SUBMITTED.

(k) A QUALIFYING PROJECT THAT PROPOSES BEDS UNDER THE ADDENDUM FOR SPECIAL POPULATION GROUPS, SECTION 7 FOR HIGH ACUITY PSYCHIATRIC PATIENTS, WILL BE AWARDED BASED ON THE PERCENTAGE OF BEDS LOCATED IN PRIVATE ROOMS PROPOSED AS PART OF THE PROJECT, SUPPORTED BY THE FLOOR PLANS PROVIDED IN THE APPLICATION, IN ACCORDANCE WITH THE TABLE BELOW.

PERCENTAGE OF HIGH ACUITY BEDS LOCATED IN PRIVATE ROOMS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENTAGE OF HIGH ACUITY BEDS LOCATED IN PRIVATE ROOMS	7 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF BEDS LOCATED IN PRIVATE ROOMS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF BEDS LOCATED IN PRIVATE ROOMS, THEN MULTIPLIED BY 7
EXAMPLE BELOW	
THE APPLICANT WITH THE HIGHEST PERCENTAGE OF BEDS IN PRIVATE ROOMS IS 90.0%	7 POINTS
APPLICANT WITH 80.0% OF BEDS IN PRIVATE ROOMS	$(.800 / .900) \times 7 = 6 \text{ POINTS}$
APPLICANT WITH 70.5% BEDS IN PRIVATE ROOMS	$(.750 / .900) \times 7 = 5 \text{ POINTS}$

PERCENTAGES OF BEDS IN PRIVATE ROOMS SHALL BE ROUNDED TO THE NEAREST 1/1000 AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(4) Submission of conflicting information in this section may result in a lower point award. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from the conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section 4312. Requirements for approval -- all applicants

Sec. 4312. (1) 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.

(2) The applicant certifies all outstanding debt obligations owed to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.

850 (3) The applicant certifies that the health facility for the proposed project has not been cited for a
 851 state or federal code deficiency within the 12 months prior to the submission of the application. If a code
 852 deficiency has been issued, then the applicant shall certify that a plan of correction for cited state or
 853 federal code deficiencies at the health facility has been submitted and approved by the Bureau of Health
 854 Systems within the Department or, as applicable, the Centers for Medicare and Medicaid Services. If
 855 code deficiencies include any unresolved deficiencies still outstanding with the Department or the Centers
 856 for Medicare and Medicaid Services that are the basis for the denial, suspension, or revocation of an
 857 applicant's health facility license, poses an immediate jeopardy to the health and safety of patients, or
 858 meets a federal conditional deficiency level, the proposed project cannot be approved without approval
 859 from the Bureau of Health Systems.

860
 861 **Section 4413. Project delivery requirements - terms of approval for all applicants**

862
 863 **Sec. 4413. An applicant shall agree that, if approved, the project shall be delivered in compliance with**
 864 **the following terms of CON approval:**

865
 866 (1) Compliance with these standards.

867 (2) Compliance with the following applicable quality assurance standards:

868 (a) The proposed licensed psychiatric beds shall be operated in a manner that is appropriate for a
 869 population with the ethnic, socioeconomic, and demographic characteristics including the developmental
 870 stage of the population to be served.

871 (b) The applicant shall establish procedures to care for patients who are disruptive, combative, or
 872 suicidal and for those awaiting commitment hearings, and the applicant shall establish a procedure for
 873 obtaining physician certification necessary to seek an order for involuntary treatment for those persons
 874 that, in the judgment of the professional staff, meet the Mental Health Code criteria for involuntary
 875 treatment.

876 (c) The applicant shall develop a standard procedure for determining, at the time the patient first
 877 presents himself or herself for admission or within 24 hours after admission, whether an alternative to
 878 inpatient psychiatric treatment is appropriate.

879 (d) The inpatient psychiatric hospital or unit shall provide clinical, administrative, and support
 880 services that will be at a level sufficient to accommodate patient needs and volume, and will be provided
 881 seven days a week to assure continuity of services and the capacity to deal with emergency admissions.

882
 883 (3) Compliance with the following access to care requirements:

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

886 (b) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

887 (i) not deny acute inpatient mental health services to any individual based on ability to pay, source of
 888 payment, age, race, handicap, national origin, religion, gender, sexual orientation or commitment status;

889 (ii) provide acute inpatient mental health services to any individual based on clinical indications of
 890 need for the services; and

891 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
 892 source provided annually. Compliance with selective contracting requirements shall not be construed as
 893 a violation of this term.

894 **(iv) ADOPT AND MAINTAIN A POLICY THAT INCLUDES A PLAN FOR PROVIDING INPATIENT**
 895 **PSYCHIATRIC SERVICES TO EXISTING OR POTENTIAL PSYCHIATRIC INPATIENTS WHOSE**
 896 **LENGTH OF STAY AT APPLICANT'S PSYCHIATRIC HOSPITAL EXCEEDS, OR MAY EXCEED, 45**
 897 **CONSECUTIVE INPATIENT DAYS IN ACCORDANCE WITH APPLICABLE MEDICARE, MEDICAID,**
 898 **CMH, OR OTHER THIRD-PARTY PAYOR MEDICAL NECESSITY CRITERIA FOR INPATIENT**
 899 **PSYCHIATRIC ADMISSIONS AND AN APPROPRIATE CARE PLAN.**

900
 901 (4) Compliance with the following monitoring and reporting requirements:

902 (a) The average occupancy rate for all licensed beds at the psychiatric hospital or unit shall be at
 903 least 60 percent (%) for adult beds and 40 percent (%) for child/adolescent beds for the second 12
 904 months of operation, and annually thereafter.

905 (i) Calculate average occupancy rate for adult beds as follows:

906 (A) Add the number of adult patient days of care to the number of child/adolescent patient days of
 907 care provided in the flex beds; divide this number by the adult bed days, then multiply the result by 100.

908 (ii) Calculate average occupancy rate for child/adolescent beds as follows:

909 (A) Subtract the number of child/adolescent patient days of care provided in the flex beds from the
 910 number of child adolescent patient days of care; divide this number by the child/adolescent bed days,
 911 then multiply the result by 100.

912 (b) Flex beds approved under section 40-9 shall be counted as existing adult inpatient psychiatric
 913 beds.

914 (c) After the second 12 months of operation, if the average occupancy rate is below 60% for adult
 915 beds or 40% for child/adolescent beds, the number of beds shall be reduced to achieve a minimum of
 916 60% average annual occupancy for adult beds or 40% annual average occupancy for child/adolescent
 917 beds for the revised licensed bed complement. However, the psychiatric hospital or unit shall not be
 918 reduced to less than 10 beds.

919 (d) The applicant shall participate in a data collection network established and administered by the
 920 Department or its designee. The data may include, but is not limited to: annual budget and cost
 921 information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as
 922 well as the volume of care provided to patients from all payor sources. The applicant shall provide the
 923 required data on a separate basis for each licensed site; in a format established by the Department; and
 924 in a mutually agreed upon media. The Department may elect to verify the data through on-site review of
 925 appropriate records.

926 (e) The applicant shall provide the Department with a notice stating the date the beds or services are
 927 placed in operation and such notice shall be submitted to the Department consistent with applicable
 928 statute and promulgated rules.

929 (f) An applicant required to enter into a contract with a CMH(s) or the Department pursuant to these
 930 standards shall have in place, at the time the approved beds or services become operational, a signed
 931 contract to serve the public patient. The contract must address a single entry and exit system including
 932 discharge planning for each public patient. The contract shall specify that at least 50% or 80% of the
 933 approved beds, as required by the applicable sections of these standards, shall be allocated to the public
 934 patient, and shall specify the hospital's or unit's willingness to admit patients with an involuntary
 935 commitment status. The contract need not be funded.

936

937 (5) Compliance with this Section shall be determined by the Department based on a report submitted
 938 by the applicant and/or other information available to the Department.

939

940 (6) Nothing in this section prohibits the Department from taking compliance action under MCL
 941 333.22247.

942

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

945

946 **Section 4514. Project delivery requirements - additional terms of approval for child/adolescent**
 947 **service**

948

949 **Sec. 4514. (1)** In addition to the provisions of Section 4413, an applicant for a child/adolescent
 950 service shall agree to operate the program in compliance with the following terms of CON approval, as
 951 applicable:

952 (a) There shall be at least the following child and adolescent mental health professionals employed,
 953 either directly or by contract, by the hospital or unit, each of whom must have been involved in the
 954 delivery of child/adolescent mental health services for at least 2 years within the most recent 5 years:

- 955 (i) a child/adolescent psychiatrist;
 956 (ii) a child psychologist;
 957 (iii) a psychiatric nurse;
 958 (iv) a psychiatric social worker;
 959 (v) an occupational therapist or recreational therapist; and
 960 (b) There shall be a recipient rights officer employed by the hospital or the program.
 961 (c) The applicant shall identify a staff member(s) whose assigned responsibilities include discharge
 962 planning and liaison activities with the home school district(s).
 963 (d) There shall be the following minimum staff employed either on a full time basis or access to on a
 964 consulting basis as needed:
 965 (i) a pediatrician;
 966 (ii) a child neurologist;
 967 (iii) a neuropsychologist;
 968 (iv) a speech and language therapist;
 969 (v) an audiologist; and
 970 (vi) a dietician.
 971 (e) A child/adolescent service shall have the capability to determine that each inpatient admission is
 972 the appropriate treatment alternative consistent with Section 498e of the Mental Health Code, being
 973 Section 330.1498e of the Michigan Compiled Laws.
 974 (f) The child/adolescent service shall develop and maintain a coordinated relationship with the home
 975 school district of any patient to ensure that all public education requirements are met.
 976 (g) The applicant shall demonstrate that the child/adolescent service is integrated within the
 977 continuum of mental health services available in its planning area by establishing a formal agreement with
 978 the CMH(s) serving the planning area in which the child/adolescent specialized psychiatric program is
 979 located. The agreement shall address admission and discharge planning issues which include, at a
 980 minimum, specific procedures for referrals for appropriate community services and for the exchange of
 981 information with the CMH(s), the probate court(s), the home school district, the Michigan Department of
 982 Human Services, the parent(s) or legal guardian(s) and/or the patient's attending physician.
 983
 984 (2) Compliance with this Section shall be determined by the Department based on a report submitted
 985 by the program and/or other information available to the Department.
 986
 987 (3) The agreements and assurances required by this Section shall be in the form of a certification
 988 agreed to by the applicant or its authorized agent.
 989

990 **Section 4615. Department inventory of beds**

991
 992 **Sec. 4615.** The Department shall maintain, and provide on request, a listing of the Department
 993 Inventory of Beds for each adult and child/adolescent planning area.
 994

995 **Section 4716. Planning areas**

996
 997 **Sec. 4716.** The planning areas for inpatient psychiatric beds are the geographic boundaries of the
 998 groups of counties as follows.
 999

<u>Planning Areas</u>	<u>Counties</u>
1000 1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
1001 2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
1002 3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
1003	
1004	
1005	
1006	
1007	

1008	4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo,
1009		Oceana, Ottawa
1010		
1011	5	Genesee, Lapeer, Shiawassee
1012		
1013	6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland,
1014		Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
1015		
1016	7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford,
1017		Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee,
1018		Montmorency, Otsego, Presque Isle, Roscommon, Wexford
1019		
1020	8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron,
1021		Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon,
1022		Schoolcraft
1023		
1024		

Section 4817. Effect on prior CON review standards; comparative reviews

Sec. 4817. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~September 21, 2016~~MARCH 21, 2019 and effective on ~~December 9, 2016~~MAY 24, 2019.

(2) Projects involving replacement beds, relocation of beds, flex beds under Section ~~409~~, or an increase in beds, approved pursuant to Section ~~76~~(3), are reviewed under these standards and shall not be subject to comparative review.

(3) Projects involving initiation of services or an increase in beds, approved pursuant to Section ~~65~~(1), are reviewed under these standards and shall be subject to comparative review.

APPENDIX A

**RATIO OF ADULT INPATIENT PSYCHIATRIC
BEDS PER 10,000 ADULT POPULATION**

The ratio per 10,000 adult population, for purposes of these standards, effective April 1, 2015, and until otherwise changed by the Commission, is as follows:

PLANNING AREA	ADULT BEDS PER 10,000 ADULT POPULATION
1	3.09143
2	2.40602
3	2.44460
4	2.39174
5	3.07912
6	1.75052
7	0.83839
8	2.26654
STATE	2.64279

1051
1052
1053
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1058

APPENDIX B

CON REVIEW STANDARDS
FOR CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS

The use rate per 1000 population age 0-17, for purposes of these standards, effective April 1, 2015, and until otherwise changed by the Commission, is 25.664.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

**CON REVIEW STANDARDS
FOR PSYCHIATRIC BEDS AND SERVICES
--ADDENDUM FOR SPECIAL POPULATION GROUPS**

(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; definitions

Sec. 1. (1) This addendum supplements the CON review standards for psychiatric beds and services and shall be used for determining the need for projects established to better meet the needs of special population groups within the mental health populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7 and 7-8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Psychiatric Beds and Services.

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

(4) For purposes of this addendum, the following terms are defined:

(a) "Developmental disability unit" means a unit designed for psychiatric patients (adult or child/adolescent as applicable) who have been diagnosed with a severe, chronic disability as outlined in Section 102, 42 USC 15002, of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) and its update or future guideline changes.

(b) "Geriatric psychiatric unit" means a unit designed for psychiatric patients aged 65 and over.

(c) "HIGH ACUITY PSYCHIATRIC UNIT" MEANS A DISTINCT PSYCHIATRIC UNIT FOR INDIVIDUALS WHO ARE CURRENTLY EXHIBITING THREE OR MORE TO A MODERATE DEGREE OR TWO OR MORE TO A SEVERE DEGREE OF THE FOLLOWING: CONFUSION, IRRITABILITY, BOISTEROUSNESS, POOR IMPULSE CONTROL, UNCOOPERATIVENESS, HOSTILITY, VERBAL THREATS, PHYSICAL THREATS, OR ATTACKING OBJECTS. THIS TERM ALSO INCLUDES PATIENTS WHO ARE UNWILLING OR UNABLE TO STOP ATTEMPTS AT SELF HARM OR SUICIDE OR PATIENTS WHO HAVE A HISTORY OF VIOLENCE TO SELF OR OTHERS ON AN INPATIENT PSYCHIATRIC UNIT.

(d) "Medical psychiatric unit" means a unit designed for psychiatric patients (adult or child/adolescent as applicable) who have also been diagnosed with a medical illness requiring hospitalization, e.g., patients who may be on dialysis, require wound care or need intravenous or tube feeding.

Section 2. Requirements for approval -- applicants proposing to increase psychiatric beds -- special use exceptions

Sec. 2. A project to increase psychiatric beds in a planning area which, if approved, would otherwise cause the total number of psychiatric beds in that planning area to exceed the needed psychiatric bed supply or cause an increase in an existing excess as determined under the applicable CON review standards for psychiatric beds and services, may nevertheless be approved pursuant to this addendum.

Section 3. Statewide pool for the needs of special population groups within the mental health populations

Sec. 3. (1) A statewide pool of additional psychiatric beds consists of 370-850 beds needed in the state is established to better meet the needs of special population groups within the mental health populations. The number of beds in the DEVELOPMENTAL DISABILITY, GERIATRIC AND MEDICAL

1113 ~~PSYCHIATRIC~~ pools ~~is~~ ARE based on ~~five~~ SEVEN AND A HALF percent of the statewide bed need for
 1114 psychiatric inpatient beds rounded up to the next ten WITH A MINIMUM OF 50 CHILD/ADOLESCENT
 1115 BEDS IN EACH SPECIAL POOL, AS APPLICABLE. THE NUMBER OF BEDS IN THE HIGH ACUITY
 1116 POOL IS BASED ON TEN PERCENT OF THE STATEWIDE BED NEED FOR PSYCHIATRIC
 1117 INPATIENT BEDS ROUNDED UP TO THE NEXT TEN WITH A MINIMUM OF 50 CHILD/ADOLESCENT
 1118 BEDS. Beds in the pool shall be distributed as follows and shall be reduced in accordance with
 1119 subsection (2):

1120 (a) Developmental disability beds will be allocated 440-160 adult beds and 20-50 child/adolescent
 1121 beds.

1122 (b) Geriatric psychiatric beds will be allocated 440-160 adult beds.

1123 (c) Medical psychiatric beds will be allocated 440-160 adult beds and 20-50 child/adolescent beds.

1124 (d) HIGH ACUITY PSYCHIATRIC BEDS WILL BE ALLOCATED 220 ADULT BEDS AND 50
 1125 CHILD/ADOLESCENT BEDS.

1126
 1127 (2) By setting aside these beds from the total statewide pool, the Commission's action applies only to
 1128 applicants seeking approval of psychiatric beds pursuant to sections 4, 5, 6 and 67. It does not preclude
 1129 the care of these patients in units of hospitals, psychiatric hospitals, or other health care settings in
 1130 compliance with applicable statutory or certification requirements.

1131
 1132 (3) Increases in psychiatric beds approved under this addendum for special population groups shall
 1133 not cause planning areas currently showing an unmet bed need to have that need reduced or planning
 1134 areas showing a current surplus of beds to have that surplus increased.

1135
 1136 (4) The Commission may adjust the number of beds available in the statewide pool for the needs of
 1137 special population groups within the mental health populations concurrent with the biennial recalculation
 1138 of the statewide psychiatric inpatient bed need. Modifying the number of beds available in the statewide
 1139 pool for the needs of special population groups within the mental health populations pursuant to this
 1140 section shall not require a public hearing or submittal of the standard to the Legislature and the Governor
 1141 in order to become effective.

1142
 1143 (5) BEDS APPROVED UNDER SUBSECTIONS 4, 5, 6, AND 7 SHALL NOT BE CONVERTED TO
 1144 OR UTILIZED AS GENERAL PSYCHIATRIC BEDS.

1145 1146 **Section 4. Requirements for approval for beds from the statewide pool for special population** 1147 **groups allocated to developmental disability patients**

1148
 1149 Sec. 4. The CON commission determines there is a need for beds for applications designed to
 1150 determine the efficiency and effectiveness of specialized programs for the care and treatment of
 1151 developmental disability patients as compared to serving these needs in general psychiatric unit(s).

1152
 1153 (1) An applicant proposing to begin operation of a new adult or child/adolescent psychiatric service or
 1154 add beds to an existing adult or child/adolescent psychiatric service under this section shall demonstrate
 1155 with credible documentation to the satisfaction of the Department each of the following:

1156 (a) The applicant shall submit evidence of accreditation as follows:

1157 (i) Documentation of its existing developmental disability program by the National Association for the
 1158 Dually Diagnosed (NADD) or another nationally-recognized accreditation organization for developmental
 1159 disability care and services; or

1160 (ii) within 24-months of accepting its first patient, the applicant shall obtain NADD or another
 1161 nationally-recognized accreditation organization for the developmental disability beds proposed under this
 1162 subsection.

1163 (b) The applicant proposes programs to promote a culture within the facility that is appropriate for
 1164 developmental disability patients.

1165 (c) Staff will be specially trained in treatment of developmental disability patients.

1166 (d) The proposed beds will serve only developmental disability patients.

- 1167
1168 (2) All beds approved pursuant to this subsection shall be certified for Medicaid.
1169

1170 **Section 5. Requirements for approval for beds from the statewide pool for special population**
1171 **groups allocated to geriatric psychiatric patients**
1172

1173 Sec. 5. The CON commission determines there is a need for beds for applications designed to
1174 determine the efficiency and effectiveness of specialized programs for the care and treatment of geriatric
1175 psychiatric patients as compared to serving these needs in general psychiatric unit(s).
1176

1177 (1) An applicant proposing to begin operation of a new adult psychiatric service or add beds to an
1178 existing adult psychiatric service under this section shall demonstrate with credible documentation to the
1179 satisfaction of the Department each of the following:

1180 (a) The applicant shall submit evidence of accreditation as follows:

1181 (i) Documentation of its existing geriatric psychiatric program by the Commission on Accreditation of
1182 Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for geriatric
1183 psychiatric care and services; or

1184 (ii) within 24-months of accepting its first patient, the applicant shall obtain CARF or another
1185 nationally-recognized accreditation organization for the geriatric psychiatric beds proposed under this
1186 subsection.

1187 (b) The applicant proposes programs to promote a culture within the facility that is appropriate for
1188 geriatric psychiatric patients.

1189 (c) Staff will be specially trained in treatment of geriatric psychiatric patients.

1190 (d) The proposed beds will serve only geriatric psychiatric patients.
1191

- 1192 (2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
1193

1194 **Section 6. Requirements for approval for beds from the statewide pool for special population**
1195 **groups allocated to medical psychiatric patients**
1196

1197 Sec. 6. The CON commission determines there is a need for beds for applications designed to
1198 determine the efficiency and effectiveness of specialized programs for the care and treatment of medical
1199 psychiatric patients as compared to serving these needs in general psychiatric unit(s).
1200

1201 (1) An applicant proposing to begin operation of a new adult or child/adolescent psychiatric service or
1202 add beds to an existing adult or child/adolescent psychiatric service under this section shall demonstrate
1203 with credible documentation to the satisfaction of the Department each of the following:

1204 (a) The beds will be operated as part of a specialized program exclusively for adult or
1205 child/adolescent medical psychiatric patients, as applicable, within **ONE OF THE FOLLOWING**
1206 **SETTINGS:**

1207 (i) a licensed hospital licensed under part 215 of the code, **OR**

1208 (ii) **AN ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE OR UNIT WITH A WRITTEN**
1209 **COLLABORATIVE AGREEMENT WITH A LICENSED HOSPITAL LICENSED UNDER PART 215 OF**
1210 **THE CODE THAT IS PROVIDED AS PART OF THE APPLICATION AND INCLUDES ALL OF THE**
1211 **FOLLOWING:**

1212 **(A) PROCEDURES FOR JOINT CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR**
1213 **PHYSICIANS APPROVED TO TREAT MEDICAL PSYCHIATRIC PATIENTS**

1214 **(B) PROVISIONS FOR REGULARLY HELD JOINT PSYCHIATRIC AND MEDICAL**
1215 **CONFERENCES TO INCLUDE REVIEW OF ALL MEDICAL PSYCHIATRIC CASES.**

1216 **(C) A MECHANISM TO PROVIDE FOR APPROPRIATE TRANSFERS BETWEEN FACILITIES AND**
1217 **AN AGREED UPON PLAN FOR PROMPT CARE.**

1218 **(D) CONSULTATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND**
1219 **POLICIES AND PROCEDURES FOR THE PROVISION OF MEDICAL PSYCHIATRIC TREATMENT.**

1220 (b) The applicant shall submit evidence of accreditation as follows:

- 1221 (i) Documentation of its existing medical psychiatric program by CARF or another nationally-
 1222 recognized accreditation organization for medical psychiatric care and services; or
 1223 (ii) within 24-months of accepting its first patient, the applicant shall obtain CARF or another
 1224 nationally-recognized accreditation organization for the medical psychiatric beds proposed under this
 1225 subsection.
 1226 (c) The applicant proposes programs to promote a culture within the facility that is appropriate for
 1227 medical psychiatric patients.
 1228 (d) Staff, INCLUDING CONTRACTED STAFF, will be specially trained in treatment of medical
 1229 psychiatric patients.
 1230 (e) The proposed beds will serve only medical psychiatric patients.
 1231
 1232 (2) All beds approved pursuant to this subsection shall be certified for Medicaid.
 1233

1234 **SECTION 7. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR**
 1235 **SPECIAL POPULATION GROUPS ALLOCATED TO HIGH ACUITY PSYCHIATRIC PATIENTS**
 1236

1237 **SEC 7. THE CON COMMISSION DETERMINES THERE IS A NEED FOR BEDS FOR**
 1238 **APPLICATIONS DESIGNED TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF**
 1239 **SPECIALIZED PROGRAMS FOR THE CARE AND TREATMENT OF HIGH ACUITY PSYCHIATRIC**
 1240 **PATIENTS AS COMPARED TO SERVING THESE NEEDS IN A GENERAL PSYCHIATRIC UNIT(S).**
 1241

1242 **(1) AN APPLICANT PROPOSING TO BEGIN OPERATIONS OF A NEW ADULT OR**
 1243 **CHILD/ADOLESCENT PSYCHIATRIC SERVICES OR ADD BEDS TO AN EXISTING ADULT OR**
 1244 **CHILD/ADOLESCENT PSYCHIATRIC SERVICE UNDER THIS SECTION SHALL DEMONSTRATE**
 1245 **WITH CREDIBLE DOCUMENTATION TO THE SATISFACTION OF THE DEPARTMENT EACH OF THE**
 1246 **FOLLOWING:**

1247 **(a) THE BEDS SHALL BE OPERATED AS PART OF A SPECIALIZED PROGRAM EXCLUSIVELY**
 1248 **FOR ADULT OR CHILD/ADOLESCENT PATIENTS CLASSIFIED AS HIGH ACUITY.**

1249 **(b) THE APPLICANT SHALL SUBMIT EVIDENCE WITH CREDIBLE DOCUMENTATION**
 1250 **ACCEPTABLE TO THE DEPARTMENT OF THE FOLLOWING:**

1251 **(i) THE PROPOSED UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND**
 1252 **SHALL INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE**
 1253 **JOINT COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES**
 1254 **THROUGHOUT THE ENTIRE UNIT.**

1255 **(ii) THE PROPOSED UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO**
 1256 **MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.**

1257 **(iii) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF**
 1258 **HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-**
 1259 **ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE**
 1260 **TRAINING OR SIMILAR PROGRAMS.**

1261 **(iv) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT**
 1262 **OF AGITATED OR AGGRESSIVE PATIENTS**

1263 **(c) THE PROPOSED BEDS WILL SERVE ONLY HIGH ACUITY PSYCHIATRIC PATIENTS.**
 1264

1265 **(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR**
 1266 **MEDICAID.**
 1267

1268 **Section 78. Acquisition of psychiatric beds approved pursuant to this addendum**
 1269

1270 **Sec. 78. (1) An applicant proposing to acquire psychiatric beds from the statewide pool for special**
 1271 **population groups allocated to developmental disability shall meet the following:**

1272 (a) The applicant shall submit evidence of accreditation of the existing developmental disability
 1273 program by the National Association for the Dually Diagnosed (NADD) or another nationally-recognized
 1274 accreditation organization for developmental disability care and services.

1275 (b) Within 24-months of accepting its first patient, the applicant shall obtain NADD or another
 1276 nationally-recognized accreditation organization for the developmental disability beds proposed under this
 1277 subsection.

1278 (c) The applicant proposes programs to promote a culture within the facility that is appropriate for
 1279 developmental disability patients.

1280 (d) Staff will be specially trained in treatment of developmental disability patients.

1281 (e) The proposed beds will serve only developmental disability patients.

1282 (f) All beds approved pursuant to this subsection shall be certified for Medicaid.

1283

1284 (2) An applicant proposing to acquire psychiatric beds from the statewide pool for special population
 1285 groups allocated to geriatric psychiatric shall meet the following:

1286 (a) The applicant shall submit evidence of accreditation of the existing geriatric psychiatric program
 1287 by CARF or another nationally-recognized accreditation organization for geriatric psychiatric care and
 1288 services.

1289 (b) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another
 1290 nationally-recognized accreditation organization for the geriatric psychiatric beds proposed under this
 1291 subsection.

1292 (c) The applicant proposes programs to promote a culture within the facility that is appropriate for
 1293 geriatric psychiatric patients.

1294 (d) Staff will be specially trained in treatment of geriatric psychiatric patients.

1295 (e) The proposed beds will serve only geriatric psychiatric patients.

1296 (f) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

1297

1298 (3) An applicant proposing to acquire psychiatric beds from the statewide pool for special population
 1299 groups allocated to medical psychiatric shall meet the following:

1300 (a) The applicant shall submit evidence of accreditation of the existing medical psychiatric program
 1301 by CARF or another nationally-recognized accreditation organization for medical psychiatric care and
 1302 services.

1303 (b) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another
 1304 nationally-recognized accreditation organization for the medical psychiatric beds proposed under this
 1305 subsection.

1306 (c) The applicant proposes programs to promote a culture within the facility that is appropriate for
 1307 medical psychiatric patients.

1308 (d) Staff will be specially trained in treatment of medical psychiatric patients.

1309 (e) The proposed beds will serve only medical psychiatric patients.

1310 (f) All beds approved pursuant to this subsection shall be certified for Medicaid.

1311

1312 **(4) AN APPLICANT PROPOSING TO ACQUIRE PSYCHIATRIC BEDS FROM THE STATEWIDE**
 1313 **POOL FOR SPECIAL POPULATIONS ALLOCATED TO HIGH ACUITY PSYCHIATRY SHALL MEET**
 1314 **THE FOLLOWING:**

1315 **(a) THE PROPOSED UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND SHALL**
 1316 **INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE JOINT**
 1317 **COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THROUGHOUT**
 1318 **THE ENTIRE UNIT.**

1319 **(b) THE PROPOSED UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO MINIMIZE**
 1320 **NOISE AND LIGHT REFLECTIONS TO PROMOTE SPATIAL ORIENTATION.**

1321 **(c) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF**
 1322 **HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-**
 1323 **ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE**
 1324 **TRAINING OR SIMILAR PROGRAMS.**

1325 **(d) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT OF**
 1326 **AGITATED OR AGGRESSIVE PATIENTS.**

1327 **(e) THE PROPOSED BEDS WILL SERVE ONLY HIGH ACUITY PSYCHIATRIC PATIENTS.**

1328 (f) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR
 1329 MEDICAID.

1330
 1331 **Section 89. Project delivery requirements -- terms of approval for all applicants seeking approval**
 1332 **under section 3(1) of this addendum**

1333
 1334 **Sec. 89. (1) An applicant shall agree that if approved, the services shall be delivered in compliance**
 1335 **with the terms of approval required by the CON Review Standards for Psychiatric Beds and Services.**

1336
 1337 (2) An applicant for beds from the statewide pool for special population groups allocated to
 1338 developmental disability patients shall agree that, if approved, all beds approved pursuant to that
 1339 subsection shall be operated in accordance with the following terms of CON approval:

1340 (a) The applicant shall document, at the end of the third year following initiation of beds approved an
 1341 annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the
 1342 **applicant shall reduce beds to a number of beds necessary to result in aN 80 percent average annual**
 1343 **occupancy for the third full year of operation and annually thereafter.** The number of beds reduced shall
 1344 revert to the total statewide pool established for developmental disability beds.

1345 (b) An applicant shall staff the proposed unit for developmental disability patients with employees
 1346 that have been trained in the care and treatment of such individuals.

1347 (c) An applicant shall maintain NADD certification or another nationally-recognized accreditation
 1348 organization for developmental disability care and services.

1349 (d) An applicant shall establish and maintain written policies and procedures for each of the
 1350 following:

1351 (i) Patient admission criteria that describe minimum and maximum characteristics for patients
 1352 appropriate for admission to the developmental disability unit.

1353 (ii) The transfer of patients requiring care at other health care facilities.

1354 (iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment
 1355 plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

1356 (e) If the specialized program is being added to an existing adult or child/adolescent psychiatric
 1357 service, then the existing licensed adult or child/adolescent psychiatric service, as applicable, shall
 1358 **maintain the volume requirements outlined in Section 44-13 of the CON Review Standards for Psychiatric**
 1359 **Beds and Services.**

1360 (f) The developmental disability unit shall have a day/dining area within, or immediately adjacent to,
 1361 the unit(s), which is solely for the use of developmental disability patients.

1362 (g) The developmental disability unit shall have direct access to a secure outdoor or indoor area at
 1363 the facility appropriate for supervised activity.

1364 (h) The applicant shall maintain programs to promote a culture within the facility that is appropriate
 1365 for developmental disability patients.

1366
 1367 (3) An applicant for beds from the statewide pool for special population groups allocated to geriatric
 1368 psychiatric patients shall agree that if approved, all beds approved pursuant to that subsection shall be
 1369 operated in accordance with the following terms of CON approval:

1370 (a) The applicant shall document, at the end of the third year following initiation of beds approved an
 1371 annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the
 1372 **applicant shall reduce beds to a number of beds necessary to result in aN 80 percent average annual**
 1373 **occupancy for the third full year of operation and annually thereafter.** The number of beds reduced shall
 1374 revert to the total statewide pool established for geriatric psychiatric beds.

1375 (b) An applicant shall staff the proposed unit for geriatric psychiatric patients with employees that
 1376 have been trained in the care and treatment of such individuals.

1377 (c) An applicant shall maintain CARF certification or another nationally-recognized accreditation
 1378 organization for geriatric psychiatric care and services.

1379 (d) An applicant shall establish and maintain written policies and procedures for each of the
 1380 following:

- 1381 (i) Patient admission criteria that describe minimum and maximum characteristics for patients
 1382 appropriate for admission to the geriatric psychiatric unit.
- 1383 (ii) The transfer of patients requiring care at other health care facilities.
- 1384 (iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment
 1385 plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.
- 1386 (e) If the specialized program is being added to an existing adult licensed psychiatric service, then
 1387 the existing licensed psychiatric service shall maintain the volume requirements outlined in Section 44-13
 1388 of the CON Review Standards for Psychiatric Beds and Services.
- 1389 (f) The geriatric psychiatric unit shall have a day/dining area within, or immediately adjacent to, the
 1390 unit(s), which is solely for the use of geriatric psychiatric patients.
- 1391 (g) The geriatric psychiatric unit shall have direct access to a secure outdoor or indoor area at the
 1392 facility appropriate for supervised activity.
- 1393 (h) The applicant shall maintain programs to promote a culture within the facility that is appropriate
 1394 for geriatric psychiatric patients.

1395
 1396 (4) An applicant for beds from the statewide pool for special population groups allocated to medical
 1397 psychiatric patients shall agree that, if approved, all beds approved pursuant to that subsection shall be
 1398 operated in accordance with the following CON terms of approval.

1399 (a) The applicant shall document, at the end of the third year following initiation of beds approved an
 1400 annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the
 1401 applicant shall reduce beds to a number of beds necessary to result in a 80 percent average annual
 1402 occupancy for the third full year of operation and annually thereafter. The number of beds reduced shall
 1403 revert to the total statewide pool established for medical psychiatric beds.

1404 (b) An applicant shall staff the proposed unit for medical psychiatric patients with employees that
 1405 have been trained in the care and treatment of such individuals.

1406 (c) An applicant shall maintain CARF certification or another nationally-recognized accreditation
 1407 organization for medical psychiatric care and services.

1408 (d) An applicant shall establish and maintain written policies and procedures for each of the
 1409 following:

1410 (i) Patient admission criteria that describe minimum and maximum characteristics for patients
 1411 appropriate for admission to the medical psychiatric unit.

1412 (ii) The transfer of patients requiring care at other health care facilities.

1413 (iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment
 1414 plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

1415 (e) If the specialized program is being added to an existing licensed adult or child/adolescent
 1416 psychiatric service, then the existing adult or child/adolescent psychiatric service, as applicable, shall
 1417 maintain the volume requirements outlined in Section 44-13 of the CON Review Standards for Psychiatric
 1418 Beds and Services.

1419 (f) The medical psychiatric unit shall have a day/dining area within, or immediately adjacent to, the
 1420 unit(s), which is solely for the use of medical psychiatric patients.

1421 (g) The medical psychiatric unit shall have direct access to a secure outdoor or indoor area at the
 1422 facility appropriate for supervised activity.

1423 (h) The applicant shall maintain programs to promote a culture within the facility that is appropriate
 1424 for medical psychiatric patients.

1425
 1426 (5) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION
 1427 GROUPS ALLOCATED TO HIGH ACUITY PSYCHIATRIC PATIENTS SHALL AGREE THAT, IF
 1428 APPROVED, ALL BEDS APPROVED PURSUANT TO THAT SUBSECTION SHALL BE OPERATED IN
 1429 ACCORDANCE WITH THE FOLLOWING TERMS OF CON APPROVAL:

1430 (a) THE APPLICANT SHALL DOCUMENT, AT THE END OF THE THIRD YEAR FOLLOWING
 1431 INITIATION OF BEDS APPROVED, AND THEREAFTER, AN ANNUAL AVERAGE OCCUPANCY RATE
 1432 OF 80 PERCENT OR MORE. IF THIS OCCUPANCY RATE HAS NOT BEEN MET, THE APPLICANT
 1433 SHALL REDUCE BEDS TO A NUMBER OF BEDS NECESSARY TO RESULT IN AN 80 PERCENT

1434 AVERAGE ANNUAL OCCUPANCY FOR THE THIRD FULL YEAR OF OPERATION AND ANNUALLY
 1435 THEREAFTER. THE NUMBER OF BEDS REDUCED SHALL REVERT TO THE TOTAL STATEWIDE
 1436 POOL ESTABLISHED FOR HIGH ACUITY PSYCHIATRIC PATIENTS.

1437 (b) THE HIGH ACUITY UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND SHALL
 1438 INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE JOINT
 1439 COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THROUGHOUT
 1440 THE ENTIRE UNIT.

1441 (c) THE HIGH ACUITY UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO MINIMIZE
 1442 NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

1443 (d) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF
 1444 HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-
 1445 ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE
 1446 TRAINING OR SIMILAR PROGRAMS.

1447 (e) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT OF
 1448 AGITATED OR AGGRESSIVE PATIENTS.

1449 (f) THE HIGH ACUITY UNIT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND
 1450 PROCEDURES FOR EACH OF THE FOLLOWING:

1451 (i) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM
 1452 CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE UNIT FOR HIGH
 1453 ACUITY PATIENTS.

1454 (ii) QUALITY ASSURANCE AND ASSESSMENT PROGRAM TO ASSURE THAT SERVICES
 1455 FURNISHED TO HIGH ACUITY PATIENTS MEET PROFESSIONALLY RECOGNIZED STANDARDS OF
 1456 HEALTH CARE FOR PROVIDERS OF SUCH SERVICES AND THAT SUCH SERVICES WERE
 1457 REASONABLE AND MEDICALLY APPROPRIATE TO THE CLINICAL CONDITION OF THE HIGH
 1458 ACUITY PATIENT RECEIVING SUCH SERVICES.

1459 (iii) ORIENTATION AND ANNUAL EDUCATION/COMPETENCIES FOR ALL STAFF, WHICH SHALL
 1460 INCLUDE CARE GUIDELINES, SPECIALIZED COMMUNICATION AND PATIENT SAFETY.

1461 (g) IF THE SPECIALIZED PROGRAM IS BEING ADDED TO AN EXISTING LICENSED ADULT OR
 1462 CHILD/ADOLESCENT PSYCHIATRIC SERVICE, THEN THE EXISTING ADULT OR
 1463 CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS APPLICABLE, SHALL MAINTAIN THE VOLUME
 1464 REQUIREMENTS OUTLINED IN SECTION 13 OF THE CON REVIEW STANDARDS FOR
 1465 PSYCHIATRIC BEDS AND SERVICES.

1467 **Section 910. Comparative reviews, effect on prior CON review standards**

1468
 1469 **Sec. 910. (1)** Projects proposed under Section 4 shall be considered a distinct category and shall be
 1470 subject to comparative review on a statewide basis.

1471
 1472 (2) Projects proposed under Section 5 shall be considered a distinct category and shall be subject to
 1473 comparative review on a statewide basis.

1474
 1475 (3) Projects proposed under Section 6 shall be considered a distinct category and shall be subject to
 1476 comparative review on a statewide basis.

1477
 1478 **(4) PROJECTS PROPOSED UNDER SECTION 7 SHALL BE CONSIDERED A DISTINCT**
 1479 **CATEGORY AND SHALL BE SUBJECT TO COMPARATIVE REVIEW ON A STATEWIDE BASIS.**

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

Date: August 8, 2019

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 (UEWSL) Services/Units Standards

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 UEWSL Services/Units Standards at its June 13, 2019 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed UEWSL Services/Units Standards on July 25, 2019. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from one individual.

Written Testimony:

1.) Anne Mitchell, Private Citizen

- Supports requiring performance reporting related to outcomes and costs.

Department Recommendation:

The Department supports the language as presented at the June 13, 2019 CON Commission meeting.

MICHIGAN DEPARTMENT OF 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 Health and Human Services (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.

- 56 (o) "Region" means the geographic areas set forth in Appendix B.
- 57 (p) "Renewal of a lease" means extending the effective period of a lease for an existing UESWL unit
58 that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a
59 change in the parties to the lease.
- 60 (q) "Retreatment" means a UESWL procedure performed on the same side of the same patient
61 within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of
62 a mobile service, the term includes a retreatment performed at a different host site if the initial treatment
63 was performed by the same service.
- 64 (r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the
65 ureter by means of an endoscope that may or may not include laser technology.
- 66 (s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal
67 of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized
68 into sand-like particles, which then may be passed through the urinary tract.
- 69 (t) "UESWL service" means either the CON-approved utilization of a UESWL unit(s) at one site in
70 the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
- 71 (u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL
72 procedure.
- 73
- 74 (2) The definitions in Part 222 shall apply to these standards.
- 75

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

77

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

82

- 83 (1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
- 84 (a) The capability to provide complicated stone disease treatment on-site.
- 85 (b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
- 86 (c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of
87 the following:
- 88 (i) On-call availability of an anesthesiologist and a surgeon.
- 89 (ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
- 90 (iii) Either on-site or through a contractual agreement with another health facility, IV supplies and
91 materials for infusions and medications, blood and blood products, and pharmaceuticals, including
92 vasopressor medications, antibiotics, and fluids and solutions.
- 93 (iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator,
94 general radiography and fluoroscopy, cystoscopy, and laboratory services.
- 95 (v) On-site crash cart.
- 96 (vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a
97 cardiac intensive care unit.
- 98 (vii) Either on-site or through a contractual agreement with another health facility, a 23-hour holding
99 unit.
- 100
- 101 (2) An applicant proposing to initiate a fixed UESWL service that meets the following requirements
102 shall not be required to be in compliance with subsection (1)(b):
- 103 (a) The applicant hospital is currently an existing mobile UESWL host site.
- 104 (b) The applicant hospital has performed an average of at least 500 procedures annually for the past
105 three years prior to submitting an application.
- 106 (c) The applicant hospital operates an emergency room that provides 24-hour emergency care
107 services and at least 80,000 visits within the most recent 12-month period for which data, verifiable by the
108 Department, is available.
- 109 (d) The applicant hospital shall install and operate the fixed UESWL unit at the same site as the
110 existing host site.

111 (e) The applicant hospital shall cease operation as a host site and not become a host site for at least
 112 12 months from the date the fixed service becomes operational.

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

115
 116 Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit,
 117 other than an upgrade, proposed by an applicant that results in that applicant operating the same number
 118 of UESWL units before and after the project completion. The term does not include an upgrade of an
 119 existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL
 120 unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s)
 121 from the existing site to a different site, OR a change in the geographic location of an existing fixed
 122 UESWL service and its unit(s) from an existing site to a different site.

123
 124 (1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that
 125 involves a capital expenditure of \$125,000 or less in any consecutive 24-month period.

126
 127 (2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate one or more of
 128 the following:

129 (a) The existing equipment clearly poses a threat to the safety of the public.

130 (b) The proposed replacement UESWL unit offers technological improvements that enhance quality
 131 of care, increase efficiency, or reduce operating costs and patient charges.

132 (c) The existing equipment is fully depreciated according to generally accepted accounting principles.

133
 134 (3) An applicant proposing to replace 1 existing fixed UESWL unit with 1 mobile UESWL unit shall
 135 demonstrate that the proposed project meets all of the following:

136 (a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at
 137 **least 1,000 UESWL procedures per MOBILE unit AND 500 PER FIXED UNIT** during the most recent
 138 continuous 12-month period for which the Department has verifiable data.

139 (b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the
 140 region in which the fixed UESWL unit proposed to be replaced is located currently.

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

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

146 (ii) All sites that receive UESWL services from an existing UESWL service and propose to receive
 147 UESWL services from the proposed mobile unit and that are located in the region identified in subsection
 148 (c).

149 (d) A separate application from each host site is filed at the same time the application to replace a
 150 fixed unit is submitted to the Department.

151 (e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually
 152 pursuant to the methodology set forth in Section 10.

153
 154 (4) An applicant proposing to replace an existing fixed UESWL service and its unit(s) to a new site
 155 shall demonstrate that the proposed project meets all of the following:

156 (a) The UESWL service to be replaced has been in operation for at least 36 months as of the date an
 157 application is submitted to the Department unless the applicant meets the requirement in subsection (d)(i)
 158 or (ii).

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

160 (c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site
 161 of the UESWL service to be replaced.

162 **(d) The UESWL service and its unit(s) to be replaced performed an average of at least 4,000,500**
 163 **procedures per unit in the most recent 12-month period for which the Department has verifiable data**
 164 **unless one of the following requirements are met:**

165 (i) the owner of the building where the site is located has incurred a filing for bankruptcy under
166 chapter 7 within the last three years;

167 (ii) the ownership of the building where the site is located has changed within 24 months of the date
168 of the service being operational; or

169 (iii) the UESWL service being replaced is part of the replacement of an entire hospital to a new
170 geographic site and has only one (1) UESWL unit.

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

173
174 (5) An applicant proposing to replace a fixed UESWL unit(s) of an existing UESWL service **TO A**
175 **NEW SITE** shall demonstrate that the proposed project meets all of the following:

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

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

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

181 (d) Each existing UESWL unit(s) at the service from which a unit is to be replaced performed at least
182 an average of 4,0500 procedures per fixed unit in the most recent 12-month period for which the
183 Department has verifiable data.

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

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

188
189 (6) Equipment that is replaced shall be removed from service and disposed of or rendered
190 considerably inoperable on or before the date that the replacement equipment becomes operational.

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

192
193 Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing
194 UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile,
195 unless otherwise specified, shall demonstrate the following:

196
197 (1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic
198 location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures
199 per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In
200 computing this average, the Department will divide the total number of UESWL procedures performed by
201 the applicant's total number of UESWL units, including both operational and approved but not operational
202 fixed and mobile UESWL units.

203
204 (2) The applicant shall project an average of at least 1,000 procedures for each existing and
205 proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section
206 10 of these standards for the second 12-month period after initiation of operation of each additional
207 UESWL unit whether fixed or mobile.

208
209 (3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the
210 existing or revised contracts between the central service coordinator and each host site(s) that includes
211 the same stipulations as specified in Section 7(1)(c).

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

213
214 Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining
215 possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by
216 purchase, lease, donation, or other comparable arrangement.

220 (1) The applicant shall not be required to be in compliance with the volume requirement applicable to
 221 the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:

222 (a) It is the first acquisition of the existing fixed or mobile UESWL service for which a final decision
 223 has not been issued after May 2, 1998.

224 (b) The existing fixed or mobile UESWL service is owned by, is under common control of, or has a
 225 common parent as the applicant, and the UESWL service shall remain at the same site.

226
 227 (2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except
 228 an application approved pursuant to subsection (1), an applicant shall be required to demonstrate that the
 229 UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per
 230 **MOBILE unit AND 500 PER FIXED UNIT in the most recent 12-month period for which the Department**
 231 **has** verifiable data.

232
 233 (3) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing
 234 UESWL service shall demonstrate that the proposed project meets all of the following:

235 (a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an
 236 applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average
 237 **of at least 1,000 procedures per MOBILE unit AND 500 PROCEDURES PER FIXED UNIT in the most**
 238 recent 12-month period for which the Department has verifiable data.

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

240
 241 (4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set
 242 forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is
 243 acquired, and annually thereafter.

244 **Section 7. Additional requirements for approval for mobile UESWL services**

245
 246
 247 Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall
 248 demonstrate that it meets all of the following:

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

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

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

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

259 **(c) A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH**
 260 **PROPOSED HOST SITE.**

261
 262 (2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that
 263 proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL
 264 service and its unit(s) operates predominantly outside of Michigan and all of the following requirements
 265 are met:

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

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

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

271
 272 (3) A central service coordinator proposing to add, or an applicant proposing to become, a host site
 273 **on either an existing or a proposed mobile UESWL service shall demonstrate that it meets ALL OF the**
 274 **FOLLOWING:**

275 (a) THE requirements of Section 3(1)(C).

276 (b) THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY
 277 SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE UESWL
 278 SERVICE AND ITS UNIT(S) SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE
 279 CENTRAL SERVICE COORDINATOR OR THE APPLICANT HOST SITE.

280 Section 8. Requirements for Medicaid participation

281
 282
 283 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
 284 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
 285 to the Department within six (6) months from the offering of service if a CON is approved.

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

287
 288
 289 Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved
 290 UESWL units, shall be delivered in compliance with the following:

291 (1) Compliance with these standards.

292 (2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

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

316 (i) Not deny any UESWL services to any individual based on inability to pay or source of payment,
 317 (ii) Provide all UESWL services to any individual based on clinical indications of need for the
 318 services, and

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

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

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

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

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

331 (a) Each UESWL unit, ~~whether fixed or mobile~~, shall perform at least an average of 1,000 procedures
 332 per MOBILE unit AND 500 PER FIXED UNIT per year in the second 12 months of operation and annually
 333 thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved
 334 pursuant to these standards performed at least 100 procedures in each region that is served by the
 335 mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host
 336 sites in the same region shall be combined.

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

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

348

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

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

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

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

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

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

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

370

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

373

374 **Section 10. Methodology for projecting UESWL procedures**

375

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

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

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

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

394
395 (2) For a site or sites that provide UESWL services as of the date an application is submitted to the
396 Department, the actual number of UESWL procedures performed at each site, during the most recent
397 continuous 12-month period for which the Department has verifiable data, shall be the number used to
398 project the number of UESWL procedures that will be performed at that site or sites.

399
400 (3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as
401 applicable, shall be summed and the result is the projected number of UESWL procedures for the
402 proposed UESWL unit for purposes of the applicable sections of these standards.

403
404 (4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide
405 access to verifiable hospital-specific data and documentation using a format prescribed by the
406 Department.

407

408 **Section 11. Requirements for MIDB data commitments**

409

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

412 (a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL
413 service shall not use any of its MIDB data in support of any other application for a UESWL service for 5
414 years following the date the UESWL service to which the MIDB data are committed begins to operate.
415 The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON
416 application.

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

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

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

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

423 (c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting
424 patients regularly as of the date the director makes the final decision on that application under Section
425 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

426

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

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

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

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

436

437 **Section 12. Effect on prior planning policies; comparative reviews**

438

439 Sec. 12. (1) These CON review standards supersede and replace the CON review standards for
440 urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on
441 ~~September 25, 2014~~ **MARCH 27, 2018** and effective on ~~December 22, 2014~~ **MAY 29, 2018**.

442

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

444

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 **1.494353**.

(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 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

485
486
487 Counties assigned to each region are as follows:
488

489	Region	Counties			
490					
491	1	Livingston	Monroe	Macomb	Oakland
492		St. Clair	Washtenaw	Wayne	
493					
494	2	Clinton	Eaton	Hillsdale	Ingham
495		Jackson	Lenawee		
496					
497	3	Barry	Berrien	Branch	Calhoun
498		Cass	Kalamazoo	St. Joseph	Van Buren
499					
500	4	Allegan	Ionia	Kent	Lake
501		Mason	Mecosta	Montcalm	Muskegon
502		Newaygo	Oceana	Osceola	Ottawa
503					
504	5	Genesee	Lapeer	Shiawassee	
505					
506	6	Arenac	Bay	Clare	Gladwin
507		Gratiot	Huron	Iosco	Isabella
508		Midland	Ogemaw	Roscommon	Saginaw
509		Sanilac	Tuscola		
510					
511	7	Alcona	Alpena	Antrim	Benzie
512		Crawford	Charlevoix	Cheboygan	Emmet
513		Gd. Traverse	Kalkaska	Leelanau	Manistee
514		Missaukee	Montmorency	Oscoda	Otsego
515		Presque Isle	Wexford		
516					
517	8	Alger	Baraga	Chippewa	Delta
518		Dickinson	Gogebic	Houghton	Iron
519		Keweenaw	Luce	Mackinac	Marquette
520		Menominee	Ontonagon	Schoolcraft	
521					

APPENDIX C

522

523

524 Rural Michigan counties are as follows:

525

526	Alcona	Gogebic	Ogemaw
527	Alger	Huron	Ontonagon
528	Antrim	Iosco	Osceola
529	Arenac	Iron	Oscoda
530	Baraga	Lake	Otsego
531	Charlevoix	Luce	Presque Isle
532	Cheboygan	Mackinac	Roscommon
533	Clare	Manistee	Sanilac
534	Crawford	Montmorency	Schoolcraft
535	Emmet	Newaygo	Tuscola
536	Gladwin	Oceana	

537

538 Micropolitan statistical area Michigan counties are as follows:

539

540	Allegan	Hillsdale	Mason
541	Alpena	Houghton	Mecosta
542	Benzie	Ionia	Menominee
543	Branch	Isabella	Missaukee
544	Chippewa	Kalkaska	St. Joseph
545	Delta	Keweenaw	Shiawassee
546	Dickinson	Leelanau	Wexford
547	Grand Traverse	Lenawee	
548	Gratiot	Marquett	

549

550 Metropolitan statistical area Michigan counties are as follows:

551

552	Barry	Jackson	Muskegon
553	Bay	Kalamazoo	Oakland
554	Berrien	Kent	Ottawa
555	Calhoun	Lapeer	Saginaw
556	Cass	Livingston	St. Clair
557	Clinton	Macomb	Van Buren
558	Eaton	Midland	Washtenaw
559	Genesee	Monroe	Wayne
560	Ingham	Montcalm	

561

562 Source:

563

564 75 F.R., p. 37245 (June 28, 2010)

565 Statistical Policy Office

566 Office of Information and Regulatory Affairs

567 United States Office of Management and Budget

APPENDIX D568
569
570
571**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

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"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.

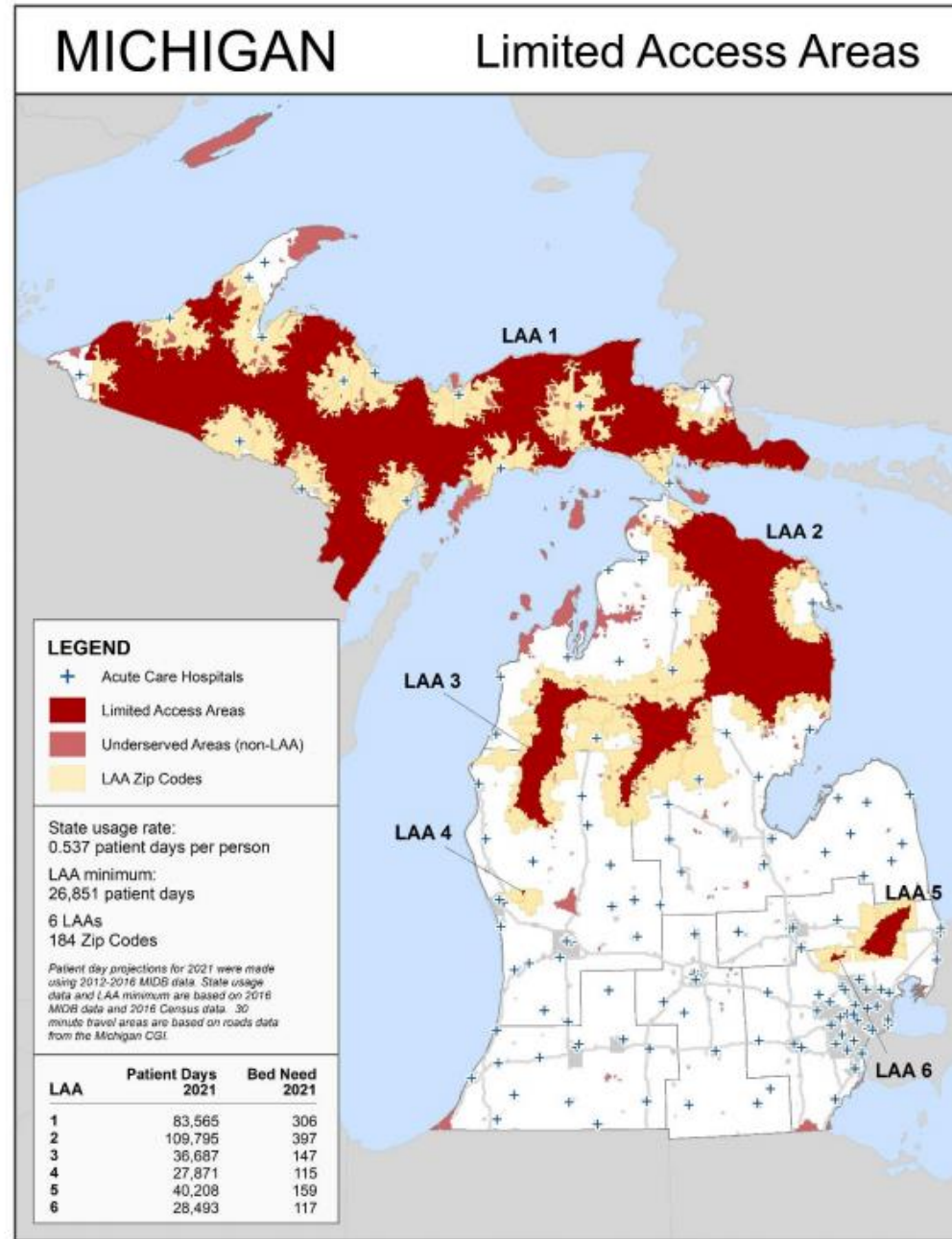
Certificate of Need: Limited Access Areas

Michigan Department of Health and Human Services
Policy & Planning Services Administration
September 19, 2019



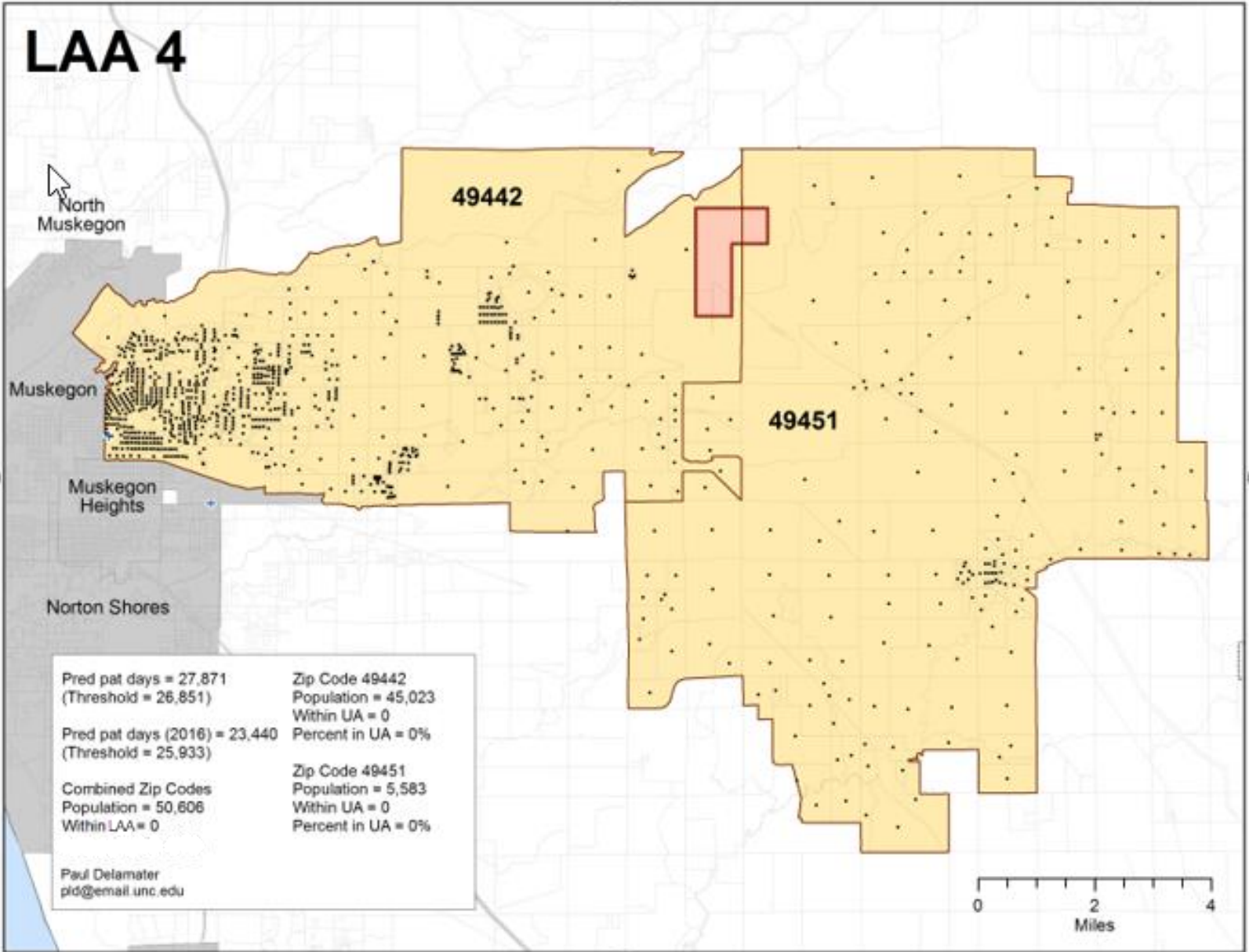
Definitions from Hospital Bed Standards:

- "**Underserved area**" means those geographic areas not within 30-minute drive time of an existing licensed acute care hospital with 24 hour/7 days a week emergency room services utilizing the most direct route using the lowest speed limits posted as defined by the Michigan Department of Transportation (MDOT).
- "**Limited access area**" means those underserved areas with a patient day demand that meets or exceeds the state-wide average of patient days used per 50,000 residents in the base year and as identified on the state of Michigan website.

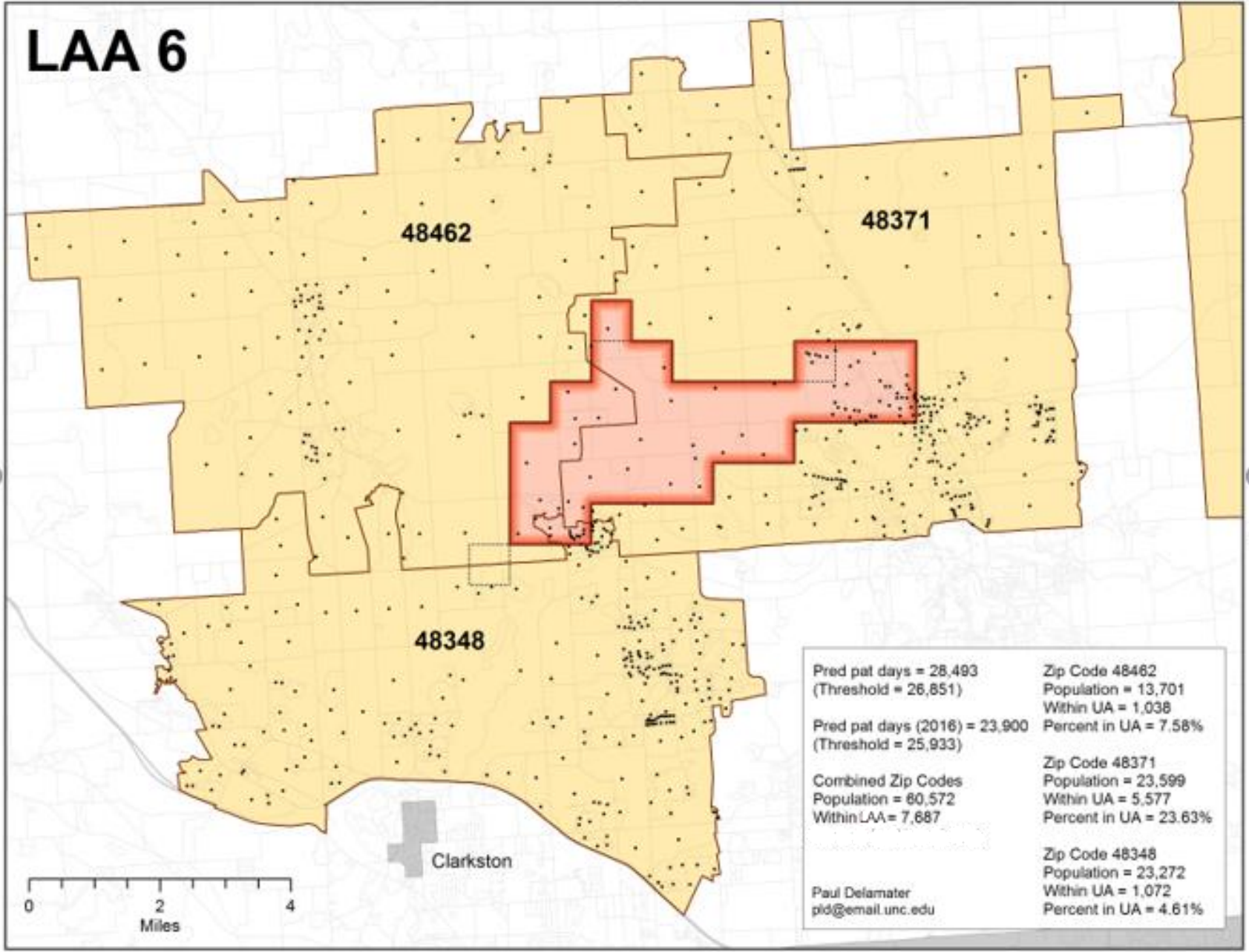


Requirements in Section 6(5)

- (g) An applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital as follows:
 - (i) In a metropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and **serve a population of 50,000 or more inside the limited access area and within 30 minutes drive time from the proposed new hospital.**
 - (ii) In a rural or micropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and **serve a population of 50,000 or more inside the limited access area and within 60 minutes drive time from the proposed new hospital.**



Bed Need: 115



Bed Need: 117

Problem Statement

- The methodology is identifying Limited Access Areas that cannot meet the requirements in Section 6(5)
 - The methodology is using full zip code population to determine the Limited Access Areas
 - The Limited Access Areas are based on smaller components of the zip code that do not contain the required population outlined in the initiation requirements

Proposed Solution

1. Fix the identification issue:
 - Work with MSU and Paul Delamater, Ph.D., to develop a solution to accurately identify the Limited Access Areas
 - This may involve a language changes in the standard
 - Review progress at December CON Commission Meeting
2. Take a deep-dive into all aspects of Limited Access Areas:
 - Hospital Bed standards are on the review schedule for 2020 and Limited Access Areas should be fully reviewed as part of the process

Changes in the Nursing Home and HLTCU Bed Need

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December 27, 2017

Executive Summary

This report further examines and explains the 7,205 bed increase (from 39,391 to 46,596) reported in the most recent update to the Nursing Home (NH) and HLTCU Bed Need (November 15, 2017). Specifically, I examined the variables used in the the bed need methodology that influence changes in the number of beds needed: the age-specific patient day use rates (based on reported utilization data and population in the base year), the projected population in the planning year, and the adjustment factor (recently modified in the Review Standards). I report the output from three calculations of the NH–HLTCU Bed Need: 1) Base Year 2013 and Planning Year 2018 (March 8, 2016), 2) Base Year 2015 and Planning Year 2018 (August 4, 2016), and 3) Base Year 2016 and Planning Year 2020 (November 15, 2017). The first and the third calculations were made on the regular cycle of updates per the requirements of the of Review Standards and are used as the main point of comparison. The second calculation was an off-cycle request to evaluate the efforts made to improve facility reporting of patient days during this period and is included simply for reference.

To examine how changes in the three variables impacted the bed need results, I implemented a series of tests to parse the large increase in beds into its component parts based on each variable individually. While these tests could not provide an “exact” measure because all three variables changed between the first and third calculations mentioned above, the nature of the tests did allow for good approximations of the relative contributions from each variable. Specifically, 15.93% of the increase (roughly 1,148 beds) was due to changes in patient day use rates between Base Years (2013 and 2016). Some of the change in patient day use rates is very likely due to an increase in the number of patient days reported per the efforts made during this period. 50.93% of the increase (roughly 3,669 beds) was due to differences in the projected population in the Planning Years (2018 and 2020), which can be further broken down into differences by the age groups used in the methodology: 0-64 years (-4 beds), 65-74 years (684 beds), 75-84 (1,178 beds), and 85+ years (1,810). Finally, I found that 33.14% of the increase (2,388 beds) was due to the recent change of the ADC (Average Daily Census) adjustment factor used in the methodology.

While the overall increase of 7,205 beds in a single cycle may appear somewhat large, it is somewhat more easy to understand when broken down into its component parts. First, improvements in reporting between 2013 and 2016 led to generally higher patient day use rates between cycles. These higher rates were then multiplied by projected population data that forecasts growth in and a further “greying” of Michigan’s population between 2018 and 2020 (which is corroborated when looking at the changes in the state’s population in the recent past). The increases from the first two parts were then magnified by the change to the ADC adjustment factor, which is used as a multiplier and thus has a greater effect on planning areas with the highest projected daily bed use.

Patient day use rates by age cohort

The initial portion of the NH–HLTCU methodology found in Section 3.(1) of the Review Standards requires updating the Base Year (BY) patient day use rates for the following four age cohorts: 0-64, 65-74, 75-84, and 85+ years. The BY use rates are based on the most recently available statewide patient day utilization data and population counts. These use rates are important for the overall methodology as they provide the “expected” use of NH–HLTCU beds in the future.

To calculate the BY use rates, first, the statewide patient days for each age cohort in the BY (gathered from the CON Annual Survey data) are summed. Next, the statewide population counts in the BY (gathered from the US Census Bureau) for each age cohort are summed. The summed patient days are then divided by the summed population for each age cohort. To complete the calculation, the result is multiplied by 1,000, which produces a rate of patient days used per 1,000 people in each age cohort in the BY.

Over the previous 2+ years, this calculation was made three times. The first (March 8, 2016) used 2013 as the BY. The second (August 4, 2016) used 2015 as the BY. The third (November 15, 2017) used 2016 as the BY. The first and the third calculations were made on the regular cycle of updates to the NH–HLTCU Bed Need per the requirements of the of Review Standards. The second calculation was an off-cycle request to evaluate the efforts made to improve facility reporting of patient days in the CON Annual Survey.

The 2013, 2015, and 2016 patient days, state population, and use rates by age cohort are found in Tables 1, 2, and 3, respectively. An initial important observation from Table 1, as it relates to the increase in the most recent NH–HLTCU Bed Need, is the statewide increase of 846,640 patient days reported to the CON Annual Survey between 2013 and 2016. Notably, this represents a 6.34% increase from 2013 for the state as a whole. Given the similarity between the number of patient days reported in 2015 and 2016, the efforts to improve facility reporting appear to have been successful (and the increase suggests that patient days were heavily *underreported* in 2013). Another interesting observation from Table 1 concerns the changes in patient days reported by age cohort between 2013 and 2016, as the NH–HLTCU methodology considers these age groups separately in the calculations. Notably, the number of patient days increased for 0-64 years (490,991 or 25.04%), 65-74 years (460,998 or 23.19%), and 75-84 years (180,834 or 5.04%), but decreased for 85+ years (-205,183 or -3.34%).

Table 1. Patient Days in 2013, 2015, 2016.

Age Cohort	2013	2015	2016
0-64	1,637,392	1,941,616	2,047,383
65-74	1,987,543	2,353,618	2,448,541
75-84	3,588,437	3,761,962	3,769,271
85+	6,135,344	6,139,965	5,930,161
<i>State</i>	<i>13,348,716</i>	<i>14,197,161</i>	<i>14,195,356</i>

The population counts in Table 2 also provide interesting results. While the state’s population grew

slightly from 2013 to 2016 (32,498 or 0.33%), the change over this period was not distributed evenly across the age cohorts. Overall, this period saw a “greying” of the state’s overall population, with increases in the groups aged 65 years and up and a decrease in the less than 65 years group. Specifically, the changes were -91,664 people (-1.09%) for 0-64 years, 105,496 (12.63%) for 65-74 years, 14,011 people (3.16%) for 75-84 years, and 4,655 people (2.23%) for 85+ years.

Table 2. Population in 2013, 2015, 2016.

Age Cohort	2013	2015	2016
0-64	8,408,209	8,351,905	8,316,545
65-74	835,439	907,140	940,935
75-84	443,520	450,619	457,531
85+	208,634	212,912	213,289
<i>State</i>	<i>9,895,802</i>	<i>9,922,576</i>	<i>9,928,300</i>

Table 3 contains the patient day use rates calculated from the data in Tables 1 and 2. The most notable change between 2013 and 2016 is that the use rates for each of the age cohorts with people less than 85 years increased, while the use rate for the 85+ year population decreased. The reason for these changes can be easily understood when compared to the changes in patient day utilization and population in these groups from 2013 to 2016. Notably, the percent change in patient days outpaced the change in population for the 0-64 years group (25.04% vs. -1.09%), 65-74 years group (23.19% vs. 12.63%), and 75-84 years group (5.04% vs. 3.16%), which resulted in higher patient day use rates. For the 85+ years group, the decrease in patient days (-3.34%) was exacerbated by an increase in the population (2.23%), which lead to the lower use rate.

Table 3. Use Rates (patient days per 1,000 people) in 2013, 2015, 2016. The statewide rate is also included for reference, but is not used in the methodology.

Age Cohort	2013	2015	2016
0-64	195	233	247
65-74	2,380	2,595	2,603
75-84	8,091	8,349	8,239
85+	29,408	28,839	27,804
<i>State</i>	<i>1,349</i>	<i>1,431</i>	<i>1,430</i>

Effect of change in use rates on bed need

To estimate the effects that the change in use rates had on the most recent Bed Need calculations, I implemented the current methodology and data, but substituted the 2013 patient day use rates in lieu of the 2016 patient day use rates. This comparison enables me to answer the question, “how much of the increase in beds can be traced to the changes in the use rates between 2013 and 2016?” The result of the NH-HLTCU Bed Need using the 2013 use rates is 45,390 beds. Given the 46,596 beds calculated

using the 2016 use rates, this results in a 1,206 bed increase due to changes in the age-specific use rates.

Projected population data

The NH-HLTCU methodology requires the use of future projections of Michigan’s population in the Planning Year (PY) for the NH-HLTCU Planning Areas in the specific age cohorts. The data are supplied by the State Demographer in the Department of Technology, Management & Budget. Per the methodology, the number of people in each planning area (in each age cohort) is multiplied by the age-group patient day use rates discussed above. The statewide PY population for the two years used in the calculations are provided in Table 4.

Table 4. Projected population in 2018 and 2020. Raw is the difference (in counts) between the 2018 and 2020 projections, while Pct is the percent difference between the two years.

Age Cohort	2018	2020	Raw	Pct
0-64	8,223,738	8,218,861	-4,877	-0.06%
65-74	989,396	1,080,117	90,721	9.17%
75-84	480,562	529,935	49,373	10.27%
85+	196,359	218,822	22,563	11.49%
<i>State</i>	<i>9,890,055</i>	<i>10,047,735</i>	<i>157,680</i>	<i>1.59%</i>

The data in Table 4 show that the projected population in Michigan was expected to increase in the higher age groups (65+ years) in these years and slightly decrease for those less than 65 years. As it pertains to the NH-HLTCU methodology, these are the age groups that utilize the most NH-HLTCU beds per capita (i.e., Table 3) and would therefore have the greatest effect on the resulting bed need calculations. The overall accuracy and trend of the population projections appear to be acceptable, given the recent population data found in Table 2.

Effect of change in projected population data on bed need

I estimated the effects of the change in the projected population year (Planning Year) on the most recent Bed Need calculations. To do this, I implemented the current methodology and data, but substituted the 2018 projected population data in place of the 2020 data. This comparison enables me to answer the question, “how much of the increase in beds can be traced to the changes in the projected population between 2018 and 2020?” The result of the NH-HLTCU Bed Need using the 2018 projected population data is 42,740 beds. Compared to the 46,596 beds calculated using the 2020 population, the result is a 3,856 bed increase due *only to* changes in the expected population. To understand this change further, I estimated the number of beds that were “needed by” each of the age cohorts from the previous calculations. The results are shown in Table 5. The table shows that roughly half (1,902) of the 3,856 bed increase is due to the expected change in the number of people in the 85+ years age group between 2018 and 2020.

Table 5. NH–HLTCU Bed Need by age group for current calculations (2020 projected population) and with 2018 projected population. Diff is the difference (in beds) between the 2018 and 2020 population projections. *Note: the age group sum of beds for 2020 and Diff is one less than the total due to rounding.*

Age Cohort	2018	2020	Diff
0-64	6,189	6,185	-4
65-74	7,848	8,567	719
75-84	12,067	13,305	1,238
85+	16,636	18,538	1,902
<i>State</i>	<i>42,740</i>	<i>46,596</i>	<i>3,856</i>

ADC adjustment factor

Like other bed-based health care services regulated by CON in Michigan, the NH–HLTCU bed need methodology includes a step to multiply the expected daily use of beds (Average Daily Census) in the Planning Year (in each planning area) by an “adjustment factor.” This step is included to account for facilities not being able to operate at full capacity over long periods of time. In the NH–HLTCU Review Standards, this step is found in Section 3.(2)(e). The bed need in the Planning Year is calculated by dividing the Planning Year ADC by an ADC adjustment factor of 0.9 (dividing by 0.9 is equivalent to multiplying by 1.11 or 111%). This result is rounded up to the next whole number under the assumption that a partial bed is a bed.

The adjustment step in the methodology was recently changed from having two distinct ADC adjustment factors to a single factor. In the past, planning areas with an unadjusted ADC of less than 100 used 0.9, while planning areas with an unadjusted ADC of 100 or greater used 0.95 as the factor (dividing by 0.95 is equivalent to multiplying by 1.05 or 105%). A variable adjustment factor is also used in the Acute Care Hospital Standards, accounting for differing expectations of efficiency based on the size of facilities (e.g., it is more difficult to run a smaller facility near capacity). The recent change in the NH–HLTCU methodology now treats all facilities equally.

Effect of change in ADC adjustment factor on bed need

The recent change in the ADC adjustment factor has a multiplicative effect based on the ADC of the planning area. For example, if Planning Area A has an unadjusted ADC of 120, then the original approach would result in a bed need of $120 / 0.95 = 127$ beds. Under the new approach, Planning Area A has a bed need of $120 / 0.9 = 134$ beds. Continuing the example, if Planning Area B has an unadjusted ADC of 3,000, the original approach would result in a bed need of $3,000 / 0.95 = 3,158$ beds. The new approach for Planning Area B results in a bed need of 3,334 beds. Hence, the ADC adjustment factor change would be responsible for a 7 bed increase for Planning Area A and a 176 bed increase for Planning Area B. This example simply demonstrates the multiplicative effect of the recent change.

I estimated the effect of the change in the ADC adjustment factor on the most recent Bed Need calculation. I used the former ADC adjustment steps with the current data. This comparison enables me to answer

the question, “how much of the increase in beds can be traced to the change in how ADC is adjusted in the methodology?” The result of the NH–HLTCU Bed Need using former ADC adjustment rules and factors is 44,208 beds. When compared to the 46,596 beds calculated using the single ADC adjustment factor of 0.9, this results in an increase of 2,388 beds.

Summary and Conclusions

The increase in NH–HLTCU beds reported in the previous sections tally 1,206 (use rates), 3,856 (projected population), and 2,388 beds (ADC adjustment factor). The sum of these separate calculations (7,450 beds) is slightly higher than the increase of 7,205 beds reported in the most recent cycle. This discrepancy is not a mistake, but simply because these components are integrated together (via multiplication) in the NH–HLTCU methodology and the tests performed to isolate the effects of each cannot account for the multiplicative effects. However, the contribution of the changes in the use rates and projected population data to the 7,205 bed increase can be calculated by using their relative contributions (based on a 7,450 bed increase). Using this approach, I estimate the increase in beds due only to changes in the age-specific use rates between 2013 and 2016 is 1,148 beds (15.93% of the 7,205 increase). I estimate that the increase due to a forecasted growing and greying state population between 2018 and 2020 is 3,669 beds (50.93% of the 7,205 increase). The increase due to the change in the ADC adjustment factor is 2,388 beds (33.14% of the 7,205 increase).

A statewide increase of 7,205 beds (18.3%) in only two years does appear to be quite large. Yet, this time period included two somewhat dramatic changes that would undoubtedly result in increases in the number of NH-HLTCU beds needed as calculated by the methodology. First, there were efforts to increase and improve facility reporting of patient utilization data between 2013 and 2016, which largely increased the use rates (that were likely artificially low due to underreporting in the prior update). Second, by changing the methodology to only include a single ADC adjustment factor of 0.9, the *only* effect could be an increase in the bed need (holding other factors equal). The most surprising finding was that roughly half of the increase in the bed need was due to differences in the projected population between 2018 and 2020; however, the forecast of a slightly larger and older state population in this time period is in line with recent past trends in Michigan and appears to be reasonable.

COMPUTED TOMOGRAPHY (CT) SERVICES WORKGROUP INTERIM REPORT

The CT services workgroup, as charged by the Certificate of Need Commission, had its initial meeting on August 6th, 2019:

- I. The meeting was called to order at 9:05 AM.
- II. Workgroup Process Presentation by Brenda Rogers, MDHHS.
- III. CT CON workgroup charges review by Geoffrey Remes, MD.
- IV. Discussion:

Charge 1. Freestanding ED CT maintenance exemption:

24-hour freestanding ED CT scanner exemption from maintenance volume on first scanner was addressed by Patrick O'Donovan from Beaumont Hospital. This does not involve a change to initiation of a new CON, only maintenance volume. There was discussion regarding the general concept of a freestanding ED with CT capability. Many conditions that would be diagnosed by CT would require transport to a hospital and are time sensitive/emergent. The discussion of this charge was deferred, pending discussion of charge #3, review of maintenance volume requirements.

Charge 2. Dedicated pediatric CT scanner requirements and definition:

Change to maintenance requirement, not initiation of new service, was addressed by representative from University of Michigan Hospitals. In summary, many pediatric patients with congenital and/or chronic pediatric diseases, which in the past did not survive beyond childhood are now living into

adulthood. These patient are still cared for by pediatric specialist, as these diseases were not generally seen in adult medicine. Diagnostic testing, including imaging, is performed at Children's Hospitals, due to specialized nature of these patients. Under the current standards, these "pediatric" patients, are viewed as "adults" when over the age of 18, yet require the same imaging resources as a younger patient.

This was discussed and questions regarding age related data arose. Representative(s) from U of M Hospitals will obtain and present age related data at next meeting.

A question raised by the workgroup for the CON Commission, noting the Commission does not wish to redefine the pediatric age range: In the current standards, Section 14, subsection 4a; could an additional subsection be added stating: *if approved under Section 12, computation of CT equivalents is to utilizes adult patient conversion factor for patients age ≥ 21 and pediatric/special needs conversion factor for patients age < 21 .* This could potentially resolve the issue as understood.

Charge 3. Review maintenance volume requirements:

Following discussion, it was concluded additional data and analysis of the 2018 Certificate of Need Annual Survey for CT Services is needed. Analysis to determine the distribution of compliant verses non-compliant scanners on a county by county basis is needed. David Walker of Spectrum Health agreed to undertake this assignment prior to the next meeting.

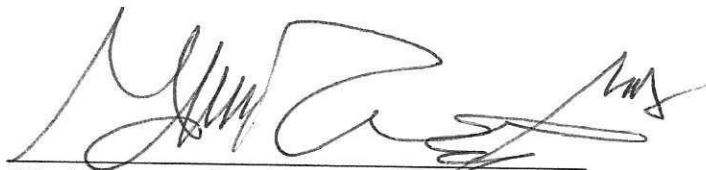
V. Summary

1. Charge 1, free standing ED CT scanner maintenance requirement is deferred until Charge 3 is decided, as this may resolve the issue.
2. Charge 2, dedicated pediatric CT maintenance requirements, U of M Hospitals will present additional data at next meeting. If the Commission could weigh in on the question posed above, this would be helpful.

3. Review of CT maintenance requirements is pending discussion with data analysis by David Walker, Spectrum Health.

4. Next Meeting scheduled for October 3, 2019.

VI. Meeting Adjourn at 11:50 AM.

A handwritten signature in black ink, appearing to read 'Geoffrey M. Remes, MD', written over a horizontal line.

Chairperson Geoffrey M. Remes, MD
Submitted: 9/4/2019

Open Heart Surgery Weights: Appendix Updates, 2019

September 6, 2019

Paul L. Delamater

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Department of Geography, University of North Carolina at Chapel Hill

Summary

The weight values found in Appendix A (adult principal and non-principal) and Appendix B (pediatric) of the Open Heart Surgery Standards were updated using 2017 MIDB data per the existing methodology outlined in the Standards. The new weights contain variations from the weight values calculated in 2016 (using 2014 MIDB data); these appear to be a potential result of the switch to ICD-10 codes, but will likely not have much of an effect because all applications will need to use these codes as well.

Appendix A

The methodology used to update Appendix A is provided in Section 9.(1), which includes the steps for calculating the weight values for principal diagnoses in 9.(1)(a) and non-principal diagnoses in 9.(1)(b). MIDB inpatient data from 2017, with the associated primary and secondary diagnostic (DX) and procedure (PX) codes for each patient record, were used. The associated DX codes can be found in Appendix A (and D). The associated PX codes were drawn from information provided by the MDHHS CON Section. The list of hospitals having operational open heart surgery programs was gathered from the 2017 CON Annual Survey results.

Table 1 contains the updated weight values for the principal diagnoses in Appendix A (the first section). In the previous update, the 2010 and 2014 weights are also included for reference. Notably, the total number of principal diagnoses decreased with the switch to ICD-10 codes.

Table 1. Procedures (PX), diagnoses (DX), and weights (W) for principal diagnoses in Appendix A

Group	2010			2014			2017		
	PX	DX	W	PX	DX	W	PX	DX	W
A	2,589	3,543	0.730737	2,980	4,790	0.622129	2,680	5,829	0.459770
B	458	714	0.641457	533	785	0.678981	577	943	0.611877
C	193	533	0.362101	180	385	0.467532	280	589	0.475382
D	5,019	22,390	0.224163	3,975	13,487	0.294728	2,542	5,499	0.462266
E	1,846	18,191	0.101479	1,636	18,259	0.089600	2,122	18,969	0.111867
F	588	43,992	0.013366	541	42,224	0.012813	344	18,891	0.018210
<i>State</i>	<i>10,693</i>	<i>89,363</i>		<i>9,845</i>	<i>79,930</i>		<i>8,545</i>	<i>50,720</i>	

The updates for the non-principal diagnoses table in Appendix A (the second section) are found in Table 2. As the results show, the updated values are quite different from the previous updates. Notably, there were many more procedures associated with secondary diagnoses than with principal diagnosis compared to previous years.

Table 2. Procedures (PX), diagnoses (DX), and weights (W) for non-principal diagnoses in Appendix A

Group	2010			2014			2017		
	PX	DX	W	PX	DX	W	PX	DX	W
A	39	2,311	0.016876	54	3,125	0.017280	172	4,376	0.039305
B	30	996	0.030120	39	1,385	0.028159	84	2,321	0.036191
C	91	7,521	0.012099	93	7,627	0.012194	373	10,592	0.035215
D	167	21,837	0.007648	211	27,363	0.007711	1,452	58,313	0.024900
E	164	111,881	0.001466	170	104,099	0.001633	1,150	104,081	0.011049
F	88	72,970	0.001206	97	79,372	0.001222	882	53,501	0.016486
<i>State</i>	<i>579</i>	<i>217,516</i>		<i>664</i>	<i>222,971</i>		<i>4,113</i>	<i>233,184</i>	

Appendix B

The methodology used to update Appendix B is provided in Section 10.(1). Table 3 contains the updated weight values, along with the weight values from 2010 and 2014 for reference.

Table 3. Procedures (PX), diagnoses (DX), and weights (W) for Appendix B

Group	2010			2014			2017		
	PX	DX	W	PX	DX	W	PX	DX	W
Congenital	1,340	5,714	0.234512	1,712	9,528	0.179681	1,118	7,071	0.158111
Other	32	1,685	0.018991	27	2,073	0.013025	27	884	0.030543
<i>State</i>	<i>1,372</i>	<i>7,399</i>		<i>1,739</i>	<i>11,601</i>		<i>1,145</i>	<i>7,955</i>	

The weight values for the Other category is somewhat different, which appears to be a result of many fewer diagnoses in this category (consistent with the results above with switch to ICD-10).

CERTIFICATE OF NEED
3rd Quarter Compliance Report to the CON Commission
 October 1, 2018 through September 30, 2019 (FY 2019)

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	3 rd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	54	231
Approved projects contacted on or before anniversary date	36	145
Approved projects completed on or before 1-year follow up	67%	
CON approvals expired	43	41
Total follow up correspondence sent	219	653
Total approved projects still ongoing	300	

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.

- Oaklawn Hospital – The Department became aware that Oaklawn Hospital’s previous lease term for the fixed Magnetic Resonance Imaging (MRI) unit had expired and Oaklawn Hospital was operating on a month-to-month lease arrangement from June of 2018 through May of 2019 without CON approval. The facility was required to submit a written corrective action plan establishing a process to ensure that CON covered services, equipment(s), and lease renewal projects needing approval are properly approved and should involve management level education about the CON process and requirements. In addition, the facility was required to pay a civil fine of \$500.
- The Department is conducting statewide compliance reviews for Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET) scanner services utilizing the most recent CON Annual Survey and MRI Utilization List data. The Department completed the process of evaluating annual survey and MRI Utilization List data, review standard requirements, and CON approved facilities for these selected services and identified the facilities for compliance investigations. The Department is in the process of setting up conference calls and contacting these facilities for further discussions. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

CERTIFICATE OF NEED
3rd Quarter Program Activity Report to the CON Commission
 October 1, 2018 through September 30, 2019 (FY 2019)

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	3 rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	85	N/A	245	N/A
Letters of Intent Processed within 15 days	85	100%	243	99%
Letters of Intent Processed Online	85	100%	245	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	3 rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	50	N/A	160	N/A
Applications Processed within 15 Days	50	100%	160	100%
Applications Incomplete/More Information Needed	30	60%	89	56%
Applications Filed Online*	48	96%	147	92%
Application Fees Received Online*	11	22%	51	32%

* 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	3 rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	37	100%	97	100%
Substantive Applications	20	100%	81	100%
Comparative Applications	0	100%	4	100%

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.

Program Activity Report to CON Commission
 FY 2019 – 3rd Quarter
 Page 2 of 2

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	3 rd 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	3 rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	21	100%	70	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	3 rd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	3 rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	83	N/A	259	N/A
FOIA Requests Processed on Time *	83	100%	259	100%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

*Request processed within 5 days or an extension filed.

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL



DANA NESSEL
ATTORNEY GENERAL

MEMORANDUM

September 11, 2019

TO: James Falahee
CON Commission Chair

FROM: Carl J. Hammaker, III 
Assistant Attorney General
Corporate Oversight Division

CC: Elizabeth Nagel
Joseph E. Potchen

RE: Legal Report for the September 19, 2019 Commission Meeting

We currently have one pending case in the Michigan Office of Administrative Hearings and Rules.

On October 5, 2018, the Department issued a proposed decision to disapprove CON Application No. 18-0050 to begin operation of a new nursing home, Regency at East Ann Arbor. Regency at East Ann Arbor appealed the proposed decision. Formal discovery in the appeal closed in June 2019. The matter is set for a status conference on October 2, 2019.

In addition to these cases, we continue to work with MDHHS staff to assist in developing standards and providing legal advice on various matters.

DRAFT - Certificate of Need (CON) Commission Work Plan - DRAFT

2019												
	January	February	March	April	May	June	July	August	September	October	November	December
Commission Meetings			Special Meeting/ Meeting			Meeting			Meeting			
Bone Marrow Transplantation (BMT) Services		BMTSAC Mtg.	BMTSAC Mtg.	BMTSAC Mtg.		Report/Draft Language/ Proposed Action	Public Hearing		Report/ Final Action			
Cardiac Catheterization Services										Public Comment Period		
Computed Tomography (CT) Scanner Services			Discussion/ Report					CT Workgroup Mtg.	Interim Report to Commission	CT Workgroup Mtg.	CT Workgroup Mtg.	CT Workgroup Mtg. or Report/Draft Language/ Proposed Action
Hospital Beds										Public Comment Period		
Megavoltage Radiation Therapy (MRT) Services/Units			Report/Draft Language/ Proposed Action	Public Hearing		Report/ Final Action				Public Comment Period		
Neonatal Intensive Care Services/Beds (NICU)			Discussion/ Report				SAC Nomination & Selection Period				NICU SAC Mtg.	NICU SAC Mtg.
Nursing Home and HLTCU Beds and Addendum (NH-HLTCU)			Discussion/ Report	SAC Nomination & Selection Period NH-HLTCU SAC Mtg.						NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.
Open Heart Surgery (OHS) Services										Public Comment Period		
Positron Emission Tomography (PET) Scanner Services										Public Comment Period		
Psychiatric Beds and Services	Workgroup Meeting	Public Hearing/ Workgroup Meeting	Report/ Final Action/ Workgroup Meeting			Report/ Draft Language Presented/ Proposed	Public Hearing		Report/Final Action			

						Action					Attachment O	
Surgical Services										Public Comment Period		
Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units	Public Comment Period		Discussion/ Report	Dept. Drafting Language	Dept. Drafting Language	Draft Language Presented/ Proposed Action	Public Hearing		Report/Final Action			
New Medical Technology Standing Committee	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring

For Approval September 19, 2019.

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) at, 517-335-6708 or 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	2022
Bone Marrow Transplantation Services	September 29, 2014	2021
Cardiac Catheterization Services	December 26, 2018	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	November 28, 2018	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 12, 2019	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	December 26, 2018	2020
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	May 24, 2019	2021
Surgical Services	November 17, 2017	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	May 29, 2018	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.