MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISION MEETING

Tuesday, December 11, 2007

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Hagenow called the meeting to order at 9:12 a.m.

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson (Left @ 3:45 p.m.)
Peter Ajluni, DO (Via teleconference from 9:00 a.m. to 10:41 a.m.)
Bradley N. Cory (Left @ 3:45 p.m.)
Dorothy E. Deremo, (Arrived @ 9:16 p.m.)
Marc Keshishian, MD
Adam Miller
Michael A. Sandler, MD
Thomas M. Smith
Kathie VanderPloeg-Hoekstra (Left @ 3:28 p.m.)
Michael W. Young, DO (Left @ 2:44 p.m.)

B. Members Absent:

None.

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Umbrin Ateequi
William Hart
John Hubinger
Joette Laseur
Irma Lopez
Nick Lyon
Andrea Moore
Stan Nash
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Sandler, seconded by Vice-Chairperson Goldman, to not take public comments on items X, XI and XII until after lunch. Motion Carried.

Motion by Commissioner Sandler, seconded by Vice-Chairperson Goldman, to accept the agenda as modified. Motion Carried.

III. Declaration of Conflicts of Interest

No conflicts were stated at this time.

IV. Review of Minutes – September 18, 2007

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to approve the minutes as presented. Motion Carried.

V. Public Comment for Action Items (i.e., VI, VII, VIII, IX, X, XI, & XII)

Computed Tomography (CT) Scanner Services

Melissa Cupp, Wiener & Associates
Matt Jordan, Xoran Technologies
Glenn Melenyk, Blue Cross Blue Shield of Michigan

Miscellaneous Standards

Dennis McCafferty, Economic Alliance for Michigan (Attachment A)
Bob Meeker, Spectrum Health (Attachment B)

Open Heart Surgery (OHS) Services

Aaron Kugelmass, Henry Ford Health System

VI. CT Scanner Services Standard Advisory Committee (SAC) – Final Report

A. Review of Proposed Language

Chairperson Shumaker of the CTSAC provided a brief overview of his final report (Attachment C) to the Commission. Ms. Ateequi reviewed the recommended changes to the CT proposed language (Attachment D).

B. Commission Discussion

Commissioner Sandler stated that he feels the proposed language should go forth to public hearing. He also stated that he is unsure about the recommendation that in the Pilot Program you have to have had submitted your CON application by October 1. He is concerned that it does not leave sufficient time for physicians to submit their application. Commissioner Deremo requested clarification by Chairperson Shumaker regarding the discussion that took place on orthodontics. Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the CTSAC report, move the proposed language forward for public hearing, and move forward to the Joint Legislative Committee (JLC). Motion Carried.

Break from 10:41 a.m. to 11:03 a.m.

VII. OHSSAC – Public Hearing Comments

A. MDCH Report

Mr. Lyon provided a brief overview of the MDCH report (Attachment E). Ms. Rogers reviewed the summary of the public hearing comments (Attachment F) and the two proposed OHS languages (Attachment G & H).

B. Commission Discussion

Commissioner Sandler requested clarification regarding how the Department would run the numbers and then make the information available to the Commission. Ms. Rogers stated that once the Department would run the methodology numbers, they would provide the information to the Commission because they are the ones who have to set the effective date. The purpose for running the numbers on a continuous basis is to ensure that when the time comes for a SAC or Workgroup to be appointed, they would be working with the most current data, but they will not be changing the methodology itself.

C. Commission Final Action

Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the OHSSAC recommendations with the proposed amendments which includes the S-3 language, and move it forward to the JLC and the Governor for the 45-day review period. Motion Carried.

VIII. Nursing Home & Hospital Long-term care (NH-HLTC) Unit Beds SAC – Final Report

A. Public Comment

Laura Hall, Michigan Consumer Task Force
Laura Hamann, Lakeview
Gail Clarkson, AHCA
Frank Wronski, Medilodge
Bette Hawkins, Kalamazoo County Advocates for Senior's Issues
Bill Buccalo, Rainbow Rehabilitation Centers
Ian Engle, Self
Phyllis Adams, Dykema
Toni Wilson, Ombudsman (Attachment I)
William Mania, MI Campaign for Quality Care (Attachment J)
Amy Barkholz, MHA (Attachment K)
Bob Meeker for Jeff Mislevy, Spectrum Health Continuing Care (Attachment L)
Renee Beniak, MI County Medical Care Facilities
Pat Anderson for Jon Nowinski, Lally Group (Attachment M)
Pat Anderson, HCAM (Attachment N)
David Stobb, Ciena Healthcare

Lunch Break from 12:26 p.m. to 1:09 p.m.

Ms. Rogers for Mary Ablan, Area Agencies on Aging Association (Attachment O)
Mark Cody, Michigan Protection Advocacy

John Weir, Kalamazoo County Health Community Services
David Herbel, MAHSA (Attachment P)
Stephanie Wahke for RoAnne Chaney, MI Disability Rights Coalition (Attachment Q)
Andrew Farmer, AARP (Attachment R)
Brain Kaser, Attorney at Law (Attachment S)
Lacey Charboneau, Citizens for Better Care
Dick Prestage, Schnepp Health Care
Tom Rau, Nexcare (Attachment T)
Kitty Knoll, Area Agency on Aging Association
Judy Sivak, Area Agency on Aging Association
Sarah Slocum, State LTC Ombudsman (Attachment U and V)
Dennis McCafferty, Economic Alliance for Michigan
Larry Horwitz, Economic Alliance for Michigan

Support NHSAC Recommendations, but Did Not Speak

Carolyn Lejuste, Red Cedar Friends
Brittany Koziol, Citizens for Better Care
Julie Angel, Citizens for Better Care
Ruth Linnemann, National Multiple Sclerosis Society MI Chapter
Paul VanWestrienen, Michigan Campaign for Quality Care
Ellen Mackstry, Michigan Advocacy Project
Stephanie Wahke, Elder Law of Michigan

Written Testimony

Linda Potter, United Cerebral Palsy (Attachment W)
Gregory Piaskowski, Self (Attachment X)
Terri Cady, Disability Network of Mid-Michigan (Attachment Y)
Jamea McKnight, Self (Attachment Z)

B. Review of Proposed Language

Chairperson Chalgian of the NHSAC provided a brief overview of the report (Attachment AA). Vice-Chairperson Goldman requested clarification regarding the NHSAC's recommendation that you can only acquire an existing nursing home if it is licensed and operating. Commissioner Cory stated he is concerned that there seems to be a diverse set of opinions between the nursing home operators, MAHSA, HCAM, Hospital Association, and the county medical care facility counsel against some non-provider groups. Further, all parties well intended, all parties trying to achieve a goal in the interests of quality care to the citizens of Michigan.

C. Commission Proposed Action

Motion by Commissioner Cory, seconded by Commissioner Keshishian, to accept the recommendations of the NHSAC and move the proposed language forward to public hearing and to the JLC. In addition, the Department will assign a Workgroup with a representative from each of the trade associations: MAHSA, MCMCF, HCAM, and the Michigan Hospital Association, along with a balance of non-providers to refine the presented quality proposal to include quality measures, other than survey process, for consideration at the March CON Commission Meeting.

Commissioner Cory clarified that he is not recommending elimination of using survey results for a quality measure, but to consider additional quality measures.

The Commission stated that these meetings would be open for anyone who wants to participate.

Motion Carried, 8-2.

Break from 2:44 p.m. to 2:55 p.m.

IX. Psychiatric Beds and Services – Public Hearing Comments

A. Commission Discussion

Ms. Rogers provided a brief overview of the Psychiatric Beds and Services Public Hearing comments (Attachment BB).

B. Commission Final Action

Motion by Commissioner Deremo, seconded by Commissioner Cory, to approve the language and move forward to the JLC and the Governor for the 45-day review period. Motion Carried.

X. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units – Public Hearing Comments

A. Commission Discussion

Ms. Rogers provided a brief overview of the UESWL Services/Units Public Hearing comments (Attachment CC).

B. Commission Final Action

Motion by Commissioner Goldman, seconded by Commissioner Deremo, to approve the language and move forward to the JLC and the Governor for the 45-day review period. Motion Carried.

XI. Cardiac Catheterization (CC) Services SAC – Public Hearing Comments

A. Commission Discussion

Ms. Rogers provided a brief overview of the CC Services Public Hearing comments (Attachment DD).

Public Comment

Dennis McCafferty, Economic Alliance for Michigan
Bob Meeker, Spectrum Health

B. Commission Final Action

Motion by Commissioner Miller, seconded by Commissioner Keshishian, to approve the language and move forward to the JLC and the Governor for the 45-day review period. Motion Carried.

XII. Standing New Medical Technology Advisory Committee (NEWTAC) – Report

Commissioner Keshishian provided a brief overview of his report (Attachment EE) regarding the NEWTAC.

Motion by Commissioner Keshishian, seconded by Vice-Chairperson Goldman, to ask the Attorney General for a formal opinion regarding if they decide to regulate vascular surgery under CON, would existing programs be grandfathered. Motion Carried.

Motion by Commissioner Keshishian, seconded by Commissioner Deremo, to receive background information and data on intra-operative Magnetic Resonance Imaging (MRI). Motion Carried.

XIII. Neurointerventional Radiology

Commissioner Keshishian provided a brief overview of his report (Attachment EE) regarding neurointerventional radiology.

Motion by Commissioner Keshishian, seconded by Vice-Chairperson Goldman, to accept the NEWTAC's recommendation to not regulate neurointerventional radiology. Motion Carried.

Chairperson Hagenow stated she will write a letter to Senator George regarding the Commission's decision to not regulate neurointerventional radiology.

XIV. Legislative Report

Mr. Lyon stated that Chairperson Hagenow, Vice-Chairperson Goldman and new Commissioner Smith were unanimously appointed to the Commission by the Senate at their Senate Hearing.

XV. Compliance Report

Mr. Lyon provided a brief overview of the compliance report (Attachment FF).

Commissioner Sandler requested information be provided as to which facility voluntarily closed in regards to PCI.

XVI. Administrative Update

A. MRT Services/Units – Update of Appendices A and B

Public Comment

Bob Meeker, Spectrum Health

Mr. Hart provided a brief overview of the two appendices (Attachment GG & HH).

Motion by Commissioner Deremo, seconded by Commissioner Cory, to accept the updated appendices regarding MRT Services/Units and give immediate effect. Motion Carried.

Mr. Hart provided a brief overview of the Preliminary Projected NH/LTC Bed Need data (Attachment II).

XVII. CON Program Update

Ms. Rogers stated the Program report (Attachment JJ) is provided for the Commissioners in their binders.

XVIII. Legal Activity Report

Vice-Chairperson Goldman stated that Mr. Styka had to leave, but a copy of the CON Legal Activity report (Attachment KK) is provided for the Commissioner's in their binders.

XIX. Future Meeting Dates

January 24, 2008 (Special Commission Meeting – Standards for 2008 Review)
March 11, 2008
June 11, 2008
September 16, 2008
December 9, 2008

XX. Public Comment

Pat Anderson, HCAM
Larry Horwitz, Economic Alliance for Michigan

XXI. Work Plan

Ms. Rogers provided a brief overview of the work plan (Attachment LL).

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the work plan. Motion Carried.

XXII. Adjournment

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to adjourn the meeting at 3:56 p.m. Motion Carried.

The Economic Alliance for Michigan
CON Commission Public Hearing – 9 a.m. Wednesday October 31, 2007

PROPOSED CHANGES IN OPEN HEART SURGERY STANDARDS

Open Heart Surgery Methodology for predicting need for additional programs.

1. The Economic Alliance for Michigan members –business and labor -- strongly believe that there is not a need for any additional Open Heart Surgery programs, anywhere in Michigan. Adding more programs, especially when the utilization of open heart surgery is steadily declining, would be a bad outcome in producing lower quality and higher costs. We wish that the refined methodology would not allow for any additional programs. However, given the extensive time and effort given to this Standard our Health Group concluded that EAM should support the MDCH revised methodology as a reasonable compromise.
2. The refinements to the OHS methodology for projecting the need for additional OHS programs in Michigan –proposed by MDCH -- were developed pursuant to the strong requests by the SAC and the Commission.
3. Those refinements have made much progress in simplifying and have gone a long way to simplify and improve the predictability of this process.
4. The MDCH staff members involved with developing these refinements to the methodology for projecting the need for new programs should be commended for their efforts and knowledge.
5. In our detailed review we did identify some other minor corrections in the (S-3) Impact Report that need to be made. Those have been shared with MDCH staff but we want to provide these suggestions in this public forum so that all might react to them.

   Sec. 6 of the CON Standards have long provided that CON-approved or operational Open Heart Surgery hospitals cannot provide data for commitment to other potential new programs. That section would require recognition that Mid-Michigan and Foote Hospitals data can not be included in the respective HSA totals of available data. Removing their data for the totals for their HSA will not have a material impact upon the results, but it is technically required.

   - In our judgment the total discharge data points available for HSA 1 appear to have been understated by about 50. This appears to have resulted from an over-subtraction of data previously committed. This would increase the number available from 555 to approximately 605.

Economic Alliance for Michigan
CON Commission Public Hearing
October 31, 2007 @ 9:00

Other SAC Recommendations Under Review

Cardiac Cath Standards

The EAM members support the recommended changes to the CON standards for Cardiac Catherization. Of particular note are the following:

1. Requiring facilities providing Cardiac Services in Michigan being required to participate in the American College of Cardiology National Cardiovascular Data Registry's CathPCI Registry.

2. Requiring facilities proposing to initiate a pediatric Cardiac Cath service to meet certain guidelines of the American Academy of Pediatrics.

3. Maintaining the limitation to maintain the provision of the CON Standards that Elective Angioplasty should only be done at hospitals with **on-site** Open Heart Surgery.

Open Heart Surgical Centers

The EAM members support the recommended changes to the CON standards for Open Heart Surgical programs. Of particular note are the following:

1. Facilities providing OHS in Michigan will be required to participate in the Society of Thoracic Surgeons database and the program's state-wide auditing.
2. Maintaining the minimum volume for new programs at 300 per year
3. Increasing the minimum volume for attending physicians from 50 to 75/ year.
4. Consulting hospitals will be required to perform a minimum of 400 cases per year for at least three consecutive years.
5. Limiting hospitals ability to commit their OHS discharge data to only the data not previously committed. Thereby eliminating the ability to hospitals to re-cycle this data every 7-years.
6. Refinements of the methodology for projecting need for new programs.

7. However, at the September Commission meeting, the Attorney General office did question the validity of the proposed standard to allow hospitals to use their own previously committed data for starting their own OHS program. We believe that this AG opinion will require the striking of Section 6 (1) (B), lines 154 – 158 of the recommended OHS standards. This will allow for equal application of the regulations to every provider.

Additional Written Comments:

Additional written comments regarding the above recommended changes in the CON Standards will be submitted on behalf or our members by:

Mr. Wayne Cass, Business Representative of the International Union of Operating Engineers and the Michigan AFL-CIO and,

Marsha Manning, Manager-SE Michigan Health Care Initiatives, General Motors Corp.

CON Commission Public Hearing
October 31, 2007
Methodology to Predict Adult Open Heart Surgery Cases
Economic Alliance for Michigan

Background:

- The (CON) Commission is tasked with identifying the need for each of the services regulated by the CON program. In Open Heart Surgery Services, the Commission has adopted a methodology using inpatient discharge data provided thru the Michigan Inpatient Data Base (MIDB) to predict open heart procedures (cases). This basic methodology was adopted by the CON program over 20 years ago.
- The 2007 OHS SAC was asked to review this methodology but was unable to complete this change because the necessary final analytic data was not available. The SAC had great concern about the codes used in the methodology and the resulting over-projection of need for new programs. As a result, the SAC, facing the 6 month statutory deadline, asked MDCH staff to develop refinements of the methodology to simplify and insure accuracy.
- From when the SAC ended in July to the September Commission meeting the MDCH made noteworthy progress in resolving most of the data concerns and simplifying the process.
- The CON Commission on September 18 approved the OHS SAC recommendations as modified by MDCH. However, the Commission expressed concern about the methodology and wanted further refinements that would reduce the over-prediction problem

Methodology Refinement:

- The OHS SAC preliminary recommendation, adopted at the 9/18/2007 Commissioner's meeting, changed the list of procedure codes that define what constitutes an open heart surgery procedure (consistent with current Open Heart Surgery Standards).
- This revised set of procedure codes were then incorporated into the computation of the weights applied to discharge diagnoses to predict the number of open heart surgeries.
- Examination of this output, when matched against actual open heart surgical procedures at hospitals with open heart surgery programs, showed projections that are substantially less than the actual number of open heart procedures performed. Conversely, hospitals that did not have open heart surgery programs showed unrealistically high projections.
- To address this process weakness, MDCH staff proposed two separate sets of weights, one for Principal Diagnoses and the other for Non-Principal Diagnoses
- In addition, the computation of the weights was limited to using the data from only those hospitals that currently have open heart surgery programs. This strengthens the predictive value of the weights since they are directly associated with actual open heart procedures and discharge diagnoses.
- The current methodology included many diagnostic codes that had statistically insignificant volumes or whose predictability value was very low (in some cases 1% or less). To simplify the methodology and improve its predictive value, the number of diagnostic codes was reduced by applying a series of decision rules.
- The first decision rule applied to these codes was that there had to be at least 100 cases per year and the "weight" had to be greater than 10% to be considered a "Category" in the methodology.
- The second and third decision rules, established to identify which codes should remain in the "All Other Heart Conditions" category, is (2) that there must be at least ten cases per year and the weight greater than one percent and (3) that there must be at least 100 cases per year (no minimum weight criteria).
- Differences between the volumes calculated by the refined methodology were than adjusted to actual OHS volumes for each HSA. This is similar to the approach used by CON for eliminating the over projections of the need for Megavoltage Radiation Therapy treatments, based on cancer diagnoses resulting from the same patient with the same diagnosis being discharged from multiple hospitals.
- The refined methodology is to be run annually, following the release of the MIDB data-set.

Spectrum Health
BUTTERWORTH CAMPUS

100 Michigan Street NE Grand Rapids MI 49503-2560
616 391 1774 fax 391 2745

December 11, 2007

Norma Hagenow, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Hagenow,

This letter is written as formal testimony about the proposed substantive actions on the December 11, 2007 agenda related to the CON Review Standards for Open-Heart Surgery, Cardiac Catheterization Services, CT Scanners, and Nursing Home and Hospital Long-term Care Beds. Spectrum Health appreciates the opportunity to comment on these proposed Standards.

Open Heart Surgery Standards

Spectrum Health endorses the conclusion that there is no need for additional open-heart surgery programs in Michigan and that the citizens of the state are well-served by the existing programs. We support the major recommendations of the Open-Heart Surgery Standards Advisory Committee (SAC), namely: 1) that all open-heart programs should participate in the STS database; 2) that the minimum volume for open-heart surgery should remain at 300 cases per year; and 3) that hospitals should not be able to repeatedly commit their inpatient data to new open-heart surgery CON applications every seven (7) years. Finally, Spectrum Health supports the so-called S-3 methodology, that was developed to minimize the overemphasis on secondary diagnoses in the need formula for open-heart surgery.

Spectrum Health supports the proposed revisions to the CON Review Standards for Open-Heart Surgery, including the S-3 need methodology, and urges their final approval.

Cardiac Catheterization Standards

Spectrum Health supports the proposed revisions to the CON Review Standards for Cardiac Catheterization. In particular, we endorse the conclusions of the Standards Advisory Committee (SAC) for Cardiac Cath Services to revise the procedure weights, to update the requirements for advanced pediatric cardiac services, and to retain the requirement that elective angioplasty should be performed only in hospitals which have on-site open-heart surgery back-up.

Spectrum Health supports the proposed revisions to the CON Review Standards for Cardiac Catheterization Services and urges their final approval.

CT Standards

Spectrum Health is supportive of the recommended changes to the CON Review Standards for CT Scanners and urges their approval for public hearing. In particular, we endorse the following recommendations of the CT SAC: 1) revision of the definition of "Replace an Existing CT Scanner," changes to the data commitment process, requirements for dedicated pediatric CT scanners, and provisions for Trauma Centers to obtain special use CT scanners

Spectrum Health urges the CON Commission to submit the proposed CON Review Standards for CT Scanners for public comment and final decision in March 2008.

Nursing Home Bed Standards

Spectrum Health has substantial concerns about the draft provisions to the CON Review Standards for Nursing Home and Hospital Long-term Care Beds proposed to address quality issues. While Spectrum Health is a strong advocate for the provision of quality healthcare, we believe that the so-called "quality" provisions are significantly flawed and do not truly measure quality in long-term care. Spectrum Health suggests that these provisions be removed from the proposed CON Review Standards before they are approved for public hearing.

Spectrum Health supports developing appropriate ways to measure quality in the nursing home and long-term care environment. However, it is our opinion that the use of the state survey results, as proposed in the draft Standards, is not an appropriate mechanism for measuring the quality in the Certificate of Need (CON) application process. Therefore, we recommend that the Commission authorize the Department to continue to study this issue by soliciting input from interested parties across the state, with the goal of providing alternative quality recommendations to the Commission at the March meeting. Spectrum Health looks forward to participating in that process.

Megavoltage Radiation Therapy (MRT)

In his administrative report, Mr. Hart will be presenting proposed updates to the appendices for the CON Review Standards for MRT. According to Section 3 of the MRT Standards, the Commission may modify the contents of the appendices at any time, without going through the normal standards revisions process. In particular, the duplication rates and factors contained in Appendix A have not been updated in several years. Assuming that the statewide duplication rates have been increasing, use of out-of-date factors in the need formula could result in approval of unnecessary MRT programs across the state. Spectrum Health urges the Commission to approve the updated appendices with an effective date within the next 30 days.

Spectrum Health appreciates the work of the Commission and its advisory committees. We are committed to the CON process, and we look forward to continue to work with the Commission in the revision of the CON Review Standards.

Respectfully,

Robert A. Meeker
Strategic Program Manager

Attachment C

Date: December 11, 2007

To: Certificate of Need Commission

From: Daniel B. Shumaker, MD FACR
Chair, CT Standards Advisory Committee

Chairperson Hagenow and Members of the Commission,

I would like to present the final report of the Computed Tomography Standards Advisory Committee (CTSAC). The committee met formally five times between the months of July and November, and benefited from numerous consultations with other experts, interested parties, and Department staff as well. We were, at all times, mindful of the Commission's desire to have the work of the CTSAC completed by the December Commission meeting and were prepared to schedule additional meetings should they be required. The charge list given us to consider constituted a great deal of work and required substantial thought and discussion. Despite the short time frame, the members of the committee remained focused, thoughtful, and thorough. Indicative of those efforts is the fact that final votes taken, acting on the charges, were almost all unanimous, or nearly so. I would like to compliment and personally thank the Committee for their thoroughness and determination to complete our work in the time allotted.

In addition to the foundational question of whether CT should remain under CON regulation as a covered clinical service, the CTSAC was given 10 separate charges to consider by the Commission. I will address each of the charges in the order in which they appear on the charge list approved by the Commission on March 13, 2007.

The foundational question:

The CTSAC recommends that CT continues to be regulated by CON as a covered clinical service.

Rationale: This recommendation was apparently intuitive based upon the committee's prior experience. There was no substantive discussion on the motion to continue regulation.

Charge 1.) Review volume commitment numbers (actual, projected, and thresholds).

The CTSAC recommends no change in the current volume commitment numbers.

Rationale: Again, there was little substantive discussion of this charge. The committee felt that there was not an access issue with current fixed and mobile scanners, and therefore, recommends no change.

Charge 2.) Review relocation criteria and definition, i.e., unit vs. service similar to recent changes in other CON standards.

The CTSAC recommends that the standards adopt language which would allow for the relocation of a unit(s) as opposed to a "service."

Rationale: The committee felt generally that there was no compelling argument to restrain a service from relocating a single scanner or scanners, and adoption of this language would have the added benefit of making the standards more uniform with those for MRI and PET. There was substantial discussion regarding the time (36 months) a scanner needs to be in operation before being relocated. Ultimately, the committee agrees with the Department that uniformity with the MRI and PET standards is useful. The CTSAC, therefore, recommends no change in this requirement.

Charge 3.) Review replace/upgrade criteria and definitions.

The CTSAC recommends that the standards include language which only recognizes "replacement" of a scanner (defined as an equipment change in the existing scanner which requires a change in the Radiation Safety Certificate) to be regulated by CON.

The CTSAC further recommends that a scanner currently operating below minimum volume requirements (7500 CT equivalents) receive a one time exemption from those requirements to replace an existing scanner if the following conditions are satisfied:

1. The existing scanner is performing at least 5000 CT equivalents in the preceding 12 month period.
2. The existing scanner at one point met the minimum volume requirements.
3. The existing scanner is fully depreciated.

The CTSAC further recommends that a scanner currently operating below minimum volume requirements on a medical school campus receive a one time exemption from those requirements to replace an existing scanner if the following condition is satisfied:

1. The existing scanner is fully depreciated.

Rationale: Obviously, the committee felt that there were a number of issues inherent in this charge.

In the first recommendation, the committee felt generally that the current definition of "replace/upgrade" is vague, makes no distinction between the two, and is not uniform with other standards (MRI and PET). The committee agrees with the Department that the proposed language serves the intent of this section of the standards and makes the standards more uniform with MRI and PET.

In the second recommendation, the committee felt generally that there was a need to allow some underperforming scanners a replacement if it was felt that the underperformance was due primarily to the fact that the existing scanner was too old, too slow, or otherwise "obsolete." The committee also anticipates a change in the enforcement policy of the Department. These underperforming scanners, under the current standards, would not be in compliance. It is expected that following the one time exemption from the minimum volume requirements for replacement, the scanner would comply with current minimum volume requirements.

In the third recommendation, the committee felt generally that there was a need to allow an underperforming scanner on a medical school campus a replacement if it was felt that the underperformance was due primarily to the fact that the scanner was too old, too slow, or otherwise "obsolete." These scanners would not be in compliance with the proposed language, so a targeted exemption was necessary. The anticipation of an enforcement policy change at the Department, as well as the expectation that the new scanner will comply with the minimum volume requirements, is the same as above.

Charge 4.) Review commitment process; make them similar to MRI and PET.

The CTSAC recommends adoption of the proposed language that would require projection of physician referral commitments for initiation of a service to be based on actual physician referrals for the preceding 12-month period, and that the referrals will be verified with data maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

Rationale: The committee felt generally that there was a need to strengthen the physician referral commitment process and be made more uniform with similar provisions in the standards for MRI and PET. The committee agreed with the Department that, in so doing, it is necessary to ensure that physician referrals do not result in an existing scanner, from which the referrals may be transferred, falling out of compliance with the standards. Also included in the proposed language is clarification of the geographic parameters for referral commitments (75 mile radius for rural and micropolitan statistical area counties and 20 mile radius for metropolitan statistical area counties); similar language currently exist in the standards for MRI and PET.

Charge 5.) Review criteria and processes for addressing emerging specialty use scanners (e.g., dental, "mini", portable, and hybrid).

The CTSAC recommends adoption of the proposed language which would establish a Pilot Program to implement hospital based portable CT scanners into a limited number of facilities. Pilot Program requirements include, but are not limited to, certification as a Level I or Level II Trauma Facility by the American College of Surgeons. Qualified facilities could obtain up to two scanners of their choice. The scanner(s) would not be subject to minimum volume requirements and would not generate volume data for future CON applications. An important provision of the Pilot Program is the accumulation of data by the Department regarding utilization, cost, and benefit for patient care as compared to full body CT scanners.

The CTSAC further recommends adoption of the proposed language which provides for expansion, replacement, relocation and acquisition of Dental CT scanners, so as to conform to existing language for non-dental scanners. The recommended volume threshold for expansion is 300 dental procedures per year. The recommended volume threshold for replacement, relocation, and acquisition is 200 dental procedures per year. The CTSAC recommends no change in the current standards for initiation of a Dental CT.

Rationale: Understandably, this charge proved to be the most challenging for the committee. The members worked extremely hard to reconcile two competing principles; first, that we had determined previously that there is not an access issue for CT, and secondly, that there are emerging technologies in CT which are not currently available to patients in Michigan. The committee was also cognizant of the fact that any proposed changes in the standards should reflect the goal of CON to balance cost, quality, and access so that the introduction of emerging technologies is done in a controlled and responsible way. The CTSAC believes the first recommendation reconciles the competing principles and accomplishes the goals of CON.

The second recommendation under this charge does not adequately reflect the amount of time, discussion, and thoughtful consideration given to the issue of Dental CT scanners by the committee. The recommendation is largely technical in nature, intended to make the language conform to that which currently exists for non-Dental CT scanners. The proposed volume requirements for expansion are proportionally the same as for non-Dental CT scanners as well. The recommendation that no change in the current standards for initiation of a Dental CT scanner was debated thoroughly. The subject and definition of a "dental procedure" was also extensively discussed.

Charge 6.) Review potential pediatric and special needs criteria and need for specific weighting.

The CTSAC recommends adoption of the proposed language which would

establish criteria for a dedicated Pediatric CT scanner; closely resembling those which currently exist in the MRI and PET standards. Attached to these criteria are additions to the Project Delivery Requirements dealing with pediatric safety and dosimetry concerns.

The CTSAC further recommends adoption of the proposed language which recognizes the increased time and effort in imaging the pediatric patient in non-pediatric CT scanners; whether or not sedation is required. The CTSAC recommends the addition of a .25 conversion factor for pediatric patients to the existing weights for the calculation of CT volume data.

Rationale: The first recommendation was first proposed by Pediatric Radiology experts on and off the committee. The technical considerations in imaging a pediatric patient are similar to those in MRI and PET which contain similar provisions in their standards. The CTSAC agrees that a facility which primarily or exclusively images these patients should be provided for in the CT standards as they are in others.

The second recommendation is an extension of the first; i.e., it recognizes the technical considerations unique to imaging the pediatric patient which require increased time and effort. The CTSAC agrees that a facility which does not primarily or exclusively image pediatric patients should be provided for in the CT standards.

Charge 7.) Review use of commitments from neighboring states.

The CTSAC recommends clarification language to the definition of a "billable procedure" by adding that the CT procedure(s) be "performed in Michigan."

Rationale: The Department suggested language to clarify in the standards the current practice of counting only billable scans in Michigan. This is meant to explicitly confirm that we are only regulating CT Scanner usage in Michigan.

Charge 8.) Review CT scanner use in simulation MRT.

The CTSAC recommends that it be established in the standards that an additional exclusion to the definition of a "CT scanner" are "CT simulators used solely for treatment planning purposes in conjunction with an MRT unit."

Rationale: The Department suggested clarifying in the standards what is already in current practice – that CT scanner use in simulation MRT is an exclusion to the definition of "CT scanner" in the standards.

Charge 9.) Technical changes in language to be uniform with other CON standards.

The CTSAC recommends acceptance of technical changes in the language suggested by the Department.

Rationale: The recommended technical changes have been inserted for clarity

and consistency with the other CON Review Standards.

Charge 10.) Other items may be considered by the SAC Chairperson, if appropriate, at the initial meeting of the SAC. Consideration of additional items by the SAC shall not affect the established deadline for the SAC of December 11, 2007.

The CTSAC did not identify additional items to consider at its initial meeting.

This concludes the final report of the Computed Tomography Standards Advisory Committee. On behalf of the members of the committee, I would like to personally compliment the Department staff on their assistance and facilitation of the process.

Respectfully submitted,

Daniel B. Shumaker, MD FACR
Chair, CT Standards Advisory Committee

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR COMPUTED TOMOGRAPHY (CT) SCANNER 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. (1) These standards are requirements for the approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.

(2) CT scanner is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, ~~and~~ 16, 17, 21, AND 22, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) ~~(4)~~ The Department shall use sections 193 and 2014, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 18 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

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

(a) "Acquisition of aN EXISTING CT scanner service" means obtaining possession or control of aN EXISTING FIXED OR MOBILE CT scanner service ~~and its~~ OR EXISTING CT SCANNER ~~unit~~(s)~~, whether fixed or mobile,~~ by contract, ownership, or ~~otherwise~~OTHER COMPARABLE ARRANGEMENT. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit, AND PERFORMED IN MICHIGAN.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(e) "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.

(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) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(h) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 2115.

(i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ~~and~~ ultrasound computed tomographic systems, AND CT

SIMULATORS USED SOLELY FOR TREATMENT PLANNING PURPOSES IN CONJUNCTION WITH AN MRT UNIT.

~~(j) "CT scanner equipment," for purposes of sections 3 and 6 of these standards, means the equipment necessary to perform CT scans. It does not include any construction or renovations activities associated with the installation of the CT scanner, or service or maintenance contracts which under generally accepted accounting principles are properly chargeable as an expense of operation.~~

(J) "CT SCANNER SERVICES" MEANS THE CON-APPROVED UTILIZATION OF A CT SCANNER(S) AT ONE SITE IN THE CASE OF A FIXED CT SCANNER SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE CT SCANNER SERVICE.

(K) "DEDICATED PEDIATRIC CT" MEANS A FIXED CT SCANNER ON WHICH AT LEAST 70% OF THE CT PROCEDURES ARE PERFORMED ON PATIENTS UNDER 18 YEARS OF AGE.

(~~k~~L) "Dental CT EXAMINATIONS~~images~~" means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.

(~~l~~M) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

(~~m~~N) "Department" means the Michigan Department of Community Health (MDCH).

~~(n) "Driving time," for purposes of these standards, means the driving time in minutes as identified by use of mapping software that is verifiable by the Department.~~

(o) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(P) "EXISTING CT SCANNER SERVICE" MEANS THE UTILIZATION OF A CON-APPROVED AND OPERATIONAL CT SCANNER(S) AT ONE SITE IN THE CASE OF A FIXED CT SCANNER SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE CT SCANNER SERVICE.

(Q) "EXISTING CT SCANNER" MEANS A CON-APPROVED AND OPERATIONAL CT SCANNER USED TO PROVIDE CT SCANNER SERVICES.

(R) "EXISTING MOBILE CT SCANNER SERVICE" MEANS A CON-APPROVED AND OPERATIONAL CT SCANNER AND TRANSPORTING EQUIPMENT OPERATED BY A CENTRAL SERVICE COORDINATOR SERVING TWO OR MORE HOST SITES.

(~~p~~S) "Expand aN EXISTING CT scanner service" means the addition of one or more CT scanners at an existing CT scanner service.

(~~q~~T) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(~~r~~U) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

(V) "HOSPITAL-BASED PORTABLE CT SCANNER" MEANS A CT SCANNER CAPABLE OF BEING TRANSPORTED INTO PATIENT CARE AREAS (I.E., ICU ROOMS, OPERATING ROOMS, ETC.) TO PROVIDE HIGH-QUALITY IMAGING OF CRITICALLY ILL PATIENTS.

(~~s~~W) "Host SITE~~facility~~" means the site at which a mobile CT scanner is AUTHORIZED~~located in order~~ to provide CT scanner services.

(~~t~~X) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing CT scanner service or the renewal of a lease.

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

(~~v~~Z) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(~~w~~AA) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(~~x~~BB) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(~~y~~CC) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(DD) "PEDIATRIC PATIENT" MEANS ANY PATIENT LESS THAN 18 YEARS OF AGE.

(EE) "RELOCATE A FIXED CT SCANNER" MEANS A CHANGE IN THE LOCATION OF A FIXED CT SCANNER FROM THE EXISTING SITE TO A DIFFERENT SITE WITHIN THE RELOCATION ZONE.

(~~z~~FF) "Relocate an existing CT scanner service" means a change in the geographic location of an existing fixed CT scanner service ~~and its unit(s)~~ from an existing site to a different site.

(~~aa~~GG) "Relocation zone," ~~for purposes of these standards,~~ means a site that is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county.

(~~bb~~HH) "Replace~~/upgrade~~ aN EXISTING CT scanner" means an equipment change OF AN EXISTING CT SCANNER, THAT REQUIRES A CHANGE IN THE RADIATION SAFETY CERTIFICATE, proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion, AT THE SAME GEOGRAPHIC LOCATION.

(~~cc~~II) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(JJ) "SEDATED PATIENT" MEANS A PATIENT THAT MEETS ALL OF THE FOLLOWING:

(I) PATIENT UNDERGOES PROCEDURAL SEDATION AND WHOSE LEVEL OF CONSCIOUSNESS IS EITHER MODERATE SEDATION OR A HIGHER LEVEL OF SEDATION, AS DEFINED BY THE AMERICAN ASSOCIATION OF ANESTHESIOLOGISTS, THE AMERICAN ACADEMY OF PEDIATRICS, THE JOINT COMMISSION ON THE ACCREDITATION OF HEALTH CARE ORGANIZATIONS, OR AN EQUIVALENT DEFINITION.

(II) WHO REQUIRES OBSERVATION BY PERSONNEL, OTHER THAN TECHNICAL EMPLOYEES ROUTINELY ASSIGNED TO THE CT UNIT, WHO ARE TRAINED IN CARDIOPULMONARY RESUSCITATION (CPR) AND PEDIATRIC ADVANCED LIFE SUPPORT (PALS).

(KK) "SPECIAL NEEDS PATIENT" MEANS A NON-SEDATED PATIENT, EITHER PEDIATRIC OR ADULT, WITH ANY OF THE FOLLOWING CONDITIONS: DOWN SYNDROME, AUTISM, ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD), DEVELOPMENTAL DELAY, MALFORMATION SYNDROMES, HUNTER'S SYNDROME, MULTI-SYSTEM DISORDERS, PSYCHIATRIC DISORDERS, AND OTHER CONDITIONS THAT MAKE THE PATIENT UNABLE TO COMPLY WITH THE POSITIONAL REQUIREMENTS OF THE EXAM.

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

Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service other than a dental CT scanner service OR HOSPITAL-BASED PORTABLE CT SCANNER SERVICE

Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the following, as applicable:

(1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the following:

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

(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.

(2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1), proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT

equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner service

Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the following, as applicable:

(1) An applicant is proposing a fixed CT scanner service for the sole purpose of PERFORMING~~generating~~ dental CT~~ct~~ EXAMINATIONS~~images~~.

(2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

(3) An applicant proposing to initiate a dental CT scanner service shall project an operating level of at least 200 dental CT EXAMINATIONS~~images~~ per year for the second 12-month period after beginning operation of the dental CT scanner.

(4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(5) The applicant has demonstrated to the satisfaction of the Department that the dental CT EXAMINATIONS~~images~~ generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

Section 5. Requirements FOR APPROVAL FOR APPLICANTS PROPOSING to expand aN EXISTING CT scanner service OTHER THAN A DENTAL CT SCANNER SERVICE OR HOSPITAL-BASED PORTABLE CT SCANNER SERVICE

Sec. 5. (1) ~~If a~~An applicant propos~~ING~~es to expand aN EXISTING fixed CT scanner service~~, the applicant~~ shall demonstrate~~ each of the following:~~

~~(a)The applicant shall project an average operating level of at least 7,500 CT equivalents for each fixed CT scanner, existing and proposed, operated by the applicant for the second 12-month period after initiation of operation of each additional CT scanner.~~

~~(b)A~~ THAT All of the applicant's fixed CT scanners, EXCLUDING CT SCANNERS APPROVED PURSUANT TO SECTIONS 13 AND 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) AN APPLICANT PROPOSING TO EXPAND AN EXISTING FIXED CT SCANNER SERVICE APPROVED PURSUANT TO SECTION 17 SHALL DEMONSTRATE THAT ALL OF THE APPLICANT'S DEDICATED PEDIATRIC CT SCANNERS HAVE PERFORMED AN AVERAGE OF AT LEAST 3,000 CT EQUIVALENTS PER DEDICATED PEDIATRIC CT SCANNER FOR THE MOST RECENT

CONTINUOUS 12-MONTH PERIOD PRECEDING THE APPLICANT'S REQUEST. IN COMPUTING THIS AVERAGE, THE DEPARTMENT WILL DIVIDE THE TOTAL NUMBER OF CT EQUIVALENTS PERFORMED BY THE APPLICANT'S TOTAL NUMBER OF DEDICATED PEDIATRIC CT SCANNERS, INCLUDING BOTH OPERATIONAL AND APPROVED BUT NOT OPERATIONAL DEDICATED PEDIATRIC CT SCANNERS.

(~~2~~3) If an applicant proposes to expand aN EXISTING mobile CT scanner service, the applicant shall demonstrate ~~each of the following:~~

~~(a) The applicant shall project an operating level of at least 4,000 CT equivalents for each existing and proposed mobile CT scanner for the second 12-month period after beginning operation of each additional CT scanner.~~

~~(b)~~ A THAT All of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

SECTION 6. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO EXPAND AN EXISTING DENTAL CT SCANNER SERVICE

SEC. 6. AN APPLICANT PROPOSING TO EXPAND AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT ALL OF THE APPLICANT'S DENTAL CT SCANNERS HAVE PERFORMED AN AVERAGE OF AT LEAST 300 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER FOR THE MOST RECENT CONTINUOUS 12-MONTH PERIOD PRECEDING THE APPLICANT'S REQUEST. IN COMPUTING THIS AVERAGE, THE DEPARTMENT WILL DIVIDE THE TOTAL NUMBER OF DENTAL CT EXAMINATIONS PERFORMED BY THE APPLICANT'S TOTAL NUMBER OF FIXED DENTAL CT SCANNERS, INCLUDING BOTH OPERATIONAL AND APPROVED BUT NOT OPERATIONAL FIXED DENTAL CT SCANNERS.

Section ~~7~~6. Requirements for APPROVAL FOR applicaNTS~~tions~~ proposing to replace~~/upgrade~~ aN EXISTING CT scanner OTHER THAN A DENTAL CT SCANNER OR HOSPITAL-BASED PORTABLE CT SCANNER

Sec. ~~7~~6. ~~In order to be approved, a~~An applicant proposing to replace~~/upgrade~~ an existing CT scanner shall demonstrate each of the following, as applicable:

~~(1) A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital shall demonstrate each of the following:~~

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

~~(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.~~

~~(c) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.~~

(~~2~~1) An applicant, other than an applicant meeting all of the applicable requirements of subsection ~~(1)~~(A), (B) OR (C) BELOW, proposing to replace~~/upgrade~~ an existing fixed CT scanner shall demonstrate that the FIXED CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 7,500 CT EQUIVALENTS PER FIXED CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.~~volume of CT equivalents, during the 12-month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 7,500 CT equivalents if the applicant operates only one fixed CT scanner, or an average of 7,500 CT equivalents for each fixed CT scanner if the applicant operates more than one fixed CT scanner at the same site.~~

(A) A HOSPITAL PROPOSING TO REPLACE AN EXISTING CT SCANNER WHICH IS THE ONLY FIXED CT SCANNER OPERATED AT THAT SITE BY THE HOSPITAL SHALL DEMONSTRATE EACH

OF THE FOLLOWING:

(I) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(II) THE HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS.

(III) THE REPLACEMENT CT SCANNER WILL BE LOCATED AT THE SAME SITE AS THE CT SCANNER TO BE REPLACED.

(B) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER SHALL BE EXEMPT ONCE FROM THE VOLUME REQUIREMENTS IF THE EXISTING CT SCANNER DEMONSTRATES THAT IT MEETS ALL OF THE FOLLOWING:

(I) THE EXISTING CT SCANNER HAS PERFORMED AT LEAST 5,000 CT EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(II) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(III) THE EXISTING CT SCANNER HAS AT ONE TIME MET ITS MINIMUM VOLUME REQUIREMENTS.

(C) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER ON AN ACADEMIC MEDICAL CENTER CAMPUS, AT THE SAME SITE, SHALL BE EXEMPT ONCE, AS OF THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS FOR REPLACEMENT IF THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(~~3~~2) An applicant proposing to replace~~/upgrade~~ an existing mobile CT scanner(s) shall demonstrate that the MOBILE CT SCANNER(S) PERFORMED ~~volume of CT equivalents, during the 12-month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was~~ at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network, IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(3) AN APPLICANT PROPOSING TO REPLACE AN EXISTING DEDICATED PEDIATRIC CT SCANNER(S) SHALL DEMONSTRATE THAT THE DEDICATED PEDIATRIC CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 2,500 CT EQUIVALENTS PER DEDICATED PEDIATRIC CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(4) An applicant under this section shall demonstrate that the EXISTING CT scanner(s) proposed to be replaced~~/upgraded~~ is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement~~/upgraded~~ CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

SECTION 8. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO REPLACE AN EXISTING DENTAL CT SCANNER

SEC. 8. AN APPLICANT PROPOSING TO REPLACE AN EXISTING DENTAL CT SCANNER SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED DENTAL CT SCANNER SHALL DEMONSTRATE THAT THE FIXED DENTAL CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(2) AN APPLICANT UNDER THIS SECTION SHALL DEMONSTRATE THAT THE EXISTING DENTAL CT SCANNER(S) PROPOSED TO BE REPLACED IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES, OR, THAT THE EXISTING EQUIPMENT CLEARLY POSES A THREAT TO THE SAFETY OF THE PUBLIC, OR THAT THE PROPOSED REPLACEMENT DENTAL CT SCANNER OFFERS TECHNOLOGICAL IMPROVEMENTS WHICH ENHANCE QUALITY OF CARE, INCREASE EFFICIENCY, AND/OR REDUCE OPERATING COSTS AND PATIENT CHARGES.

Section 9~~7~~. Requirements for approval for applicants proposing to relocate an existing CT scanner service AND/OR CT SCANNER(S) OTHER THAN AN EXISTING DENTAL CT SCANNER SERVICE AND/OR DENTAL CT SCANNER(S) OR HOSPITAL-BASED PORTABLE CT SCANNER(S)

Sec. 9~~7~~. (1) An applicant proposing to relocate AN~~its~~ existing FIXED CT scanner service ~~and its unit(s)~~ shall demonstrate that the proposed project meets all of the following:

~~(1) The CT scanner service and its unit(s) to be relocated is a fixed CT scanner unit(s).~~

(A~~2~~) The EXISTING FIXED CT scanner service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(B~~3~~) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 5 OR 7, AS APPLICABLE, HAVE BEEN MET.~~The proposed project will not result in the replacement of the CT scanner unit(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.~~

~~(4) The proposed project will not result in an increase in the number of fixed unit(s) being operated by the CT scanner service that is proposed to be relocated.~~

~~(5) The proposed site to which the CT scanner service is proposed to be relocated is in the relocation zone.~~

(D~~6~~) The CT scanner service ~~and its unit(s)~~ to be relocated performed at least an average of 7,500 CT equivalents per fixed SCANNER~~unit~~ in the most recent 12-month period~~, or most recent annualized 6-month period,~~ for which the Department has verifiable data.

(E~~7~~) The applicant agrees to operate the CT scanner service ~~and its unit(s)~~ in accordance with all applicable project delivery requirements set forth in Section 19~~3~~ of these standards.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED CT SCANNER(S) OF AN EXISTING CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING CT SCANNER SERVICE FROM WHICH THE CT SCANNER(S) IS TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 5 OR 7, AS APPLICABLE, HAVE BEEN MET.

(D) EACH EXISTING CT SCANNER AT THE SERVICE FROM WHICH A SCANNER IS TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 7,500 CT EQUIVALENTS PER FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE CT SCANNER(S) AT THE PROPOSED SITE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

SECTION 10. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO RELOCATE AN EXISTING DENTAL CT SCANNER SERVICE AND/OR DENTAL CT SCANNER(S)

SEC. 10. (1) AN APPLICANT PROPOSING TO RELOCATE AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING FIXED DENTAL CT SCANNER SERVICE TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTH AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 6 OR 8, AS APPLICABLE, HAVE BEEN MET.

(D) THE DENTAL CT SCANNER SERVICE TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE DENTAL CT SCANNER SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED DENTAL CT SCANNER(S) OF AN EXISTING DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING DENTAL CT SCANNER SERVICE FROM WHICH THE DENTAL CT SCANNER(S) IS TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 6 OR 8, AS APPLICABLE HAVE BEEN MET.

(D) EACH EXISTING DENTAL CT SCANNER AT THE SERVICE FROM WHICH A SCANNER IS TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE DENTAL CT SCANNER(S) AT THE PROPOSED SITE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

Section 118. Requirements for approval for applicants proposing to acquire an existing CT scanner service ~~and its unit(s)~~ OR AN EXISTING CT SCANNER(S) OTHER THAN AN EXISTING DENTAL CT SCANNER SERVICE AND/OR AN EXISTING DENTAL CT SCANNER(S) OR HOSPITAL-BASED PORTABLE CT SCANNER(S)

Sec. 118. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service ~~and its unit(s)~~ shall demonstrate that a proposed project meets all of the following:

(~~1~~A) THE REQUIREMENTS OF SECTIONS 5, 7, OR 9, AS APPLICABLE, HAVE BEEN MET.~~The project will not result in the replacement of the CT scanner unit at the CT scanner service to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.~~

~~(2) The project will not result in a change in the site at which the existing CT scanner service and its unit(s) is operated unless the proposed project meets the requirements of Section 7.~~

~~(3) The project will not change the number of CT scanner unit(s) at the site of the CT scanner service being acquired unless the applicant demonstrates that project is in compliance with the requirements of Section 5 as applicable.~~

(~~4~~B) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner service, for which a final decision has not been issued after ~~the effective date of these standards~~JUNE 4, 2004, an existing CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service ~~and its unit(s)~~ shall be operating at the applicable volume requirements set forth in Section 19~~3~~ of these standards in the second 12 months after the date the service ~~and its unit(s)~~ is acquired, and annually thereafter.

(~~5~~C) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, ~~except the first application approved pursuant to subsection (4), for which a final decision has not been~~

~~issued after the effective date of these standards,~~ an applicant shall be required to demonstrate that the CT scanner service ~~and its unit(s)~~ to be acquired performed at least 7,500 CT equivalents in the most recent 12-month period~~, or most recent annualized 6-month period,~~ for which the Department has verifiable data.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE CT SCANNER(S) OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 5, 7 OR 9, AS APPLICABLE, HAVE BEEN MET.
(B) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED OR MOBILE CT SCANNER(S) OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE FIXED OR MOBILE CT SCANNER(S) TO BE ACQUIRED PERFORMED AT LEAST 7,500 CT EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

SECTION 12. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING DENTAL CT SCANNER SERVICE OR AN EXISTING DENTAL CT SCANNER(S)

SEC. 12. (1) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT A PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 6, 8, OR 10, AS APPLICABLE, HAVE BEEN MET.
(B) FOR AN APPLICATION FOR THE PROPOSED FIRST ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, FOR WHICH A FINAL DECISION HAS NOT BEEN ISSUED AFTER THE EFFECTIVE DATE OF THESE STANDARDS, AN EXISTING DENTAL CT SCANNER SERVICE TO BE ACQUIRED SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENT APPLICABLE TO THE SELLER/LESSOR ON THE DATE THE ACQUISITION OCCURS. THE DENTAL CT SCANNER SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.
(C) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE CT SCANNER SERVICE TO BE ACQUIRED PERFORMED AT LEAST 200 DENTAL CT EXAMINATIONS IN THE MOST RECENT 12-MONTH PERIOD, FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED DENTAL CT SCANNER(S) OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 6, 8, OR 10, AS APPLICABLE, HAVE BEEN MET.
(B) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER(S) OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE FIXED DENTAL CT SCANNER(S) TO BE ACQUIRED PERFORMED AT LEAST 200 DENTAL CT EXAMINATIONS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

SECTION 13. PILOT PROGRAM REQUIREMENTS FOR APPROVAL OF A HOSPITAL-BASED PORTABLE CT SCANNER FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION

SEC. 13. AS A PILOT PROGRAM, AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE A HOSPITAL-BASED PORTABLE CT SCANNER SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICANT IS LIMITED TO THE INITIATION, EXPANSION, REPLACEMENT, OR ACQUISITION OF NO MORE THAN TWO HOSPITAL-BASED PORTABLE CT SCANNERS.

(2) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(3) THE HOSPITAL HAS BEEN CERTIFIED AS A LEVEL I OR LEVEL II TRAUMA FACILITY BY THE AMERICAN COLLEGE OF SURGEONS.

(4) THE APPLICANT AGREES TO OPERATE THE HOSPITAL-BASED PORTABLE CT SCANNER IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

(5) THE APPROVED HOSPITAL-BASED PORTABLE CT SCANNER WILL NOT BE SUBJECT TO CT VOLUME REQUIREMENTS.

(6) THE APPLICANT MAY NOT UTLIZE CT PROCEDURES PERFORMED ON A HOSPITAL-BASED PORTABLE CT SCANNER TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS.

(7) THE PROVISIONS OF SECTION 13 ARE PART OF A PILOT PROGRAM APPROVED BY THE CON COMMISSION AND SHALL EXPIRE AND BE OF NO FURTHER FORCE AND EFFECT, AND SHALL NOT BE APPLICABLE TO ANY APPLICATION WHICH HAS NOT BEEN SUBMITTED BY OCTOBER 1, 2008.

Section 14~~9~~. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, and acquisition

Sec. 14~~9~~. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 19~~3~~ of these standards.

(3) The approved PET/CT hybrid will not be subject to CT volume requirements.

(4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid SCANNER~~unit~~ to demonstrate need or to satisfy CT CON review standards requirements.

Section 15~~0~~. Additional requirements for approval of a mobile CT scanner service

Sec. 15~~0~~. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following:

(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.

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

(c) The requirements of sections 3, 5, or 7~~6~~, as applicable, have been met.

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

(b) A separate CON application has been filed for each host facility.

(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner network shall demonstrate that approval of the application will not replace the CT scanner and transporting equipment unless the applicable requirements of Section 76 have been met.

Section 161. Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of PERFORMINGgenerating dental CT EXAMINATIONSimages exclusively for research

Sec. 161. (1) An applicant proposing a CT scanner used for the sole purpose of PERFORMINGgenerating dental CT EXAMINATIONSimages exclusively for research shall demonstrate each of the following:

(a) The applicant operates a dental radiology program in a certified dental school.

(b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of approval in Section 193(4).

(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with the requirements of sections 4(2), 4(4) and 4(5).

SECTION 17. REQUIREMENTS FOR APPROVAL OF AN APPLICANT PROPOSING TO ESTABLISH DEDICATED PEDIATRIC CT

SEC. 17. (1) AN APPLICANT PROPOSING TO ESTABLISH DEDICATED PEDIATRIC CT SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(A) THE APPLICANT SHALL HAVE EXPERIENCED AT LEAST 7,000 PEDIATRIC (< 18 YEARS OLD) DISCHARGES (EXCLUDING NORMAL NEWBORNS) IN THE MOST RECENT YEAR OF OPERATION.

(B) THE APPLICANT SHALL HAVE PERFORMED AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES IN THE MOST RECENT YEAR OF OPERATION.

(C) THE APPLICANT SHALL HAVE AN ACTIVE MEDICAL STAFF, AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT THAT INCLUDES, BUT IS NOT LIMITED TO, PHYSICIANS WHO ARE FELLOWSHIP-TRAINED IN THE FOLLOWING PEDIATRIC SPECIALTIES:

(I) PEDIATRIC RADIOLOGY (AT LEAST TWO)

(II) PEDIATRIC ANESTHESIOLOGY

(III) PEDIATRIC CARDIOLOGY

(IV) PEDIATRIC CRITICAL CARE

(V) PEDIATRIC GASTROENTEROLOGY

(VI) PEDIATRIC HEMATOLOGY/ONCOLOGY

(VII) PEDIATRIC NEUROLOGY

(VIII) PEDIATRIC NEUROSURGERY

(IX) PEDIATRIC ORTHOPEDIC SURGERY

(X) PEDIATRIC PATHOLOGY

(XI) PEDIATRIC PULMONOLOGY

(XII) PEDIATRIC SURGERY

(XIII) NEONATOLOGY

(D) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

(I) PEDIATRIC BONE MARROW TRANSPLANT PROGRAM
(II) ESTABLISHED PEDIATRIC SEDATION PROGRAM
(III) PEDIATRIC OPEN HEART PROGRAM

(2) AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (1) SHALL BE EXEMPT FROM MEETING THE REQUIREMENTS OF SECTION 3 OF THESE STANDARDS.

Section 182. Requirements for approval -- all applicants

Sec. 182. ~~An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department~~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 193. Project delivery requirements--terms of approval for all applicants

Sec. 193. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards

(b) Compliance with applicable safety and operating standards

(c) Compliance with the following quality assurance standards:

(i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(A) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(B) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to screening and interpretation if the applicant requires the screening of requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(iv) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis (either on-site or through telecommunication capabilities) to make the final interpretation.

(v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site or available through telecommunication

capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A) within 24 hours.

(vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency patients.

(viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(X) AN APPLICANT APPROVED UNDER SECTION 17 MUST BE ABLE TO PROVE THAT ALL RADIOLOGISTS, TECHNOLOGISTS AND NURSING STAFF WORKING WITH CT PATIENTS HAVE CONTINUING EDUCATION OR IN-SERVICE TRAINING ON PEDIATRIC LOW-DOSE CT. THE SITE MUST ALSO BE ABLE TO PROVIDE EVIDENCE OF DEFINED LOW-DOSE PEDIATRIC CT PROTOCOLS.

(~~x~~XI) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(A) not deny CT scanner services to any individual based on ability to pay or source of payment;

(B) provide CT scanning services to any individual based on the clinical indications of need for the service; and

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

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

(~~xi~~XII) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site ~~or unit~~ as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~xii~~XIII) Equipment to be replaced shall be removed from service.

(~~xiii~~IV) The applicant shall provide the Department with a notice stating the date the approved CT scanner service ~~and its unit(s)~~ is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

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

(d) An applicant approved under Section 4 shall not be required to be in compliance with subsection (c) but shall be in compliance with the following quality assurance standards:

(i) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month period after beginning operation of the dental CT scanner and annually thereafter.

(ii) The CT scanner will be used for the sole purpose of dental CT EXAMINATIONS~~images~~.

(iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT

EXAMINATIONS~~images~~ generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(~~v~~VI) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the dental CT EXAMINATIONS~~images~~ for performing dental procedures has had the appropriate training and/or experience certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(~~vi~~VII) The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan population, shall:

(a) not deny dental CT scanner services to any individual based on ability to pay or source of payment;

(b) provide dental ct scanning services to any individual based on the clinical indications of need for the service; and

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

(~~vii~~VIII) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site ~~or unit~~ as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~viii~~IX) Equipment to be replaced shall be removed from service.

(~~ix~~X) The applicant shall provide the Department with a notice stating the date the approved dental CT scanner service ~~and its unit(s)~~ is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

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

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~AGREED TO BY the applicant or its authorized agent.

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

(4) An applicant for a CT scanner used for dental research under Section 16~~1~~(1) shall agree that the services provided by the CT scanner approved pursuant to Section 16~~1~~(1) shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the CT scanner used for dental research pursuant to section 16~~1~~(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The CT scanner used for dental research approved pursuant to section 16~~1~~(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than section 16~~1~~.

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

(A) THE APPLICANT AGREES TO PROVIDE QUARTERLY REPORTS TO THE DEPARTMENT

WITHIN ONE MONTH FOLLOWING THE END OF EACH CALENDAR QUARTER, STARTING WITH THE QUARTER THE APPLICANT INITIATES USE OF THE HOSPITAL-BASED PORTABLE CT SCANNER.

(B) THE DEPARTMENT WILL DEVELOP A QUESTIONNAIRE TO BE USED BY THE APPLICANT FOR THE QUARTERLY REPORT. THIS QUESTIONNAIRE, AT A MINIMUM, WILL INCLUDE INFORMATION REGARDING THE UTILIZATION, COST, AND BENEFIT FOR PATIENT CARE AS COMPARED TO THE USE OF FULL-BODY CT SCANNERS.

(C) THE DEPARTMENT WILL SUMMARIZE THE INFORMATION FROM THE QUARTERLY REPORTS AND PROVIDE AN ASSESSMENT TO THE COMMISSION PRIOR TO THE MARCH 2010 COMMISSION MEETING. THE COMMISSION MAY REQUEST UPDATES ON THE STATUS OF THE PILOT PROGRAM AT ITS DISCRETION.

Section 2014. Project delivery requirements - additional terms of approval for applicants involving mobile CT scanners

Sec. 2014. (1) In addition to the provisions of Section 193, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) A host facility shall submit only one CON application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community Health prior to ending service with an existing host facility.

(c) A CON shall be required to add a host facility.

(d) A CON shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner ~~equipment~~ as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner ~~unit~~ at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner ~~unit~~ of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT SCANNER services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the Department by the central service coordinator under the terms of Section 193(1)(c)(xi).

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the owner or the governing body of~~ AGREED TO BY the applicant or its authorized agent.

Section 215. Determination of CT Equivalents

Sec. 215. For purposes of these standards, CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

(D) THE CONVERSION FACTOR FOR PEDIATRIC/SPECIAL NEEDS PATIENTS DOES NOT APPLY TO PROCEDURES PERFORMED ON A DEDICATED PEDIATRIC CT SCANNER.

Table 1 Category	Number of Billable CT Procedures		Conversion Factor		CT Equivalents
Head Scans w/o Contrast	_____	X	1.00	=	_____
(includes dental CT EXAMINATIONS~~images~~)					
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS W/O CONTRAST (INCLUDES DENTAL CT EXAMINATIONS)		X	1.25	=	
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS WITH CONTRAST		X	1.50	=	
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS W/O & W CONTRAST		X	2.00	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS W/O CONTRAST		X	1.75	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS WITH CONTRAST		X	2.00	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS W/O & W CONTRAST		X	3.00	=	
TOTAL CT EQUIVALENTS					_____

Section 2216. Documentation of projections

Sec. 2216. ~~(1)~~ An applicant required to project volumes ~~of service~~ under sections 3, 4 and 5 shall DEMONSTRATE THE FOLLOWING, AS APPLICABLE:~~specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation the Department shall determine whether the projections are reasonable.~~

(1) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 3 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL PHYSICIAN REFERRALS THAT RESULTED IN AN ACTUAL SCAN FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION. HISTORICAL PHYSICIAN REFERRALS WILL BE VERIFIED WITH THE

DATA MAINTAINED BY THE DEPARTMENT THROUGH ITS "ANNUAL HOSPITAL STATISTICAL SURVEY" AND/OR "ANNUAL FREESTANDING STATISTICAL SURVEY."

(2) An applicant required to project ~~volumes of service~~ under Section 4 shall demonstrate that the projection is based on a combination of the following for the most recent 12-month period immediately preceding the date of the application:

(a) the number of dental procedures performed by the applicant, and

(b) the number of committed dental procedures performed by referring licensed dentists.

~~(3)~~ FURTHER, ~~T~~The applicant and the referring licensed dentists shall substantiate the numbers ~~in subsection (2)~~ through the submission of HIPAA compliant billing records.

(3) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 5 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL UTILIZATION AT THE APPLICANT'S SITE FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION.

(4) AN APPLICANT SHALL DEMONSTRATE THAT THE PROJECTED NUMBER OF REFERRALS TO BE PERFORMED AT THE PROPOSED SITE UNDER SUBSECTIONS (1) AND (2) ARE FROM AN EXISTING CT SCANNER SERVICE THAT IS IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE, AND WILL CONTINUE TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE SUBSEQUENT TO THE INITIATION OF THE PROPOSED CT SCANNER SERVICE BY AN APPLICANT. IN DEMONSTRATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICANT SHALL PROVIDE EACH OF THE FOLLOWING:

(A) A WRITTEN COMMITMENT FROM EACH REFERRING PHYSICIAN THAT HE OR SHE WILL REFER AT LEAST THE VOLUME OF CT SCANS TO BE TRANSFERRED TO THE PROPOSED CT SCANNER SERVICE FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE CT SCANNER SERVICE PROPOSED BY AN APPLICANT.

(B) THE NUMBER OF REFERRALS COMMITTED MUST HAVE RESULTED IN AN ACTUAL CT SCAN OF THE PATIENT AT THE EXISTING CT SCANNER SERVICE FROM WHICH REFERRAL WILL BE TRANSFERRED. THE COMMITTING PHYSICIAN MUST MAKE AVAILABLE HIPAA COMPLIANT AUDIT MATERIAL IF NEEDED UPON DEPARTMENT REQUEST TO VERIFY REFERRAL SOURCES AND OUTCOMES. COMMITMENTS MUST BE VERIFIED BY THE MOST RECENT DATA SET MAINTAINED BY THE DEPARTMENT THROUGH ITS "ANNUAL HOSPITAL STATISTICAL SURVEY" AND/OR "ANNUAL FREESTANDING STATISTICAL SURVEY."

(C) THE PROJECTED REFERRALS ARE FROM AN EXISTING CT SCANNER SERVICE WITHIN A 75-MILE RADIUS FOR RURAL AND MICROPOLITAN STATISTICAL AREA COUNTIES OR 20-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA COUNTIES.

Section 23~~17~~. Effect on prior CON review standards; comparative reviews

Sec. 23~~17~~. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~March 9, 2004~~SEPTEMBER 19, 2006 and effective ~~June 4, 2004~~DECEMBER 27, 2006.

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

APPENDIX A

CON REVIEW STANDARDS FOR CT SCANNER SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:
65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

Michigan Department of Community Health (MDCH) Report
Open Heart Surgery (OHS) Services – A Revised Methodology
December 11, 2007

In opening, we wish to note that it is generally acknowledged that Michigan has a mature network of open heart programs and that it appears that there is no need for additional OHS programs in the State of Michigan. Adding more programs, especially when the utilization of open heart surgery is steadily declining, may result in a negative outcome by producing lower quality and higher costs. However, as situations evolve and time passes, there may be a need for additional programs.

The current methodology for OHS services utilizes a methodology adopted by the Certificate of Need (CON) Commission over 20 years ago. The 2007 OHS Standard Advisory Committee (SAC) had as one of its goals, to review the methodology and make the appropriate updates. As final analytic data were not available to the SAC upon its statutorily designated 6 month deadline, the SAC recommended that the Department generate the needed data to permit updating of the relevant utilization weights.

The Department included the results of this task to the CON Commission at their September meeting. Examination of this data, when matched against actual OHS procedures at hospitals with open heart surgery programs, showed projections that were substantially less than the actual number of OHS procedures performed. Conversely, hospitals that did not have open heart surgery programs showed unrealistically high projections. The CON Commission felt a need for a more comprehensive review of the methodology as well as a need for recommendations for any potential modifications in order to take action. The Commission asked the Department to develop potential modifications and to solicit comments related to "methodology questions, which would include, but not be limited to weighting, volume, and use of primary versus secondary data [diagnosis]."

Refinements to the OHS methodology for projecting the need for additional OHS programs in Michigan – proposed by MDCH and identified as S-3 – were developed pursuant to strong requests by the SAC, the public, and the Commission. In developing this model, the Department worked with a broad group of stakeholders and solicited public comment/input. These refinements have made much progress in strengthening the open heart methodology and have gone a long way to improve the predictability of this process.

Following much work and analyses, the Department posted draft language for consideration at the October 31 Public Hearing. This language includes Proposed Amendments that incorporate the revised methodology of S-3.

In brief, the Department's proposed methodology incorporates two separate sets of weights, one for Principal Diagnoses and the other for Non-Principal Diagnoses. Additionally, computation of the weights is limited to using the data from only those hospitals that currently have OHS programs; this strengthens the predictive value of the

weights since they are directly associated with actual open heart procedures and discharge diagnoses. For the computation, the third major modification is the incorporation of all available procedure codes ("any mention") within each diagnostic code. As part of the work, the Department also spent more time on a more detailed review of the procedure codes and categorization of the diagnostic codes.

The Department has received overall strong support for these recommended refinements to the OHS methodology developed pursuant to the requests by the SAC and the Commission. The refinements are included in the OHS language (that references S-3) before the CON Commission for Final Action today, and that includes all other revisions recommended by the SAC. We recommend the Commission take final action, moving this language forward and transmitting it to the Joint Legislative Committee and the Governor for the 45-day review period.

Summary of October 31, 2007 Public Hearing Comments: Public Hearing on Open Heart Surgery Services (OHS),

Open Heart Surgery (OHS) Services:

Name	Organization	Supports proposed Recommendations	Doesn't support proposed Recommendations	Comments
Dennis McCafferty	The Economic Alliance for Michigan	Yes Supports: 1. Requiring facilities providing OHS in Michigan to participate in the STS database and the program's state-wide auditing 2. Maintaining the minimum volume for new programs at 300 per year 3. Increasing the minimum volume for attending physicians from 50 to 75 per year 4. Consulting hospitals required to perform a minimum of 400 cases per year for at least 3 consecutive years 5. Limiting hospitals ability to commit their OHS discharge data to only the data not previously committed. (eliminating the ability of hospitals to recycle this data every 7 years) 6. Refinement of the methodology for projecting need for new programs		1.Strongly believes that there is no need for any additional OHS programs, anywhere in Michigan. 2. Refinements in the OHS methodology, developed pursuant to the requests by the SAC and the Commission, have gone a long way to simplify and improve the predictability of this process.
Sean Gehle	The Michigan Health Ministries of Ascension Health (St. John)	Yes Supports most of the recommendations	Does not support: 1. The language in the proposed amendment, page 8 , line 378 that appears to give the Department's authority to "modify" the methodology related Open Heart utilization weights without requiring SAC action, a public hearing, or submittal of the standard to the Legislature and Governor in order to become effective (If the intent of the Dept. is simply to re-run or update the weights periodically, the language needs to be reworded)	

Name	Organization	Supports proposed Recommendations	Doesn't support proposed Recommendations	Comments
Aaron Kugelmass MD, OHS SAC member	Henry Ford Health System	Yes Supports: 1. Revision to the methodology 2. Data Commitment Process 3. Participation in the STS quality improvement database		*Currently, all existing OHS programs in Michigan participate in the STS database. The new programs shall be required to do the same.*
Robert Meeker	Spectrum Health	Yes Supports: 1. Participation in the STS quality improvement database 2. Min. Volume for OH surgery should remain at 300 cases per year 3. Hospitals should not be able to repeatedly commit their inpatient data to new open-heart surgery CON applications every 7 years Proposed S-3 methodology		
Wayne Cass	EAM/ International Union of Operating Engineers, Local 547	Yes Supports: 1. Facilities providing OHS in Michigan participating in the STS database and statewide auditing, 2. Maintaining the minimum volume for new programs at 300 per year, 3. Increase the min.volume for physicians from 50 to 75/year, 4. Consulting hospitals to perform a min. of 400 cases per year for at least 3 consecutive years 5. Proposed action to limit the ability of hospitals to commit their OHS discharge data to only the data not previously committed, 6. Methodology for projecting the potential need for new OHS programs, 7. Recommended additions & deletions in the procedure codes that define OHS, 8. Elimination of invalid number of OHS procedures projected by the proposed methodology to the actual number of OHS procedures performed		
Lynn C. Orfgen	Crittenton Hospital Medical Center	Yes Supports: 1. Opening of a new cardiac surgical program should be based on a demonstrated real & valid assessment of a community's need for such a program and the population demographics to support it 2. All programs have a demonstrated commitment to quality based on governance, structure and outcome	Does not support: 1. No changes in the current standards based primarily on volume criteria for program approval	

Name	Organization	Supports proposed Recommendations	Doesn't support proposed Recommendations	Comments
		measurements for maintenance of programs currently in existence, and that the state rejects arbitrary and inconsistent volume statistics as the sole criteria by which programs are maintained 3. The State performs an ongoing assessment of a community's need for existing programs and the population's access to readily available acute cardiac care services in their community		

MDCH supports the proposed standards with a minor modification. Instead of updating utilization weights on an annual basis, the Department recommends that the update of the utilization weights coincide with the three-year review cycle of the OHS standards. While the department supports the identified need to have regular and routine updates of the weights, there is no clear demonstrated need for this to happen annually. An automatic update of the appendix to be done at the same time that the open heart standards are scheduled for review is appropriate.

Pursuant to the Commission's proposed action at its September 18th meeting, moving the language forward for Public Hearing (held on October 31st), while also asking that both the comments at the public hearing and the Department look at:

1) the geographic implications of the current language,
2) the implications for new programs,
3) the implications of Sections 6(1)(b) and 6(2)(b) in terms of the potential of double-counting of data, and
4) methodology questions, which would include, but not be limited to weighting, volume, and use of primary versus secondary data [diagnosis].

Following much work and analysis, the Department brought forth to the Public Hearing (held on October 31st) a second set of language with Proposed Amendments that incorporated a revised methodology (S-3). The Department received overall strong support for the refinements in the OHS methodology, developed pursuant to the requests by the SAC and the Commission, as presented in the OHS language with the Proposed Amendments (S-3).

1. Update utilization weights on an annual basis – The Department agrees to slight modifications to the language to clarify that the intent of the Department is to simply update the utilization weights periodically, according to **the approved methodology described in the standards**. The Departments shall notify the Commission when the updates are made, and the effective date of the updated utilization weights. The updated open heart utilization weights shall be included as an amended appendix to the standards.
   However, the Department recommends that the update of the utilization weights coincide with the three-year review cycle of the OHS standards, instead of annually.

2. Volume criteria for OHS program – The Department agrees with the SAC's recommendation to maintain the minimum volume requirement for new programs at 300 per year, as a proxy measure for quality, while agreeing that more work needs to be done to ensure the best quality measures.

3. MIDB data commitments – The Department is in agreement with the SAC's recommendation in the proposed standards that would not allow the reuse of data that had been committed to an open heart program, as long as that program continues to function. Hospitals would be limited to committing only the data not previously committed, after a 7-year period. However, an exception was proposed in Sections 6(1)(b) and 6(2)(b) that would allow a hospital that committed its data elsewhere to reuse its own previously committed data in order to obtain its own open heart program. According to legal advice received by Ron Styka, and forwarded to the Commission, the provisions of Sections 6(1)(b) and 6(2)(b) are not supported by a rationale basis. As such, the Department agrees with the assessment, and has deleted this segment of the proposed language.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

(By the 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. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve open heart surgery services.

(2) Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, ~~5~~, 6, 8, and 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 5 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) FOR PURPOSES OF~~As used in~~ these standards:

(a) “Adult open heart surgery” means open heart surgery offered and provided to individuals age 15 and older AS DEFINED IN SUBSECTION (I).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of open heart surgery.

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

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

(e) "Department" means the Michigan Department Of Community Health (MDCH).

(f) "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.

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

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

(i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(J) "OPEN HEART SURGICAL CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM DURING WHICH ONE OR MORE OPEN HEART SURGERY PROCEDURES ARE PERFORMED.

(Kj) "Open heart surgery service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An open heart surgery service performs open heart surgery procedures on an emergent, urgent and scheduled basis.

(Lk) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and children age 14 and YOUNGERbelow, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(Ml) "Planning area" means the groups of counties shown in Section 10.

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

Section 3. Requirements for ALL APPLICANTS PROPOSING TO INITIATE OPEN HEART SURGERY SERVICESapproval -- all applicants

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new service shall BE OPERATING OR APPROVED TO OPERATE Ahave in place, or meet the CON review standards for initiation of diagnostic and therapeutic adult or pediatric cardiac catheterization services, respectively.

(2) A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service performing a minimum of 400350 open heart surgical CASESprocedures per year FOR 3 CONSECUTIVE YEARS. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will at least annually measure, evaluate, and report to the medical staff and governing body, the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 4. Requirements for approval -- all applicants for adult open heart surgery services

Sec. 4. (3) An applicant proposing to initiate adult (non-pediatric) open heart surgery as a new service shall demonstrate that 300 adult open heart surgical CASESprocedures BASED ON result from application of the methodology SET FORTHdescribed in Section 8.

Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services

Sec. 5. (4) An applicant proposing to initiate pediatric open heart surgery as a new service shall demonstrate that 100 pediatric open heart surgical CASESprocedures BASED ONresult from application of the methodology SET FORTHdescribed in Section 9.

SECTION 4. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING OPEN HEART SURGERY SERVICE

SEC. 4. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED TO PERFORM OPEN HEART SURGERY SERVICES MAY ALSO ACQUIRE THE EXISTING OPEN HEART SURGERY SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF ACQUISITION. THE OPEN HEART SURGERY SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

(2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS, AS SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS, ON THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE APPLICANT AGREES TO OPERATE THE OPEN HEART SURGERY SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS.

SECTION 5. REQUIREMENTS FOR ALL APPLICANTS

SEC 5. 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 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart surgery services shall not use any of its adult MIDB data in support of any other application for adult open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD, A HOSPITAL(S) MAY ONLY COMMIT ITS ADULT MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR ADULT OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric open heart surgery services shall not use any of its pediatric MIDB data in support of any other application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD, A HOSPITAL(S) MAY ONLY COMMIT ITS PEDIATRIC MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR PEDIATRIC OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart surgery service or have a valid CON issued under ~~former Part 221 or~~ Part 222 to operate an adult or pediatric open heart surgery service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231~~(9)~~ of the Code, being Section 333.22231~~(9)~~ of the Michigan Compiled Laws.

Section 7. Project delivery requirements -- terms of approval for all applicants

Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical CASES~~procedures~~ or 100 pediatric open heart surgical CASES~~procedures~~, as applicable, by the end of the third 12 full months of operation, AND ANNUALLY THEREAFTER.

(ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery CASES~~procedures~~, as the attending surgeon, shall perform a minimum of 75~~50~~ adult open heart surgery CASES~~procedures~~ per year. The annual case load for a physician means adult open heart surgery CASES~~procedures~~ performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

(iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.

(iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for emergency CASES~~procedures~~ 24 hours a day, 7 days a week.

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

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

(i) provide open heart surgery services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment; and

(ii) maintain information by source of payment to indicate the volume of care from each source provided annually.

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

(e) The applicant shall prepare and present to the medical staff and governing body reports describing activities in the open heart surgery service including complication rates and other morbidity and mortality data.

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

(G) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS SPECIFIED BY THE DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. THE APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE. PARTICIPATION SHALL CONTINUE ANNUALLY THEREAFTER. THE OUTCOMES DATABASE MUST UNDERGO STATEWIDE AUDITING.

(H) AN APPLICANT THAT FAILS TO COMPLY WITH THE QUALITY ASSURANCE STANDARDS UNDER SUBSECTION (C) SHALL BE REQUIRED TO PROVIDE ITS QUALITY AND RISK ADJUSTED OUTCOMES DATA FROM THE DATA REGISTRY TO THE DEPARTMENT, OR ITS DESIGNEE, AS PART OF THE DEPARTMENT'S ENFORCEMENT AND COMPLIANCE ACTIVITIES.

(~~g~~I) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) The agreements and assurances required by this section shall be in the form of a certification AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT~~authorized by the governing body of the applicant~~.

Section 8. Methodology for computing the number of adult open heart surgical CASES~~procedures~~

Sec. 8. (1) An applicant shall apply the methodology set forth in this section for computing the number of adult open heart surgical CASES~~procedures~~. In applying discharge data in the methodology, each applicable inpatient record shall be used only once. This methodology shall utilize only the inpatient discharges that have one or more of the cardiac diagnoses in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall identify the discharges that were from patients aged 15 years and older. These discharges shall be considered "adult discharges."

(b) Using the "adult discharges" identified in Subdivision (a), an applicant shall count the number of discharges with a principal diagnosis corresponding to each of the first six categories (Groups A through F) of ICD-9-CM codes listed in Subsection (2). When a patient has a principal diagnosis which falls into one of these six groups (exclude Other Heart Conditions), then they shall be categorized by that diagnosis and their case shall be removed from the data to be used in Subdivisions (c), (d) and (e) so that each applicable inpatient record shall be counted only once.

(c) The procedure in this subdivision shall be used to determine in which diagnosis group each appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with ~~the first category of Valves (~~Group A~~: ICD-9-CM codes 394.0-397.99 and 424.0-424.99)~~ and shall search through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record has a non-principal diagnosis code for this grouping, it shall be assigned to ~~the Valve g~~Group A and shall be removed from all subsequent search actions. The remaining inpatient records shall then be searched for the presence of the ~~Valve~~GROUP A codes. After all the inpatient records with ~~Valve codes~~GROUP A have been removed, the above procedure shall be repeated for each of the remaining five groups (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient records for codes representing ~~the Congenital Anomalies (~~Group B~~: ICD-9-CM codes 745.0-747.99)~~. NOTE: The above procedure shall not apply to ~~the All Other Heart Conditions category (~~Group G~~)~~.

(d) Add the count of the number of records for each principal diagnosis group (separately) that was identified under Subdivision (b) with the count of the number of records for its respective non-principal

diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first six diagnostic groups (excluding ~~All Other Heart Conditions -~~ Group G).

(e) Using the remaining discharge data, an applicant shall count the discharges that were from patients that have a principal diagnosis or any of the first four non-principal diagnoses using the ICD-9-CM codes for ~~the All Other Heart Conditions category (~~Group G~~)~~ listed in Subsection (2).

(f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its corresponding Adult Open Heart Utilization Weight and add the products together to produce the number of adult open heart surgical CASES~~procedures~~ for the applicant.

(2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES~~PROCEDURES~~

Group	Major ICD-9-CM Code Group	Category	Adult Open Heart Utilization Weights
~~A~~	~~394 - 397.9~~ ~~424 - 424.99~~	~~Valves~~	~~.0808~~
A~~B~~	745 - 747.99	Congenital Anomalies	.125246~~.0766~~
B	394 – 397.9 424 – 424.99	VALVES	.086804
C	410 – 410.99	ACUTE MYOCARDIAL INFARCT	.071210
D~~C~~	414 - 414.99	Other Chronic Ischemic	.062683~~.0632~~
E~~D~~	411 - 411.99	Other Acute & Sub Acute Ischemic	.012538~~.0510~~
~~E~~	~~410 - 410.99~~	~~Acute Myocardial Infarct~~	~~.0400~~
F	413 - 413.99 786.5 - 786.59	Angina & Chest Pain	.000546~~.0102~~
G	164.1, 212.7 390 - 393 398 - 405.99 412, 415 - 423.9 425 - 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51, 901.0 996.02, 996.03	All Other Heart Conditions	.002085~~.0029~~

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Subsection (2) are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development~~, Michigan Department of COMMUNITY~~Public~~ Health, utilizing the 2005~~1986~~ Michigan Inpatient Data Base.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical CASES~~procedures~~

Sec. 9. (1) An applicant shall apply the methodology set forth in this section for computing the number of pediatric open heart surgical CASES~~procedures~~. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall count the discharges that were from

patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Subsection (2). Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Other Heart" category in Subsection (2). Discharge records which do not have one or more of the Other Heart codes listed in Subsection (2) shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "Other Heart" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical CASES~~procedures~~ for the applicant.

(2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES~~PROCEDURES~~

Major ICD-9-CM Grouping	Category	Pediatric Open Heart Utilization Weights
745.0-747.99	Congenital Anomalies	.210888~~.1286~~
164.1, 212.7 390-429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0, 996.02	Other Heart	.042973~~.0147~~

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development~~, Michigan Department of COMMUNITY~~Public~~ Health, utilizing the 2005~~1986~~ Michigan Inpatient Data Base.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA		COUNTIES	
1	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
2	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE

3	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
4	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	

~~7~~	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

~~**Section 11. Application of Rule 325.9403**~~

~~Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under these standards or standards that became effective on December 5, 1988 shall expire 1 year from its effective date, unless the project is initiated. One 6-month extension may be granted by the Department if the applicant shows that substantial progress toward initiation of the approved open heart surgery service has been made and an obligation for capital expenditure, if any, will occur within the extended time period.~~

~~(2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery procedure is performed.~~

Section 11~~12~~. Effect on prior planning policies; comparative reviews

Sec. 11~~1~~2. (1) These CON Review Standards supersede and replace the CON Review Standards for Open Heart Surgery Services approved by the CON Commission on MARCH 9, 2004~~March 11, 2003~~ and effective on JUNE 4, 2004~~May 12, 2003~~.

~~(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan (SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals recognized by the Department as Level II providers under Part 221 may continue to provide Level II cardiac services consistent with the 1985-90 State Medical Facilities Plan.~~

~~(~~(2~~3~~) Projects reviewed under these standards shall not be subject to comparative review.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

(By the 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. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve open heart surgery services.

(2) Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, ~~5~~, 6, 8, and 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 5 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) FOR PURPOSES OF~~As used in~~ these standards:

(a) “Adult open heart surgery” means open heart surgery offered and provided to individuals age 15 and older AS DEFINED IN SUBSECTION (I).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of open heart surgery.

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

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

(e) "Department" means the Michigan Department Of Community Health (MDCH).

(f) "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.

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

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

(i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(J) "OPEN HEART SURGICAL CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM DURING WHICH ONE OR MORE OPEN HEART SURGERY PROCEDURES ARE PERFORMED.

(Kj) "Open heart surgery service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An open heart surgery service performs open heart surgery procedures on an emergent, urgent and scheduled basis.

(Lk) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and children age 14 and YOUNGERbelow, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(Ml) "Planning area" means the groups of counties shown in Section 10.

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

Section 3. Requirements for ALL APPLICANTS PROPOSING TO INITIATE OPEN HEART SURGERY SERVICESapproval -- all applicants

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new service shall BE OPERATING OR APPROVED TO OPERATE Ahave in place, or meet the CON review standards for initiation of diagnostic and therapeutic adult or pediatric cardiac catheterization services, respectively.

(2) A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service performing a minimum of 400350 open heart surgical CASESprocedures per year FOR 3 CONSECUTIVE YEARS. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will at least annually measure, evaluate, and report to the medical staff and governing body, the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 4. Requirements for approval -- all applicants for adult open heart surgery services

Sec. 4. (3) An applicant proposing to initiate adult (non-pediatric) open heart surgery as a new service shall demonstrate that 300 adult open heart surgical CASESprocedures BASED ON result from application of the methodology SET FORTHdescribed in Section 8.

Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services

Sec. 5. (4) An applicant proposing to initiate pediatric open heart surgery as a new service shall demonstrate that 100 pediatric open heart surgical CASESprocedures BASED ONresult from application of the methodology SET FORTHdescribed in Section 9.

SECTION 4. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING OPEN HEART SURGERY SERVICE

SEC. 4. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED TO PERFORM OPEN HEART SURGERY SERVICES MAY ALSO ACQUIRE THE EXISTING OPEN HEART SURGERY SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF ACQUISITION. THE OPEN HEART SURGERY SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

(2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS, AS SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS, ON THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE APPLICANT AGREES TO OPERATE THE OPEN HEART SURGERY SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS.

SECTION 5. REQUIREMENTS FOR ALL APPLICANTS

SEC 5. 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 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart surgery services shall not use any of its adult MIDB data in support of any other application for adult open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD, A HOSPITAL(S) MAY ONLY COMMIT ITS ADULT MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR ADULT OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric open heart surgery services shall not use any of its pediatric MIDB data in support of any other application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD, A HOSPITAL(S) MAY ONLY COMMIT ITS PEDIATRIC MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR PEDIATRIC OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart surgery service or have a valid CON issued under ~~former Part 221 or~~ Part 222 to operate an adult or pediatric open heart surgery service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231~~(9)~~ of the Code, being Section 333.22231~~(9)~~ of the Michigan Compiled Laws.

Section 7. Project delivery requirements -- terms of approval for all applicants

Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical CASES~~procedures~~ or 100 pediatric open heart surgical CASES~~procedures~~, as applicable, by the end of the third 12 full months of operation, AND ANNUALLY THEREAFTER.

(ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery CASES~~procedures~~, as the attending surgeon, shall perform a minimum of 75~~50~~ adult open heart surgery CASES~~procedures~~ per year. The annual case load for a physician means adult open heart surgery CASES~~procedures~~ performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

(iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.

(iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for emergency CASES~~procedures~~ 24 hours a day, 7 days a week.

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

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

(i) provide open heart surgery services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment; and

(ii) maintain information by source of payment to indicate the volume of care from each source provided annually.

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

(e) The applicant shall prepare and present to the medical staff and governing body reports describing activities in the open heart surgery service including complication rates and other morbidity and mortality data.

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

(G) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS SPECIFIED BY THE DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. THE APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE. PARTICIPATION SHALL CONTINUE ANNUALLY THEREAFTER. THE OUTCOMES DATABASE MUST UNDERGO STATEWIDE AUDITING.

(H) AN APPLICANT THAT FAILS TO COMPLY WITH THE QUALITY ASSURANCE STANDARDS UNDER SUBSECTION (C) SHALL BE REQUIRED TO PROVIDE ITS QUALITY AND RISK ADJUSTED OUTCOMES DATA FROM THE DATA REGISTRY TO THE DEPARTMENT, OR ITS DESIGNEE, AS PART OF THE DEPARTMENT'S ENFORCEMENT AND COMPLIANCE ACTIVITIES.

(~~g~~I) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) The agreements and assurances required by this section shall be in the form of a certification AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT~~authorized by the governing body of the applicant~~.

Section 8. Methodology for computing the number of adult open heart surgical CASES~~procedures~~

Sec. 8. (1) THE WEIGHTS FOR THE ADULT PRINCIPAL AND NON-PRINCIPAL DIAGNOSES TABLES FOUND IN APPENDIX A ARE CALCULATED USING THE FOLLOWING METHODOLOGY. FOR THESE TWO TABLES, ONLY THE MIDB DATA FROM LICENSED HOSPITALS THAT HAVE OPERATIONAL OPEN HEART SURGERY PROGRAMS IN MICHIGAN WILL BE USED. USING A HOSPITAL'S ACTUAL INPATIENT DISCHARGE DATA, AS SPECIFIED BY THE MOST RECENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AN APPLICANT SHALL IDENTIFY THE DISCHARGES THAT WERE FROM PATIENTS AGED 15 YEARS AND OLDER. THESE DISCHARGES SHALL BE KNOWN AS THE "ADULT DISCHARGES."

(A) TO CALCULATE THE WEIGHTS FOR THE PRINCIPAL DIAGNOSIS, THE FOLLOWING STEPS SHALL BE TAKEN:

(I) FOR EACH DIAGNOSTIC GROUP IN THE PRINCIPAL WEIGHT TABLE, THE NUMBER OF DISCHARGES IS COUNTED.

(II) FOR THE DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(A)(I), ANY OCCURANCE OF AN OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY CASE.

(III) THE NUMBER OF OPEN HEART SURGERY CASES FOR EACH DIAGNOSIS CATEGORY WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(A)(I). THIS WILL BE THE WEIGHT FOR THAT DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

(IV) ALL DISCHARGES UTILIZED FOR THE COMPUTATION OF THE PRINCIPAL WEIGHT TABLE ARE TO BE REMOVED FROM SUBSEQUENT ANALYSES.

(B) TO CALCULATE THE WEIGHTS FOR THE NON-PRINCIPAL DIAGNOSIS TABLE, THE FOLLOWING STEPS SHALL BE TAKEN, SEPARATELY, IN THE SEQUENCE SHOWN, AND EACH REMAINING DISCHARGE WILL BE EXAMINED FOR ANY MENTION OF THE DIAGNOSTIC CODES FROM THAT GROUP. IF A MATCH IS FOUND, THAT DISCHARGE IS ASSIGNED TO THAT DIAGNOSTIC GROUP AND REMOVED FROM SUBSEQUENT ANALYSES:

(I) FOR EACH DIAGNOSTIC GROUP TAKEN SEPARATELY, IN THE SEQUENCE SHOWN, ANY OCCURANCE OF AN OPEN HEART PROCEDURE CODE FOR EACH DISCHARGE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY CASE. IF A MATCH IS FOUND, THE DISCHARGE

WILL BE COUNTED AS AN OPEN HEART SURGICAL CASE FOR THAT DIAGNOSTIC GROUP AND REMOVED FROM SUBSEQUENT ANALYSES.

(II) THE NUMBER OF OPEN HEART SURGERY CASES FOR EACH NON-PRINCIPAL DIAGNOSIS CATEGORY IDENTIFIED IN SUBSECTION 8(1)(B)(I) WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(B). THIS WILL RESULT IN THE NON-PRINCIPAL WEIGHT FOR THAT DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

(2) An applicant shall apply the methodology set forth in this section for computing the PROJECTED number of adult open heart surgical CASES~~procedures~~ USING BOTH THE PRINCIPAL AND NON-PRINCIPAL DIAGNOSIS TABLES. ~~In applying discharge data in the methodology, each applicable inpatient record shall be used only once. This methodology shall utilize only the inpatient discharges that have one or more of the cardiac diagnoses in Subsection (2). In applying this methodology, t~~The following steps shall be taken in sequence:

(a) FOR EACH DIAGNOSTIC GROUP IN THE PRINCIPAL WEIGHT TABLE IN APPENDIX A, IDENTIFY THE CORRESPONDING NUMBER OF DISCHARGES.~~Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall identify the discharges that were from patients aged 15 years and older. These discharges shall be considered "adult discharges."~~

(B) MULTIPLY THE NUMBER OF DISCHARGES FOR EACH DIAGNOSTIC GROUP BY THEIR RESPECTIVE GROUP WEIGHT TO OBTAIN THE PROJECTED NUMBER OF OPEN HEART SURGERY CASES FOR THAT GROUP. ALL DISCHARGES IDENTIFIED IN SUBSECTION 8(2)(A) ARE REMOVED FROM SUBSEQUENT ANALYSIS.

(C~~b~~) THE NON-PRINCIPAL WEIGHT TABLE IDENTIFIES THE SEQUENCE THAT MUST BE FOLLOWED TO COUNT THE DISCHARGES FOR THE APPROPRIATE GROUP. AN APPLICANT SHALL START WITH THE FIRST DIAGNOSTIC GROUP AND~~Using the "adult discharges" identified in Subdivision (a), an applicant~~ shall count the number of discharges with ANY MENTION OF a NON-principal diagnosis corresponding to THAT SPECIFIC DIAGNOSTIC GROUP.~~each of the first six categories (Groups A through F) of ICD-9-CM codes listed in Subsection (2).~~ When a DISCHARGE THAT BELONGS IN THE SPECIFIC~~patient has a~~ NON-principal diagnosTIC~~is~~ GROUP IS IDENTIFIED, IT IS ASSIGNED TO THAT GROUP. THIS DISCHARGE IS THEN~~which falls into one of these six groups (exclude Other Heart Conditions), then they shall be categorized by that diagnosis and their case shall be~~ removed from the data BEFORE COUNTING DISCHARGES FOR THE NEXT DIAGNOSTIC GROUP.~~to be used in Subdivisions (c), (d) and (e) so that each applicable inpatient record shall be counted only once.~~ THE DISCHARGES COUNTED FOR EACH GROUP WILL BE USED ONLY WITH THE NON-PRINCIPAL DIAGNOSIS WEIGHT TABLE IN APPENDIX A AND WILL BE ENTERED INTO ITS RESPECTIVE DIAGNOSTIC GROUP. MULTIPLY THE NUMBER OF DISCHARGES FOR EACH DIAGNOSTIC GROUP BY THEIR RESPECTIVE GROUP WEIGHT TO OBTAIN THE PROJECTED NUMBER OF OPEN HEART SURGERY CASES FOR THAT GROUP.

(D) THE TOTAL NUMBER OF PROJECTED OPEN HEART CASES IS THEN CALCULATED BY SUMMING THE PROJECTED NUMBER OF OPEN HEART CASES FROM BOTH PRINCIPAL AND NON-PRINCIPAL WEIGHT TABLES.

~~(c) The procedure in this subdivision shall be used to determine in which diagnosis group each appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with the first category of Valves (Group A: ICD-9-CM codes 394.0-397.99 and 424.0-424.99) and shall search through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record has a non-principal diagnosis code for this grouping, it shall be assigned to the Valve group and shall be removed from all subsequent search actions. The remaining inpatient records shall then be searched for the presence of the Valve codes. After all the inpatient records with Valve codes have been removed, the above procedure shall be repeated for each of the remaining five groups (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient records for codes~~

representing the Congenital Anomalies (Group B: ICD-9-CM codes 745.0-747.99). NOTE: The above procedure shall not apply to the All Other Heart Conditions category (Group G).

(d) Add the count of the number of records for each principal diagnosis group (separately) that was identified under Subdivision (b) with the count of the number of records for its respective non-principal diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first six diagnostic groups (excluding All Other Heart Conditions - Group G).

(e) Using the remaining discharge data, an applicant shall count the discharges that were from patients that have a principal diagnosis or any of the first four non-principal diagnoses using the ICD-9-CM codes for the All Other Heart Conditions category (Group G) listed in Subsection (2).

(f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its corresponding Adult Open Heart Utilization Weight and add the products together to produce the number of adult open heart surgical procedures for the applicant.

(2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL PROCEDURES

Group	Major ICD-9-CM Code Group	Category	Adult Open Heart Utilization Weights
A	394 - 397.9 424 - 424.99	Valves	.0808
B	745 - 747.99	Congenital Anomalies	.0766
C	414 - 414.99	Other Chronic Ischemic	.0632
D	411 - 411.99	Other Acute & Sub Acute Ischemic	.0510
E	410 - 410.99	Acute Myocardial Infarct	.0400
F	413 - 413.99 786.5 - 786.59	Angina & Chest Pain	.0102
G	390 - 393 398 - 405.99 412, 415 - 423.9 425 - 429.99	All Other Heart Conditions	.0029

(3) The major ICD-9-CM groupings and Open Heart utilization weights in APPENDIX ASubsection (2) are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESSformer Division of Planning and Policy Development, Michigan Department of COMMUNITYPublic Health, utilizing the MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT1986 Michigan Inpatient Data Base.

(A) THE DEPARTMENT SHALL UPDATE THE OPEN HEART UTILIZATION WEIGHTS EVERY 3 YEARS, BEGINNING WITH THE YEAR 2007ON AN ANNUAL BASIS, ACCORDING TO THE METHODOLOGY DESCRIBED IN SUBSECTION (1) ABOVE, UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT.

(B) UPDATES TO THE UTILIZATION WEIGHTS MADE PURSUANT TO THIS SUBSECTION SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE.

(C) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE UPDATED UTILIZATION WEIGHTS.

(D) THE UPDATED OPEN HEART UTILIZATION WEIGHTS ESTABLISHED PURSUANT TO THIS SUBSECTION SHALL SUPERCEDE THE WEIGHTS SHOWN IN APPENDIX A AND SHALL BE INCLUDED AS AN AMENDED APPENDIX TO THESE STANDARDS.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical CASES~~procedures~~

Sec. 9. (1) THE WEIGHTS FOR THE PEDIATRIC DIAGNOSIS TABLE FOUND IN APPENDIX B ARE CALCULATED USING THE FOLLOWING METHODOLOGY. ONLY THE MIDB DATA FROM LICENSED HOSPITALS IN MICHIGAN WILL BE USED.

(A) USING A HOSPITAL'S ACTUAL INPATIENT DISCHARGE DATA, AS SPECIFIED BY THE MOST RECENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AN APPLICANT SHALL COUNT THE DISCHARGES THAT WERE FROM PATIENTS OF ANY AGE THAT HAVE A DIAGNOSIS (ANY MENTION) OF THE ICD-9-CM CODES LISTED IN THE "CONGENITAL ANOMALIES" CATEGORY IN APPENDIX B. EACH IDENTIFIED RECORD SHALL BE COUNTED ONLY ONCE SO THAT NO RECORD IS COUNTED TWICE. AN APPLICANT SHALL REMOVE THESE CASES FROM SUBSEQUENT ANALYSES.

(B) FOR THOSE DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(A), ANY OCCURANCE OF AN OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY CASE.

(C) THE NUMBER OF OPEN HEART SURGERY CASES FOR THE "CONGENITAL ANOMALIES" CATEGORY WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(A). THIS WILL BE THE WEIGHT FOR THE "CONGENITAL ANOMALIES" DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

(D) USING A HOSPITAL'S REMAINING INPATIENT DISCHARGES, AN APPLICANT SHALL IDENTIFY THE DISCHARGES THAT WERE FROM PATIENTS AGED 14 YEARS AND YOUNGER. THESE DISCHARGES SHALL BE KNOWN AS THE "PEDIATRIC DISCHARGES."

(E) USING THE "PEDIATRIC DISCHARGES" IDENTIFIED IN SUBDIVISION (D), AN APPLICANT SHALL COUNT THE NUMBER OF DISCHARGES THAT HAVE A DIAGNOSIS (ANY MENTION) OF THE ICD-9-CM CODES LISTED IN THE "ALL OTHER HEART CONDITIONS" CATEGORY IN APPENDIX B. DISCHARGE RECORDS WHICH DO NOT HAVE ONE OR MORE OF THE “ALL OTHER HEART CONDITIONS” CODES LISTED IN APPENDIX B SHALL NOT BE USED. EACH IDENTIFIED RECORD SHALL BE COUNTED ONLY ONCE SO THAT NO RECORD IS COUNTED TWICE.

(F) FOR THOSE DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(E), ANY OCCURANCE OF AN OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY CASE.

(G) THE NUMBER OF OPEN HEART SURGERY CASES FOR THE "ALL OTHER HEART CONDITIONS" CATEGORY WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(E). THIS WILL BE THE WEIGHT FOR THE "ALL OTHER HEART CONDITIONS" DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

(2) An applicant shall apply the methodology set forth in this section for computing the PROJECTED number of pediatric open heart surgical CASES~~procedures~~. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in APPENDIX B~~Subsection (2)~~. In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB~~Michigan Inpatient Data Base~~DATA available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of

the ICD-9-CM codes listed in the "Congenital Anomalies" category in APPENDIX B~~Subsection (2)~~. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "ALL Other Heart CONDITIONS" category in APPENDIX B~~Subsection (2)~~. Discharge records which do not have one or more of the "ALL Other Heart CONDITIONS" codes listed in APPENDIX B~~Subsection (2)~~ shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "ALL Other Heart CONDITIONS" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical CASES~~procedures~~ for the applicant.

~~(2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:~~

~~DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL PROCEDURES~~

~~Major ICD-9-CM Grouping~~	~~Category~~	~~Pediatric Open Heart Utilization Weights~~
~~745.0-747.99~~	~~Congenital Anomalies~~	~~.1286~~
	~~Other Heart~~	~~.0147~~
~~390-429.99~~		
~~786.5-786.59~~		

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights IN APPENDIX B are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development~~, Michigan Department of COMMUNITY~~Public~~ Health, utilizing the MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT ~~1986 Michigan Inpatient Data Base~~.

(A) THE DEPARTMENT SHALL UPDATE THE OPEN HEART UTILIZATION WEIGHTS EVERY 3 YEARS, BEGINNING WITH THE YEAR 2007~~ON AN ANNUAL BASIS~~, ACCORDING TO THE METHODOLOGY DESCRIBED IN SUBSECTION (1) ABOVE, UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT.

(B) UPDATES TO THE UTILIZATION WEIGHTS MADE PURSUANT TO THIS SUBSECTION SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE.

(C) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE UPDATED UTILIZATION WEIGHTS.

(D) THE UPDATED OPEN HEART UTILIZATION WEIGHTS ESTABLISHED PURSUANT TO THIS SUBSECTION SHALL SUPERCEDE THE WEIGHTS SHOWN IN APPENDIX B AND SHALL BE INCLUDED AS AN AMENDED APPENDIX TO THESE STANDARDS.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA	COUNTIES		
1	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
2	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
3	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
4	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	

~~7~~	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

~~**Section 11. Application of Rule 325.9403**~~

~~Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under these standards or standards that became effective on December 5, 1988 shall expire 1 year from its effective date, unless the project is initiated. One 6-month extension may be granted by the Department if the applicant shows that substantial progress toward initiation of the approved open heart surgery service has been made and an obligation for capital expenditure, if any, will occur within the extended time period.~~

~~(2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery procedure is performed.~~

Section 11~~12~~. Effect on prior planning policies; comparative reviews

Sec. 11~~1~~2. (1) These CON Review Standards supersede and replace the CON Review Standards for Open Heart Surgery Services approved by the CON Commission on MARCH 9, 2004~~March 11, 2003~~ and effective on JUNE 4, 2004~~May 12, 2003~~.

~~(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan (SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals recognized by the Department as Level II providers under Part 221 may continue to provide Level II cardiac services consistent with the 1985-90 State Medical Facilities Plan.~~

~~(~~(2~~3~~) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES
PRINCIPAL DIAGNOSIS

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	394 – 397.9 421 – 421.9 424 – 424.99	VALVES	.755521
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	AORTIC ANEURYSM	.474638
C	745 – 747.99	CONGENITAL ANOMALIES	.304878
D	414 – 414.99	OTHER CHRONIC ISCHEMIC	.175495
E	410 – 410.99	ACUTE MYOCARDIAL INFARCT	.119218
F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	ALL OTHER HEART CONDITIONS	.013789

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	CONGENITAL ANOMALIES	.021698
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	AORTIC ANEURYSM	.020900
C	410 – 410.99	ACUTE MYOCARDIAL INFARCT	.014470
D	394 – 397.9 421 – 421.9 424 – 424.99	VALVES	.008064
E	414 – 414.99	OTHER CHRONIC ISCHEMIC	.001879

F	212.7	ALL OTHER HEART CONDITIONS	.001190
	398 – 398.99		
	411 – 411.99		
	423 – 423.9		
	425 – 425.9		
	427 – 427.9		
	428 – 428.9		
	901 – 901.9		
	996.02, 996.03		

SOURCE: CALCULATED BASED ON THE 2005 MICHIGAN INPATIENT DATA BASE

APPENDIX B

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES

MAJOR ICD-9-CM CODE GROUP	CATEGORY	PEDIATRIC OPEN HEART UTILIZATION WEIGHTS
745.0 – 747.99	CONGENITAL ANOMALIES	.174027
164.1, 212.7 390 – 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0 – 901.9 996.02	ALL OTHER HEART CONDITIONS	.018182

SOURCE: CALCULATED BASED ON THE 2005 MICHIGAN INPATIENT DATA BASE

Testimony to Certificate of Need Commission
Monday, Dec. 11, 2007

Good Morning. My name is Toni Wilson, and I come before you today as a member of the Michigan Campaign for Quality Care, as a former local long-term care ombudsman, a member of the Long Term Care Supports & Services Advisory Commission and as a private citizen who has personally lived through the experience of seeking quality nursing home placement for a loved one.

I am deeply concerned that the Certificate of Need process does not currently have any standards for consideration of quality of care in its decision process when considering whether to grant additional beds to nursing home chains and owners. Since the primary source of payment for these beds is state and federal tax dollars, our citizens have every right to expect the Certificate of Need Commission to help see to it that the money is spent wisely, and that we are not throwing good money after bad. If a nursing home corporation has a two-year history of survey results that is more than twice the state average, they should absolutely not be allowed to add new beds to their operations until they have corrected the problems that exist in the current facilities they operate.

I understand that an objection that has been raised to this plan is that state surveys are too subjective and therefore not good measures of performance. Of course, as with anything done by humans, including care delivery, I have to agree that the survey system is not perfect. However, having worked as a long-term care ombudsman for seven years, I can tell you that the survey system is based on uniform federal standards developed with OBRA '87 guidelines and is still the most objective measure of performance quality that we have. The ombudsmen assigned to any given facility can usually give you a fairly close approximation of what a survey outcome will be, because they visit facilities often enough to predict the compliance issues that the state will find when they arrive. Although the ombudsmen's observations are made differently than the Bureau of Health Systems, they are surprisingly accurate and concurrent with survey data, because the issues objectively do exist.

Further, there is no really good facility that is going to be locked out of new beds because their surveys have had double the state average number of citations for two years running. This plan ensures mediocrity at best. I wish the standards were higher. It is my understanding that there currently would be only four nursing homes in the state that would be affected by the standards proposed.

Another concern I have is that consideration of a facility's Medicaid participation will be eliminated in the CON decision-making process. I am concerned both as an advocate and as a private citizen. In February, 2006, I accompanied my mother-in-law to search the Washtenaw County area for a nursing home for my father-in-law, who had suffered his second debilitating stroke. In one nursing home we visited, a facility with a fairly good survey history and few complaints to the ombudsman, the admissions coordinator was fairly new and didn't recognize me as a local ombudsman when I approached her with my family. I verified with her that the facility was fully dually certified, and she told us that they were able to take my father-in-law for the period of his Medicare coverage, but he would have to move as soon as this payment source was finished. (My father-in-law had the funding to pay privately for at least three years, but we were apparently being judged on looks, and we were all exhausted and disheveled from being in the hospital for long hours with this very ill man. We were not asked if he had any money.)

When I told the admissions director that my understanding of "fully dually certified" meant that he could stay regardless of payment source after his Medicare beneficiary period was over, she told me that she was very sorry, but that was not true! Although I had not intended to do so in the course of our search, I identified myself to her as a long-term care ombudsman, at which time she became visibly upset and left the room to go get "help". After sitting there for 15 minutes awaiting her return, we simply walked out the door. Even then, my mother-in-law would not allow me to file a complaint in the hopes that he might eventually be able to go there. He mercifully died before he needed long-term care placement; the only other places that told us they had beds available also had a long-running substandard quality of care.

If access is even a problem in some areas for a man with funds to pay, in a fully dually certified facility, with an ombudsman in the family, think of the person who has no cash resources, no knowledge resources, and no accurate information. As an ombudsman, I received countless phone calls from consumers unable to locate a Medicaid bed in a facility of even their third or fourth choice. I spent countless hours counseling people who were going to be forced to move at the end of their Medicare beneficiary periods, sometimes even by calls to family members who were told to "come and pick your mother up". It was definitely a hardship for the vulnerable residents who were forced to move. If Medicaid participation is not taken into account in CON requirements, access will become even more of a problem than it is already.

I have also heard that there could be "unintended consequences" to the plan to consider quality in the CON process, including a chill to the long-term care industry's business climate. What part of improved quality of care could possibly be bad for this business? This should be a draw for customers and providers alike. The *intended* consequence—improved quality of care across the state—is a lofty goal and sure to win the respect of the *quality* providers who know they can meet the standards your committee is proposing. Just as our state wouldn't want to attract the business of toy companies that use lead-based paint as a cost-containment measure, we wouldn't want to attract long-term care providers that can't clear the relatively low bar we are setting to try to make things better for our 40,000 vulnerable sick, aged and disabled citizens who live in long-term care facilities. Please. Adopt the quality standards for them, as well as for your own loved ones who may find themselves living in a long-term care facility one day.

Thank you for your time and attention.
Toni Wilson

BILL MANIA TESTIMONY TO THE CON COMMISSION
DECEMBER 11, 2007

Good Morning. My name is William Mania, and I am the statewide chairperson for Michigan Campaign for Quality Care, a volunteer ombudsman for Citizens for Better Care, and a Long Term Care Advisory Commissioner. I also lived in three different nursing homes over a period of six years before moving out to an assisted living with the help of the Nursing Facility Transition Service and the MI Choice program. One nursing home was a very nice place to live; one was very bad, and the one I lived in for the longest fell somewhere in the middle. All three were owned by large corporations.

I am here today to tell you that I strongly support the Standards Advisory Committee's proposed plan to consider basic health and safety standards and have all of their enforcement and bed tax debts paid to the state before they can be allowed to grow their businesses by adding more beds. I was surprised to learn that the Certificate of Need process does not take into account the history of a company's quality of care before they let people add beds now, but it sure helps to explain a lot of things I experienced and saw while living in the nursing home.

In my experience, the annual survey process was a start to finding and fixing the problems in nursing homes, but really needed to be tougher. I know some people don't agree with me. I think the surveys are the best standard we have to compare Michigan nursing homes with one another to see where the problems with quality of care are the worst. I can tell you that the state agreed with me about my judgment of the nursing homes where I lived; when I was there, the one I thought was bad had over 30 citations in the year when I was there.

I also support the "special population beds" being added, as long as there is adequate training for the staff in how to deal with the residents the beds are set aside for. As a person with a spinal cord injury, I can tell you that all of nursing home staff people I dealt with had little to no training in how to care for people with my disability. I am also concerned about the training for staff dealing with residents who have dementia; from what I saw, there is a real need to increase the training for staff who take care of dementia residents.

I hope your Commission will vote to support the proposed standards exactly as they are presented. If I ever have to go back into a nursing home, I will personally thank you for it. And thank you for hearing my testimony today.

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

Testimony on behalf of the MHA to the CON Commission on the proposed nursing home and long-term-care language December 11, 2007

My name is Amy Barkholz, Senior Director, Advocacy, at the Michigan Health & Hospital Association. The MHA represents 146 nonprofit community hospitals in the state. I'm here this afternoon to provide brief comments on the proposed language to amend the nursing home and long term care standards. Many hospitals own or have affiliation arrangements with nursing homes and long term care units. In addition, ensuring adequate patient access to high quality nursing care facilities is of paramount importance to all of our hospital members, who must contend daily with the challenges of working with patients and their family members to ensure hospital patients are discharged to appropriate care settings.

The MHA applauds the charge and the efforts of the nursing home and long-term-care SAC to include meaningful quality measures and performance standards in the CON process. **We are concerned, however, about the proposed language *as written* utilizing survey information to deny a provider the ability to obtain a Certificate of Need, who would otherwise qualify.** Specifically, the MHA is concerned that this measurement tool, as currently proposed, is not accurate or consistent enough as implemented across the state to provide a fair or appropriate quality assessment. We are further concerned that good quality nursing homes and long term care providers may be inappropriately denied the ability to upgrade their patient services through the CON application process, and conversely, we are concerned that other applicants may be inappropriately granted access to the CON process based on the proposed criteria. We believe proposed language that would deny a CON to a provider based on the survey data from another affiliated facility is unfair and punishes patients and good quality providers.

Given our state's ongoing challenge to meet the long term care needs of Michigan's citizens, we support further review of the SAC's recommendations with regard to the use of survey data to ensure that we do not cause more harm to nursing home residents and reduce access to good quality care. **The MHA supports the specific suggestions of the Michigan Association of Homes and Services for the Aging. We believe MAHSA has identified alternative quality measurements to the current proposal and we support a focused work group to review these alternatives prior to the CON Commission's March meeting.** Thank you.

SPENCER JOHNSON, PRESIDENT

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December 06, 2007

Norma Hagenow, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Hagenow,

This letter is written as formal testimony about the proposed revisions to the CON Review Standards for Nursing Home and Hospital Long-term Care Beds. Spectrum Health appreciates the opportunity to comment on these proposed Standards.

Spectrum Health is appreciative of the hard work of the Nursing Home Standards Advisory Committee (NHSAC) and its work groups in confronting difficult issues in their review of the Standards. We are supportive of many of the recommended changes. However, we have substantial concerns about the draft provisions proposed to address quality issues. Spectrum Health believes that the so-called "quality" provisions are significantly flawed and do not truly measure quality in long-term care. Spectrum Health suggests that these provisions be removed from the proposed CON Review Standards before they are approved for public hearing.

Spectrum Health is a strong advocate for the provision of quality healthcare and supports developing appropriate ways to measure quality in the nursing home and long-term care environment. However, it is our opinion that the use of the state survey results, as proposed in the draft Standards, is not an appropriate mechanism for measuring the quality in the Certificate of Need (CON) application process. As they are currently conducted, the state surveys have the propensity to include subjective and inconsistent citations. Survey results indicate compliance with state regulations and, as such, do not provide an accurate measure of the quality of care provided by a licensed nursing home. We respectfully recommend that references to results of the state nursing home survey process be removed from the proposed CON Review Standards.

The unintended consequences of the proposed quality language could result in decreased access to nursing homes across the state and fewer nursing homes which qualify for CON approval to improve the living conditions for residents in their facilities. The proposed quality measures, as adopted by the NHSAC, discriminate against large, older facilities. The plans of such nursing homes to improve their facilities may be denied CON approval to do so under these proposed requirements. CON should encourage nursing home operators to develop additional private rooms and bathrooms, or other possible projects which enhance the quality of life of their residents. Under the proposed requirements, nursing home operators desiring to make necessary improvements for the benefit of their residents could be denied CON approval to do so, because of relatively few, lower-level citations.

These concerns are amplified by the intention that these purported quality indicators be applied to all nursing homes operated by the same entity. If one facility fails to qualify for CON approval under the proposed quality thresholds, all facilities under common ownership similarly would be disqualified from CON approval for initiation, acquisition, expansion or replacement of nursing home beds. This approach could result in the perverse situation in which a nursing home with a good record of compliance would be prevented from receiving CON approval for needed improvements, merely because another facility under common ownership has a relatively high number of citations. Taken to the extreme conclusion, high quality nursing homes could be forced to close because of CON disapprovals based on the poor survey results of other facilities in the same system. Ultimately, these circumstances would affect the willingness of nursing home operators, both current and potential, to provide long-term care services in Michigan.

In addition to the reasons stated above, another problem created by including state survey results in the CON Review Standards is the issue of out-of-state operators desiring to come into Michigan to open or acquire a nursing home. The State of Michigan would not have the ability to examine the survey results from other states when reviewing a CON application from an out-of-state applicant. This situation would create a CON review process that is unequal among applicants and, in fact, that discriminates against existing Michigan providers. Under the law, all applicants should meet identical CON requirements and standards.

Spectrum Health had representatives attending meetings of the NHSAC, and they registered our concerns as the proposed Standards were being developed. However, the opportunities for presenting public comment at the SAC meetings were limited. Members of the public were discouraged from presenting their concerns, if their perspectives were the same as others making comments. Furthermore, the dates of the meetings of the work groups, where most of the issues were discussed and recommended language was developed, were not announced to the public. Non-SAC members were not invited to participate in

work group deliberations. Given these circumstances, we believe that the spirit, if not the letter, of open meetings requirements was not embraced in the development of the proposed revisions to the Nursing Home CON Standards.

For these reasons we ask that the quality measures, as proposed, be removed from the proposed CON Review Standards for Nursing Home and Hospital Long-term Care Beds submitted for public hearing. Because the issue of quality nursing home care is of primary importance, we recommend that the Commission authorize the Department to continue to study this issue by soliciting input from interested parties across the state, with the goal of providing alternative quality recommendations to the Commission at the March meeting.

Spectrum Health appreciates the opportunity to present our views on the proposed language for the CON Standards for nursing home beds, and we look forward to the opportunity to develop a fair and objective remedy to the concerns we have raised.

Respectfully,

Jeff Mislevy, Executive Director
Long Term Care Operations
Spectrum Health Continuing Care

Jon A. Nowinski, CPA:

Thank you for the opportunity to speak to this Commission. I am a shareholder in the CPA Firm, Lally Group PC, in Jackson, Michigan. Our Firm has served the Long Term Care industry since 1965. I have been providing accounting and consulting services to nursing homes since 1995. I also come here today as a Michigan citizen with parents in their 80's. They could need nursing home care in the near future.

I come here today to speak in opposition of the proposed CON Standards, especially in the use of survey results to disqualify an operator from improving or replacing their current facility, or purchasing a new one. I believe that it should be the goal of this Commission to provide Michigan senior citizens with access to nursing home care at as many new and improved facilities as possible. I fear that the proposed standards will reduce the number of new and improved facilities by creating additional barriers and disincentives to investments. These new standards could therefore make it more likely that a Michigan senior would be living in an outdated facility.

I am specifically concerned about the effect the proposed standards will have on the ability of nursing home operators to access capital and financing for improvements. My practice has included the task of presenting nursing home improvement proposals to commercial lenders on behalf of clients wanting to obtain financing. The two biggest issues typically raised by the bank are related to cash flow and uncertainty. A facility needs to be profitable enough to repay an improvement loan, so regulations that drive up the cost of improvements, or reduce the owner's ability to make a profit, reduce the likelihood that improvement loans will be approved. The bank also wants some comfort that the operations will continue in a stable environment. Regulations that prevent needed improvements increase the level of uncertainty in the industry and make loans less available and more expensive.

The definition of common ownership and common control also raise concerns. Is it the intention of this Commission to disqualify a facility if it has the same passive investor, such as a Limited Partner, in common with another facility that has been disqualified? Is it the intention of this Commission to disqualify the facility owned by someone whose parent or sibling owns a disqualified facility? The proposed rules would appear to answer both questions "yes", but this outcome remains unreasonable.

I am also concerned about the focus on the New Design Model. Is there evidence that this is an economically viable requirement in the current reimbursement environment? If it's not, will the State's policy be, that it is better for a senior to live in an old facility, instead of a new one that does not meet the New Design Model? That situation will be the result if these rules prevent improvements that do not comply.

I can understand the State's desire to protect citizens who access nursing home care, but this desire should not slow down or prevent the replacement and renovation of existing nursing facilities.

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December 11, 2007

I am Patricia Anderson, Executive Vice President for the Health Care Association of Michigan. HCAM represents 240 for-profit, non-profit and county owned nursing facilities across the state caring for over 20,000 residents on a daily basis. Our members strive to provide the highest quality of care each and every day for these citizens.

HCAM has participated in the Nursing Home Standards Advisory Committee as a member of the SAC, an alternate and on many of the workgroups. The NH/HLTCU SAC was given an extensive charge to address in a short time period, less than the normal six months for SACs. This was the first broad review of these standards in the past 15 years or more. For example, the data to compute the bed need is from 1987 for the age cohorts and 1990 for the census. This extensive review was well overdue and overwhelming.

The SAC has completed its task and has brought the proposed language to you for action. The proposed language signifies a major shift in policy for the nursing home industry. This shift brings along with it considerable risk of the potential for adverse impact on the residents served in the nursing homes and the provider community. It seems critical to not rush to completion without taking adequate time to consider the impact of these changes. Various concerns had been brought to the SAC in their final meetings but time had run out to appropriately address the issues and complete the task on schedule. The risk for unintended consequences is high.

As an alternate to the SAC and a participant in many of the workgroup meetings, I felt very uncomfortable at the end in moving the proposed standards forward without time to fully comprehend what they mean. Time ran out to get requested data to understand who the quality thresholds would impact, and to deal with issues related to fairness for both in-state and out-of-state provider networks and large national chain organizations. We did not have time to ask the financial market their impression of these proposed standards on their ability to finance new facilities, renovations or acquisitions. The average age of the Michigan nursing homes is over 40 years – we need to promote replacement and having willing financiers.

Additionally, HCAM does have concerns with the proposed quality measures because they only reflect survey results and not other perhaps better measures of quality. HCAM is not opposed to the inclusion of quality measures but they must go beyond the survey process. These measures could be: customer satisfaction, staff satisfaction, quality measures as reported to the Centers for Medicare and Medicaid Services and staff turnover. These measures relate more to the customers' point of view of the service provided to them. The proposed quality measures also include the Quality Assurance Assessment Program or provider tax debt which has already been addressed in legislation and related Medicaid policy. The inclusion here seems duplicative to the law and established policy.

HCAM also has concerns regarding the cost of requiring the new model design at 80% single occupancy rooms. The 80% number was used in the pilot program but there has been no rationale reason for 80% as versed to 50%. As CON is required to consider the cost of healthcare we need to know that this requirement increases cost substantially. The estimated cost for nursing homes built under this requirement is $85,000 to $110,000 per bed. Currently Medicaid reimburses cost per bed at $53,500 and pays for about 70% of nursing home care. How will these standards bridge this cost gap? The data gathered from the pilot addendum should be reviewed to determine the appropriate percent of single occupancy rooms. The pilot data was given to the SAC but was lost in the need to complete the task outlined in the charge.

HCAM is supportive of the addendum changes to the Special Population Groups. These proposed standards are addressing critical access issues and reflect the change in the individuals served in nursing homes. The original special population groups were appropriate when established but since their creation the environment has changed. The proposed standards do reflect this change and hopefully will meet the needs of these special population groups. The biggest factor in their implementation is the ability to secure appropriate reimbursement for these services.

In lieu of proposing action on these draft Standards, HCAM respectfully requests that the Commission authorize MDCH to organize a workgroup to finalize the proposed language for presentation to the Commission for action at the March 2008 Commission meeting. The workgroup would be organized as follows:

- MDCH would determine the composition of the workgroup with a balance of providers and consumer advocates, but with additional input from the financial/lending community and insurance industry as to the impact of the proposed requirements on the availability and cost of financing and insurance for Michigan providers.

- An individual from MDCH would chair the workgroup and it would act by consensus to review and finalize the language of the proposed Standards.

- Interested members of the public would receive notice of the meetings and have an opportunity to attend and provide input in a manner determined by MDCH.

HCAM urges the Commission to delay proposed action to approve these Standards, except for the Addendum on Special Populations which is in final form, and to allow a workgroup an opportunity to bring back a final version for action at the March 2008 Commission meeting.

Thank you for the opportunity to testify and I am available to answer any questions.

Attachment O

Area Agencies on Aging Association of Michigan

Mary Ablan
Executive Director

December 11, 2007

To: Ms. Norma Hagenow, Chair, Certificate of Need Commission
From: Mary Ablan, M.A., M.S.W., Executive Director, Area Agencies on Aging Association
Re: Testimony on SAC recommendations affecting nursing facilities

I would like to submit the following testimony regarding the recommendations of the Standards Advisory Committee affecting nursing facilities:

I represent the 16 Area Agencies on Aging that have been serving older adults in this state for more than 30 years. Area Agencies on Aging are part of a nationwide network of over 600 agencies created by the federal Older Americans Act. That law directs us to advocate for the independence, dignity and quality of life, and we take that responsibility very seriously. That is why we are submitting this testimony on the standards affecting nursing facilities.

We support the recommendations on quality measures, and urge you to adopt these as a first step in ensuring a basic standard of health and safety in nursing facilities.

More specifically, we support the use of survey data as a reasonable benchmark for basic health and safety parameters. There is no other universal measure of nursing home performance, and only facilities with the most serious deficiencies would be denied a certified of need. Expansion opportunities should be reserved for those facilities with an acceptable track record.

We also support the recommendation that requires the state to consider the performance of all facilities under common ownership and control. Providers with deficient homes should focus on fixing those facilities rather than expanding to new ones. This recommendation also provides an incentive for providers to maintain quality in all of their facilities, not just a select few that are targeted for expansion.

The recommendations also create incentives to accept consumers on Medicaid and thus provide access to care for the most vulnerable with low incomes.

Thank you for this opportunity to submit testimony.

6105 West St. Joseph, Suite 204 • Lansing, MI 48917-4850
Phone: 517-886-1029 • Fax: 517-886-1305 • Web Site: www.mi-seniors.net

mahsa

CON Testimony

December 11, 2007

By David Herbel

President and CEO

Michigan Association of Homes and Services for the Aging
6512 Centurion Drive, Suite 300
Lansing, MI 48917
(517)323-3687 • www.mahsahome.org

mahsa

Testimony before the CON Commission

December 11, 2007

Good morning. My name is David Herbel, President and CEO of the Michigan Association of Homes and Services for the Aging. MAHSA represents more than 200 members of charitable, religious and fraternal organizations which provide the full continuum of long term care services to Michigan seniors.

While MAHSA is supportive of a number of the updates to the nursing home standards, we believe that the overall charge to the Standards Advisory Committee was too large in scope to be addressed in the established timeline and more work remains to be done.

We believe that if the proposed standards are advance forward as written, the impact of their unintended consequences would be to reduce access to nursing home beds in your communities and quality would still not be addressed. Listed below are just a few examples of MAHSA's concerns.

High Occupancy Standards

Currently, a nursing home that maintains 97% occupancy for 3 years cannot expand unless all other nursing homes in its entire planning area have had the same experience.

The Department told the NHSAC that of Michigan's 433 nursing homes, 10 met the 97% occupancy requirement for the last 12 quarters, and not one met the planning area criteria. Thus, none of those 10 facilities would be eligible for expansion under the existing high occupancy standard.

MAHSA believes that we, the long term care community, need to stop the practice of driving consumers into empty beds, by affording the consumer choice and allowing all high occupancy providers in Michigan the ability to expand.

POSITION: MAHSA requests the Commission amend Section 6 to allow all high occupancy nursing homes in Michigan to expand, not just the rural facilities. This can be accomplished by adopting the proposed language in subsection (III) (B) (lines 406-408 on the draft handout) for rural facilities and removing the language in subsection (II) (B) (lines 381-384 on the draft handout).

Special Population Beds - Religious Use

The NHSAC has established two new special use bed categories: 1) TBI/SCI (400 beds) and 2) behavioral (400 beds). In order to create these new groups, the NHSAC has eliminated others; one of the eliminated groups is religious use beds.

MAHSA member organizations have been caring for seniors for more than 100 years. We are proud of our members' religious ministries and the support each provides to their respective faith. This religious use pool of approximately 300 beds has historically been used by our charitable religious members to create new ministries based on the movements of their congregations. These organizations were established for a specific religious purpose while serving church members who wish to live out their lives in a manner consistent with their beliefs. While MAHSA represents many organizations with long commitments to the elderly, the list of those religious organizations that have been serving their congregations for more than 100 years is as follows.

- Jewish Home and Aging Services
- Clark Retirement Community
- Evangelical Homes of Michigan
- Holland Home
- Lutheran Homes of Michigan
- Michigan Masonic Pathways
- Volunteers of America
- United Methodist Retirement Communities

Are you, the CON Commissioners, sure that these are the provider organizations you wish to sacrifice to expand other special interest categories?

POSITION: MAHSA requests the reinstatement of the Religious Use Beds pool.

Quality Measures

MAHSA members fully realize that the Department of Community Health has charged the current Standards Advisory Committee to consider inclusion of performance criteria in the CON application process. Make no mistake that MAHSA supports all quality measures that ensure the safety of our residents and enhance service delivery. This is especially critical as the quality debate rages on both nationally with the Presidential candidates in Iowa and more recently here in the Michigan.

MAHSA could strongly support the inclusion of performance standards if we could validate the impact upon the LTC community prior to its implementation. Here are two suggestions MAHSA would like to offer:

- Refine all of the quality criteria with a quantitative process. At present no one has been able to define for MAHSA the impact of the proposed policy language.

Or

- Implement a process that includes the voice of all stakeholders in defining quality, not just a federally imposed process, which is driven from Baltimore and Chicago. This can be accomplished by implementing a nationally recognized performance evaluation process statewide. The MAHSA membership has such a program already in use entitled "Defining Excellence." Attached for your review is an overview of the MAHSA program.

Relocating Existing Beds

Generally, nursing home licenses are not allowed to be split and sold between providers. Traditionally, the provider who has extra beds returns them to the statewide pool for use at no additional cost to the end user. Other reasons to support our opposition are:

- Under the proposed language neither the seller nor the recipient facility would need to satisfy the new quality measures to be eligible for the relocation of beds. This sidestepping of the overall intent of these new standards should not be overlooked. Moreover, it is a great illustration of the futility of the proposed quality measure language.

- Also, the proposed language will only promote the expansion of existing facilities vs. the development of new and smaller innovative design models, because it only allows the relocation of beds to currently-licensed providers.

POSITION: MAHSA opposes inclusion of Section 7.

In fairness to all concerned, MAHSA would ask the Commission to place this process in total, on hold for no more than 90 days. Given the existing ambiguity, conflicts in public policy and inability to quantify the impact on the long term care system, we have no other option. Let's convene a special work group populated by experts with demonstrated histories in the CON programs and truly measure the impact of these standards upon cost, quality and access prior to their implementation.

Thank you for your time.

Should you have any questions, please feel free to contact me at (517) 323-3687 or by e-mail at dherbel@mahsahome.org

Respectfully submitted,

David E. Herbel
President and CEO
MAHSA

Attachment

mahsa
Defining Excellence

Defining Excellence for Michigan: MAHSA Member Performance
MAHSA is very excited to present its plan to work with members to better define quality and performance for the Michigan long term care provider community. In this time of increasing regulatory oversight and inconsistency, it is more important than ever that we more clearly identify what quality means to consumers and how to measure it across all long term care settings. It is our hope that this important project will address and transcend the barriers to overall program performance encountered daily by our members.

General Process
The core of MAHSA's Defining Excellence for Michigan Project is information. We are working with My InnerView to help provide standardized customer satisfaction, employee satisfaction and other performance measures to those members who wish to be program Early Adopters. After that time, MAHSA will review the products and move the project to all members. Early Adopters will be focusing on skilled nursing home data, but there are plans to extend across the entire long term care continuum of programs in 2008.

Specific Purpose
Defining Excellence will identify suitable measures, as well as define and benchmark program performance for all long term care settings in Michigan. These data gathering and analysis activities lay the foundation for understanding performance, identifying global opportunities, identifying best practices and promoting improvement. In addition, performance information can lay the groundwork for thinking about organizational future, core products, and capabilities.

Overall Goals

1. Foster the use of documented evidence in the evaluation of quality and effectiveness as related to survey criteria, Michigan state policy and federal regulation, as well as development of benchmarks, indicators, and measures.
2. Describe a more accurate and multi-dimensional picture of outcomes and effectiveness for MAHSA member programs, not relying solely on a select number of clinical indicators or federally driven survey criteria.
3. Assist in making MAHSA member aging services and nursing home care at the level of the very best in the nation

The My InnerView Package

My InnerView offers evidence-based management tools to enable long-term care leaders to directly enhance quality of life and quality of care for their residents, families and staff, while achieving financial success.

The My InnerView Quality Profile presents the essential areas of performance in a usable format, identifying organizational benchmarks with peers, state, and national providers. The Quality Profile includes organization-submitted information about clinical outcomes as well as Survey and Certification information. MAHSA, with a group of member clinicians and Early Adopters, will identify an additional 30 metrics that will more accurately measure member performance. Consistent reporting of these metrics across MAHSA members will enhance our ability to document and publish the non-profit difference.

Resident satisfaction surveys will be conducted and summarized by My InnerView annually, although some facilities may opt to do resident satisfaction shortly after discharge for short term residents. Resident satisfaction surveys include relevant quality of life factors that are critical for this population. Employee satisfaction surveys will also be conducted and summarized by My InnerView annually. The first national report on employee satisfaction was just completed in 2006, and can be viewed from www.myinnerview.com.

Michigan Disability Rights Coalition

With Liberty and Access For A

December 10, 2007

To the Certificate of Need Commission:

In 2004 Governor Granholm appointed me to Chair the Medicaid Long-Term Care Task Force. One of the charges to the Task Force was to:

> Examine and report on the current quality of Medicaid long-term care services in Michigan and make recommendations for improvement in the quality of Medicaid long-term care services and home-based and community-based long-term care services provided in Michigan.

In 2005 the Task Force made the following strategic recommendation regarding a quality long-term care and supports system:

> Align regulations, reimbursement, and incentives to promote this vision of quality and move toward that alignment in all sectors of the LTC system. Ensure that the consumer is the focus of quality assurance system.

In keeping with this strategic direction and as a long-time advocate for people with disabilities, I wholeheartedly support the proposed new standards. These standards are:

- Set a bottom line for basic health and safety before a nursing home owner or corporation can build, renovate, or buy a nursing home.
- Only bar providers with very serious compliance issues. Problems like decertification, loss of license, bankruptcy, having more than two times the state average number of citations in two consecutive surveys would block providers from expanding.
- Require the state to consider all nursing homes with common ownership or control when conducting a CON review.
- Not count building-related citations against the provider. If the building is the problem, the new standards are not a barrier to fixing the building.
- Require nursing home owners to pay any Quality Assurance Assessment Program (QAAP) (provider tax) and Civil Money Penalty (CMP) fines before expanding.

These are reasonable standards that begin to design a long-term care and supports system that puts the consumer as the focus of a quality system. Some of the most vulnerable citizens of Michigan deserve these CON standards. It is time to place their interests above the financial interests of some businesses.

Sincerely, RoAnne Chaney
Health Policy Project Manager

780 West Lake Lansing Rd., Suite 200 ■ East Lansing, MI 48823-8452
(517) 333-2477 / (800) 760-4600 voice/TDD ■ (517) 333-2677 fax

TO: Michigan Certificate of Need Commission
FROM: Andrew Farmer, Associate State Director for Health & Supportive Services
AARP
RE: PROPOSED NH-HLTCU BEDS SAC RECOMMENDED STANDARDS
[Item XI of December 11, 2007 CON Tentative Commission Agenda]
DATE: December 11, 2007

TESTIMONY OF AARP IN SUPPORT OF LANGUAGE PROPOSED BY THE COMMISSION'S NH-HLTC BED SAC

While it of course has never made any moral, fiscal or political sense for public or private entities to do business with bad operators of business with poor track records and substandard delivery, it ought to be quite a bit more obvious to any reasonable person that increasing business to already questionable actors makes a whole lot less sense.

With that in mind AARP is pleased to observe language in this SAC's proposal which begins to move the Michigan Certificate of Need process for nursing facility awards in positive directions – indeed out and away from what has for too long been a status quo of rewarding lackluster nursing facility operators by giving them even greater capacity for continued and probably greater failure.

But AARP would first like to emphasize, with all due respect to all the talented appointees who obviously worked so hard and invested great thought and leadership into the crafting these new provisions and process, how we nevertheless view this progress, if adopted by the full Commission, still only as baby steps in the direction of CON-specific reform.

Our first plea within our testimony today therefore is that the Commission strongly reject any pressure or other further attempts to reduce or otherwise weaken or delay what this Committee has forged. Some external opponents to the language, which you otherwise know was adopted unanimously by consumer and industry leadership alike on the SAC, may still persist in criticizing the results as too strident, or, even try to confuse CON issues, processes and yourselves with separate regulatory systems directly responsible for evaluating compliance with quality standards in certification and licensure.

They may even argue those separate regulatory systems lack sufficient accuracy and operational integrity to write and enforce citations for non-compliance to an extent which, suggests or even alleges outright, that those systems can provide no validity for the basing of CON application decisions. AARP urges Commissioners to be on guard against attempts at such subterfuge and maintain the State policy boundary for this prudent CON reform opportunity versus the separate discussion critical exponents already enjoy full recourse to within that other system.

The only criticism AARP otherwise offers at this juncture does not particularly focus on the SAC's work per se but on the CON provisions, in whatever current or proposed iterations, on describing and awarding Special Population Beds. AARP has spoken previously to this SAC to raise the question of whether the Special Population construct might violate current federal nursing facility regulations. Since 1987, these have called for every single admission to a nursing facility to receive and participate in comprehensive interdisciplinary assessment, leading to multidisciplinary comprehensive care planning.

The comprehensive plans of care and the residents they are written with and for receive at least quarterly review and updating and/or as significant changes of the resident's condition or wishes occur, sometimes triggering a new interdisciplinary assessment. The beating heart of what was and is thus known as the Federal Nursing Home Reform Act (OBRA '87) drills down to the ground zero proposition, stemming from a preceding National Institute of Medicine study, that there is only one, true, clinical and moral special population: the individual -- including consideration and respect of his or her own cultural and religious identity.

Continuation of so-called Special Populations Beds as a practice in Certificate of Need undercuts the demands in federal law that each facility resident be diagnosed and treated as an global individual and not according to what room or building they're placed in. AARP suggests this issue be revisited in the next CON NH-HLTC review cycle.

In conclusion, AARP supports and applauds the language proposed by this NH-HLTC SAC as-is and urges the Michigan Certificate of Needs' Commission's swift and complete adoption of them. Thank you for this opportunity to testify before your Commission this morning.

BRIAN A. KASER
ATTORNEY AT LAW

BRIAN KASER, PLC

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LANSING, MI 48906
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LEGAL COUNSEL TO

HEALTH CARE PROVIDERS
ELDER SERVICE ORGANIZATIONS
NONPROFITS

December 10, 2007

Norma Hagenow
Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
7th Floor, Capitol View Building
201 Townsend Street
Lansing, MI 48913

Re: Proposed revision of Nursing Home CON Review Standards

Dear Ms. Hagenow:

This letter offers comment on the work product of the 2007 NH SAC, approved on November 28, 2007 and recently posted on the MDCH website. My comments relate to the posted draft labeled, "For CON Commission Proposed Action on December 11, 2007."

My comments are offered out of my 24 years of experience working with the CON program. They are submitted on my own initiative, at my own expense.

A great deal of controversy has surrounded the importation into the Standards of what the Commission's charge calls "quality measures." I agree that that addition to the Standards has many defects, but my comments address instead two less-known changes, both of which, I believe, will keep new and innovative providers out of the nursing home arena and which may well cause capital to flee the Michigan elder services market.

Acquisition of Existing Nursing Homes.

The definition of "acquisition of an existing nursing home" is proposed to be changed (line 34 and following). Current Standards define that as the change of ownership of a licensed nursing home, and have done for many years. The SAC proposes to restrict the definition to include only nursing homes that are licensed *and operating*.

CON staff has long held that what a Standard does not address cannot be done, regardless of the presence of universal review criteria in section 22225 of the Code. Thus, this change will mean that only a licensed and operating nursing facility may be acquired by a new operator. A facility that has its license but is not operating may never be sold, under the SAC proposal. That means that facilities that are not operating, regardless of reason, will eventually lose their licenses. The Commission's charge did not ask the SAC to initiate such a sweeping change.

Facilities can go out of operation for a number of reasons, among which are regulatory sanctions imposed by MDCH itself, but which also include financial difficulty, bankruptcy, physical plant damage and even death of the owner. Where regulatory action closes a facility, one might accept that the owner "deserves" to lose the valuable license and CON. But do consider the collateral damage such an event will cause.

Many nursing homes operate in buildings that are leased, or financed. Their capital comes from passive sources with little or no control over operations. If loan and lease documents are properly done, the lender or lessor might exercise a "lights out" power, retake the property and sell or lease to another operator, a common creditor's remedy. The language would deprive lessors and lenders of their reentry powers, because with the defaulting facility out of operation, only the highly specialized building, useless for other purposes, could be sold or re-let.

Lenders and landlords currently in the market have not planned for this change. They will be caught up as innocent bystanders in the predictable confrontations between MDCH and operators over termination of operations. There will be at least two predictable consequences.

First, lenders and landlords, with the loss of their property value at stake, will fund litigation to fight MDCH closure of sub-par facilities. These will be "bet the farm" cases.

Second, landlords, and especially lenders, will not risk new capital in a state in which remedies are so limited. Improvements to existing facilities and even new design model facilities will be that much harder to finance, and, I predict, will not be created.

CON changes set precedents, as you know. If non-operating nursing beds cannot be transferred, when other facilities and services come up for review, the Commission may well be asked to declare why they should not have the same or similar treatment. Examples might include an imaging center closed for equipment replacement, or a hospital without all beds set up and operating. It is not easy to speculate, but one must wonder whether limitation of this concept can be defended.

Finally, I must suggest that making a closed facility unsalable may well raise conflicts with the federal Bankruptcy Court, which holds the power to operate, close or sell any asset held by a debtor. I fear that this provision will place the CON program into confrontation with one or more federal Trustees or creditor committees.

What is needed. Where MDCH action or other adverse events lead to a nursing home's cessation of operation, the CON standards should allow a suitable purchaser to take up the lease or financing and operate the "franchise" that the CON affords. Any licensed facility should be transferable, and should be transferable until its license is revoked and avenues of appeal are exhausted.

Medicaid Participation and Comparative Review

The SAC recommendation makes very substantive changes to the comparative review criteria that reverse years of MDCH practice in this area. Specifically, sections 10(2) and 10(3) are proposed to make past participation in Medicaid and Medicare very significant elements in any comparative review. Currently, only predicted bed certification and payor mix dominate the comparative review scoring. In Act 619, the legislature even went so far as to empower MDCH to enforce Medicaid participation predictions made in CON applications. See Code section.

The adverse effect of the change is this: Only existing nursing homes will be able to prevail in comparative reviews over new providers. The current providers will be able to expand by adding beds as they become available, while new projects, like new design model facilities on new sites and even traditional nursing homes will lose 17 possible comparative review points out of a total possible 47, solely because they are new to the field. The Code does not support such a preference for existing facilities over new entrants.

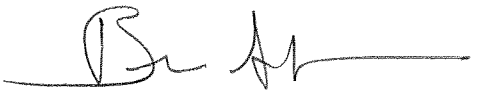
I am especially concerned about Continuing Care Retirement Communities, and within that group of elder care institutions, those which hope to offer contracts registered under the Living Care Disclosure Act. They are by definition new facilities, in which nursing care is a small but indispensable component. As written, the SAC proposal would advantage a large nursing home adding apartments as an afterthought over a new center with a continuum of residential and on-site nursing care as its primary mission.

What is needed. Restrict the SAC to its charge, and restore the prior text, which evaluated applications and their projected services, rather than the past payor mix of their proponents.

Thank you for your attention to these comments. By copy of this letter, I am distributing them to all Commission members. I look forward to answering questions about them at Tuesday's meeting.

Very truly yours,

BRIAN KASER PLC



Brian A. Kaser

cc: Commission Members
Ms. A. Moore

53 Bed Rural	245 Bed Urban
50 Employees	220 Employees
52 Residents	230 Residents
Active Family Support	Limited Family Support
Less than 25 admits per year	More than 400 admits per year
0 Residents under 65 years old	28 Residents under 65 years old
0 Mental illness	27 Mental illness
0 Residents fed via tube	25 Residents fed via tube
0 Dialysis	7 Dialysis
20 Residents with depression/behavior	91 Residents with depression/behavior

To: CON Commission

December 10, 2007

My name is Lucille Kangas and I have been a resident at Houghton Co MCF for six years. I have served as president of the resident council for five years. I am also on the Single Point of Entry, Long Term Care Connection Consumer Advisory Board.

In my role as president of the resident council and on behalf of all nursing home residents it is important for me to express my support for the implementation of new standards for the expansion and ownership of new nursing homes in the State of Michigan. These standards, particularly a review of past performance, are needed to protect existing and future nursing home residents. Expansion and new ownership without these standards could place nursing home residents in jeopardy and lower the quality of service in Michigan's long term care system.

Therefore I support the proposed Certificate of Need Standards currently under review.

Lucille Kangas

MICHIGAN LONG TERM CARE OMBUDSMAN

MEMORANDUM

DATE: December 11, 2007

TO: Certificate of Need Commissioners

FROM: Sarah Slocum, State Long Term Care Ombudsman

SUBJECT: Proposed Nursing Home/HLTCU Standards

My name is Sarah Slocum, and as the State Long Term Care Ombudsman, my job is to advocate on behalf of the residents of licensed long term care facilities. It has been my privilege to serve on the Nursing Home/Hospital Long Term Care Unit (NH/HLTCU) Standard Advisory Committee. We have spent the last six months working in good faith to bring you a set of proposed revisions to the NH/HLTCU Certificate of Need (CON) standards. I am here today to strongly support adoption of these standards, and to ask you to move them forward without delay.

The standards add several components to the NH/HLTCU standards which I believe are long overdue.

First, establishing a baseline of required health and safety in long term care facilities that must be maintained for a provider to build, buy, renovate, or expand their nursing home business. The standard we propose is very modest and would only prevent long term care providers with the most serious compliance problems from expanding. The standards also encourage expansion of New Design Model type nursing facilities, in which more residents have private rooms, smaller living groups, and a generally more home-like environment.

Second, these proposed standards would link ownership of nursing facilities, and require the Department of Community Health to consider the track record of all facilities under common ownership or control in making CON decisions. Providers who consistently meet state and federal requirements will be rewarded, while those who consistently fall below these requirements will need to bring poor performing facilities in their organization up to a minimal level of compliance before a CON could be granted.
Third, I support the other revisions in this document and adoption of this entire set of revisions as put forward by the NH/HLTCU Standard Advisory Committee.

State Long Term Care Ombudsman, Sarah Slocum, 7109 W. Saginaw, P.O. Box 30676, Lansing, MI 48909. Telephone 517/335-1560, Fax 517/373-4092

Third, I support the other revisions in this document and adoption of this entire set of revisions as put forward by the NH/HLTCU Standard Advisory Committee.

I am very pleased to have participated in the development of these standards, and hope you will act quickly on them so that long term care facility residents can count on a future where only the better providers are allowed to expand.

United Cerebral Palsy of Michigan
Life without limits for people with disabilities™

3401 E. Saginaw
Suite 216
Lansing MI 48912
517 203-1200
fax 517 203-1203
toll free 800 828 2714

www.ucpmichigan.org
ucp@ucpmichigan.org

December 10, 2007

Re: Comments re Proposed Standards for Nursing Home Certificate of Need

Dear Commissioners:

United Cerebral Palsy of Michigan is a non-profit disability advocacy organizati working for full citizenship for people with cerebral palsy and other disabilities. are writing to express our support for the proposed standards for approval of applications for new nursing home beds. It is our understanding that many members of the nursing home industry oppose the standards and are requesting more time for consideration of alternatives. We support the standards and urge the Commission **not** to delay acting upon them.

We believe the standards are fully justified and are, in fact, not onerous. Michigan citizens want every new nursing home bed to be in a home run by an owner committed to quality services. There is no justification for approving new beds for an applicant that operates a home or homes that have had more than twice the statewide average number of D level citations for two or more consecutive years, which is the proposed standard. Nursing home owners who do not meet this bar are not the providers we want caring for our vulnerable citizens.

Providers argue that the standards use survey data and that the surveys are subjective and unfair. But the surveys are the only universal standard we have, and any provider has the right to appeal a citation with which it disagrees. Furthermore, the industry, which claims it can and should be permitted to police its own quality, has not put forward any comprehensive alternative standard to assure the health and safety of the individuals in its care.

For these reasons, we urge the Commission to adopt the standards presented to it after months of consideration by a group which included members from all stakeholder groups, including the nursing home industry.

Thank you for consideration of these comments.

Sincerely,

Linda Potter

Linda Potter, J.D.
Executive Director

Dear Andrea:
I received your name from the Olmstead Coalition. I simply want to make a short comment on the new Standards for Nursing Home Certificate of Need.
I have a 92 year old mother in a nursing home, it is a county medical care facility in Northwest Michigan and she receives very good care. As mom gets more and more frail, I become more aware of her vulnerability. If she was in a facility that provided care that was wanting, why would anyone want to allow that organization, business, corporation etc. to expand its circle of poor or substandard care thru a CON process? As such, I do not wish to reward facilities that have exhibited failures in protecting the people whose care is entrusted to them with the ability to expand and enhance their bottom line.
As the caregiver of my vulnerable, 92 year old mother I support the new standards.
Thank You
Gregory E, Piaskowski
228 Midtown Drive
Traverse City MI 49684
231-922-1899

Disability Network of Mid-Michigan

1160 James Savage Road, Ste. C
Midland, MI 48640-6814
Phone: 989.835.4041
Fax: 989.835.8121

FAX

MAY CONTAIN CONFIDENTIAL INFORMATION

To: CERTIFICATE OF NEEDS COMM. From: TERRI

Fax: 517 241 1200 Pages (including cover): 4

Date: 12-11-07 Re: SAC RECOMMENDATIONS

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Comments:

PLEASE ACCEPT THIS TESTIMONY IN SUPPORT OF THE SAC RECOMMENDATIONS TO THE CON COMMISSION

Michigan Certificate of Need Commission
Public Comment
December 11, 2007

RE: Recommendations of the Standards Advisory Committee

Commission members,

Thank you for the opportunity to publicly support the recommendations of the advisory committee. Having reviewed the recommendations, it is evident a great deal of consideration went into outlining the supports we should be able to expect for Michigan citizens needing nursing level care.

As I read, I was challenged to find what support had not been sufficiently identified. I was comforted in the details, especially when addressing individuals who may receive services under 'special population groups'. The clarification of appropriate supports and 'size limits', if you will, further aids to assure more individualized supports are provided, not only for a variety of care needs, but for preferences as well.

The safeguards built in to assure adequate supports are commendable. The history of provider quality has great value to Michigan citizens. This is not to say that new providers should be excluded, and I believe these standards do a fair job of welcoming all providers to do quality business.

Nursing home and hospital long-term care providers should rest confidently knowing that their good work will be recognized. We want strong providers to have opportunities to expand and those who can not meet an expected standard to go by the wayside. These recommendations provide the flexibility that providers need and the quality we should be able to count on. Building in a reasonable level of allowances, nursing home and hospital long term care providers will not be put in jeopardy for one bad survey or when the need for a closure arises. Rather, the standards, as recommended, look at the track record, and defend continued quality. Additionally, new providers are not penalized in their youth, but are given a clear chance to make their mark.

This Commission chose to appoint a Standards Advisory Committee to review CON standards and put purposeful effort into selecting its members. We have confidence in the Commission's selection of appointees, as there is a fair, well-educated, and experienced representation of this service sector. The expertise is not only evidenced in the experience these members bring to the table, but in the depth with which they reviewed the standards. You put before them an important task and they did not take that lightly. As I said, we have confidence in the Commission's selection of appointees. I ask that you have equal confidence in their recommendations.

Thank you,

Terri Cady
Disability Network of Mid-Michigan
1160 James Savage
Midland, MI 48640
cady@dnmm.org
1-800-782-4160

DISABILITYnetwork
Mid-Michigan

Certificate of Need Commission
Public Comment
December 11, 2007

I am not up for the trip to Lansing to speak with you today. Please accept this letter as a record of my support for consistently applied nursing home standards. My name is Jamea McKnight and I have lived in a nursing home.

My experience began quite unexpectedly, when during surgery at the age of 45, I acquired a virus, which led to a variety of autoimmune and physical changes in my body, requiring a higher level of nursing care. I had to relearn to do a number of things, like speak and walk. As my body fought the effects of the virus, more complications developed, including significant weight gain due to the steroid treatment that I had to endure. My stay went from weeks, to months, to years.

My experience with the nursing home was not particularly pleasant. There are some people there who are genuinely kind, who have a smile for everyone, and if something comes up, will find a way to meet your needs. The fact is, most of the people are there to do a job and will get to things when they can. The care offered from one nursing home to another is not consistent, let alone from one hallway to another. Whatever you can do to improve care, I ask you to do. People deserve to know what kind of care they are getting when they go to a nursing home.

One of my biggest concerns is how people are treated, health-wise and dignity-wise. An example for you would be after meal time. They line up everybody like a cattle train and take everyone in the same bathroom one at a time to void. No one cleans the seat in between. Conversations for the next hour are rather loud and unprofessional, including comments like "oh, you did make a doo-doo".

A more private incident did not yield any better results. I remember the date was October 14, 2006. I'm not sure why I remember it, but I do. It was 7:10am and I had to go to the bathroom. Shift change had just occurred at 7am. I quietly told my aid that I needed some help getting to the restroom. She yelled down the hall to the charge nurse, asking if she knew that I needed to go to the bathroom. She concluded that I had surely just used the restroom prior to shift change, and did not need to go. She further instructed me that I was on a bladder training program and would need to wait two hours. Well, I didn't just go to the bathroom, and even if I had, I don't think that should have made a difference.

The most frustrating thing that I see is the waiting. Before I got a motorized wheelchair, I had a manual one that I could not move very well on my own. It was not uncommon for me to push the call button and wait 30-45 minutes for someone to come and check on me. Once I had even fallen.

I am not interested in reopening grievances, as I filed many. I do want to tell my story so that people don't think that everything is OK or that just because one nursing home is doing well that things are nice everywhere, because they are not.

If consistent standards were applied, regardless of the age of the building, the date of opening, the experience of the provider, etc., people could confidently rely on care from a nursing home for themselves or a loved one. The only thing I am confident of right now is that I never want to go back. Please take a step forward in making sure that care is consistent and fair for everyone, everywhere.

Thank you,

Jamea McKnight
1116 Madison
Saginaw, MI
48603

Nursing Home and Hospital Long-Term-Care Unit Beds
Standard Advisory Committee
Final Report to the Commission

December 11, 2007

The Nursing Home and Hospital Long-Term-Care Unit Beds Standards were scheduled for Commission review in 2007. A public hearing was held on January 9, 2007 to receive public testimony. The Commission established the Nursing Home Standard Advisory Committee (SAC) at the March 13, 2007 Commission Meeting to address the areas identified by the public hearing testimony. The Commission assigned the SAC to make recommendations at the December 11, 2007 Commission Meeting on the following charge items:

1. Consider inclusion of quality measures (i.e., OSCAR database and licensing certification) for all applicants including the owner/operator and facilities under common ownership, proposing to initiate, expand, or acquire a facility. If recommended, specific quality measures criteria must be provided.

2. Review the Addendum for Special Population Group Beds. Consider possible elimination of the addendum or modification of the addendum criteria, including, but not limited to, the inclusion of a category for patients with a psychiatric diagnosis, traumatic brain injuries, and spinal cord injuries.

3. Review the Addendum for New Design Model Pilot Program. Consider possible elimination of the addendum, extension of the Pilot Program timeframe set forth in Section 3(1), or possible removal of the pilot status to make the New Design Model a permanent addendum of the standards.

4. Review the high occupancy provision in Section 6(c) for potential modification to a facility-specific high occupancy provision.

5. Review definitions and methodologies, and examine other options.

6. Review Long-Term Care policies and regulations of the State within the context of CON scope and authority.

The SAC held its first meeting on July 25, 2007 and has held 5 additional meetings. Task groups were utilized to help facilitate the recommendations. The following are the recommendations in each charge item:

1. Quality Measures.

   The SAC recommends the inclusion of quality measures that apply to the applicant facility and all nursing homes under common ownership or control both

in Michigan and out-of-state. The total number of facilities, which meet the quality measures could not exceed 14% or up to 5 of its facilities. The quality measures criteria applies differently depending on the CON activity. The measures are as follows:

- A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- Termination of a medical assistance provider enrollment and trading partner agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).
- Two state rule violations showing failure to comply with the state minimum staffing requirements and/or a federal repeat citation arising out of a standard survey documenting potentially harmful resident care deficits resulting from insufficient staff within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- Repeat citations at the harm or substandard quality of care level issued within the last three years. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

Additionally, the SAC recommends that when a home with quality issues is acquired, that it must participate in a quality improvement program, such as My Innerview, Advancing Excellence, or another comparable program for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health System, and shall post the annual report in the facility being acquired.

2. Addendum for Special Population Group Beds.

The SAC recommends the following categories no longer be eligible for additional beds. The current programs can be acquired, but should a facility de-license any of the beds, the beds will be removed from the pool.

- Alzheimer's Disease with 384 beds.
- Health Needs for Skilled Nursing Care (HNSNC) with 173 beds.
- Religious with 292 beds.

With the recommendation for removal of HNSNC beds, the SAC recommends the addition of a rural high occupancy provision with the following criteria:

- Planning area must have a population density of less than 28 individuals per square mile.
- The facility must have an average occupancy rate of 92% for the most recent 24 months.

The SAC recommends the following categories be maintained with modified criteria:

- Hospice with 130 beds.
- Ventilator Dependant with 179 beds.

The SAC recommends the following categories be added to the addendum:

- Behavioral Patients with 400 beds.
- Traumatic Brain Injury/Spinal Cord Injury Patients with 400 beds.

3. Addendum for New Design Model Pilot Program.

The SAC evaluated the pilot program. The Department reported that since December 3, 2004, eleven facilities have been approved under the addendum utilizing a total of 428 beds. The SAC recommends maintaining the New Design Model as regular criteria within the Standards.

4. High Occupancy.

The SAC evaluated the current high occupancy provision within the Standards. The current provision requires that the facility and the planning area have twelve quarters of occupancy rates at 97%. The Department supplied occupancy rates on 433 facilities. Of those facilities, 10 met the 97% for 12 quarters, while none of the planning areas met the criteria. Thus, no facility would be eligible for high occupancy under the current criteria. The SAC recommends no change to the high occupancy criteria.

5. Definitions and methodologies.

The SAC identified the Bed Need Methodology, the Wayne County Planning Areas, and the Comparative Review Criteria as the items necessitating review with the following recommendations.

A. Bed Need Methodology.

The SAC recommends that the use rate and bed need methodology within the Standards be maintained. However, the Department shall be required to recalculate the use rate and the bed need on a biennial basis utilizing the most recent data available.

B. Wayne County Planning Areas.

The SAC evaluated the necessity of Wayne County being divided into three separate planning areas. The 2006 estimated population of each county was reviewed, with the ten largest counties data provided below. The SAC recommends no change to the Wayne County planning areas.

Ten Largest Michigan Counties

Rank	County	July 2006 (Est. Population)	Percentage of State Population
1	Wayne: Area 84: 604,176 (5.98%) Area 85: 401,331 (3.98%) Area 86: 966,346 (9.57%)	1,971,853	19.53%
2	Oakland	1,214,255	12.03%
3	Macomb	832,861	8.25%
4	Kent	599,524	5.94%
5	Genesee	441,966	4.38%
6	Washtenaw	344,047	3.41%
7	Ingham	276,898	2.74%
8	Ottawa	257,671	2.55%
9	Kalamazoo	240,720	2.38%
10	Saginaw	206,300	2.04%
	Totals:	6,386,095	63.25%

C. Comparative Review Criteria.

The SAC recommends comparative review criteria on the measures as follows:

- Percentage of Medicaid days during the most recent 12 months.

- Percentage of Medicaid licensed beds at the facility during the most recent 12 months.
- Percentage of Medicare participation during the most recent 12 months.
- Deduction of points for non-renewal or revocation of license and non-renewal or termination of Medicaid or Medicare certification.
- Participation in a culture change model.
- Percentage of applicant's cash.
- Facility which is fully equipped with sprinklers.
- Percentage of private rooms.

6. Long-Term Care policies and regulations.

   No specific items were identified for this charge item. However, the SAC evaluated long-term-care policies and regulations as applicable to each of charge items 1 – 5. No recommendations are made by the SAC.

The SAC has concluded their work on the charge items and has drafted changes to the Standards for possible proposed action.

Respectfully submitted,

Douglas Chalgian, Chairperson
Nursing Home Standard Advisory Committee

Summary of October 31, 2007 Public Hearing Comments: Psychiatric Beds and Services,

Psychiatric Beds and Services

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Sean Gehle	The Michigan Health Ministries of Ascension Health	Yes		
Paul Ippel	Kent County CMH/d/b/a network 180			*We work with local providers, such as Forest View, to keep lengths of stay appropriate, to divert those appropriate to lesser intensity services, and allow our customers to remain close to their homes while inpatient.* *Nonetheless, Network 180 frequently experiences shortages in bed availability at local hospitals, leading network 180 to contract with 11 hospitals in the western half of Michigan in order to obtain sufficient inpatient capacity. Unfortunately, this results in Kent County consumers being placed as far as 100 miles from home for inpatient treatment.*
Sherry Oegema, Work Group member	Holland Hospital	Yes Supports: 1. Reduction of the minimum size of a psychiatric unit 2. Adjustments to the definitions of planning area and relocation zone 3. Reduction of the minimum occupancy requirements to 60% for adult beds and		

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
		40% for child and adolescent beds 4. High occupancy provision for adding needed psychiatric beds 5. Differential requirements for larger and smaller psychiatric units		
Elizabeth Palazzolo, work Group member	Henry Ford Health System	Yes Supports: 1. Revise the definition of the Planning Area from individual counties to the Health Service Area, 2. Expansion of the replacement zone from 2 miles to 15 miles, 3. High occupancy language allowing facilities the flexibility to expand, 4. Requirement that the number of licensed beds be reduced if the applicant does not meet occupancy targets after adding beds		
The Department recommends that the Commission take final action to approve the revised Psychiatric Beds and Services Standards. Testimony was received identifying an access issue within Kent County. The proposed language contains facility specific high occupancy provision and should help address this situation within Kent County and other counties with high occupancy facilities. Additionally, testimony supporting the recommended changes was received from three organizations.				

Summary of October 31, 2007 Public Hearing Comments: Urinary Extracorporeal Shock Wage Lithotripsy Services/Unit

Urinary Extracorporeal Shock Wave Lithotripsy Services/Units

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Sean Gehle	The Michigan Health Ministries of Ascension Health	Yes		
Ann Stevens	Greater Michigan Lithotripsy (GML)	Yes with most of the recommendations Supports: 1. Initiation and replacement of lithotripsy machines	Does not support: 1. CON requirement for expansion of an existing mobile lithotripsy route, 1,800 procedures per unit annually is excessive	*GML recommends that an existing mobile lithotripsy service should qualify for expansion when its existing mobile unit(s) average 1,200 procedures, and should be able to project an average of at least 800 procedures for each existing and proposed machine on the route.*

The Department supports the proposed standards.

No additional change is recommended based on the lithotripsy comment received during public hearing.

Summary of October 31, 2007 Public Hearing Comments: Cardiac Catheterization (CC) Services,

Cardiac Catheterization (CC) Services

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Dennis McCafferty	The Economic Alliance for Michigan	Yes Supports: 1. Requiring facilities providing CC services in Michigan to participate in the ACC-NCDR/Cath PCI Registry 2. Facilities proposing to initiate a pediatric cardiac cath service to meet certain guidelines of the American Academy of Pediatrics 3. Maintaining the provision of the CON standards that elective angioplasty be done at hospitals with on site OHS		
Sean Gehle	The Michigan Health Ministries of Ascension Health	Yes		
Robert Meeker	Spectrum Health	Yes Supports: 1. Significant improvements in updating procedure weights, 2. Requirements for advanced pediatric CC services, 3. Elective angioplasty should be performed only in hospitals which have on-site OHS back-up, conforming to the guidelines of ACC		
Wayne Cass	EAM/ International Union of Operating Engineers, Local 547	Yes Supports: 1. Facilities providing CC services in Michigan participating in the ACC-NCDR/Cath PCI Registry 2. Facilities proposing to initiate a pediatric CC service to meet certain guidelines of the American Academy of Pediatrics 3. Elective angioplasty should only be done at hospitals with on-site OHS services.		
MDCH supports the proposed standards.				

NEWTAC Recommendations: Interventional Neuroradiology
CON Commission Meeting, December 11, 2006

Overview: The Certificate of Need (CON) Commission requested that the New Medical Technology Advisory Committee (NEWTAC) evaluate interventional neuroradiology procedures and determine whether these procedures should be under CON review. Dr. Suresh Mukherji, University of Michigan interventional neuroradiologist, presented an overview of this field, defined by CPT codes. He advised the committee that interventional neuroradiology consists of both diagnostic and therapeutic procedures. Attached you will find a listing of CPT codes, used by BCN/BCSM to provide data regarding interventional neuroradiology utilization.

Findings: NEWTAC reviewed these BCBSM/BCN data that demonstrated the combined total of 29,436 procedures performed in inpatient and outpatient settings.

- However, only a small fraction of these procedures was performed for therapeutic purposes.
- It became clear that occurrences where diagnostic procedures evolved into therapeutic procedures were relatively small.
- Also, therapeutic procedures are occasionally performed on an emergency basis.
- In addition, a national shortage of interventional neuroradiologists has resulted in other non-specialists performing these procedures.
- Approximately thirty facilities in Michigan currently perform both diagnostic and therapeutic procedures.

Outcome: A review of the materials and information at the NEWTAC meeting resulted in a consensus vote supporting not regulating this sub specialty processures of interventional neuroradiology under CON.

- The alternative to an interventional radiological procedure is surgery, which is often more expensive.
- These procedures must be performed emergently.
- Many hospitals are currently performing these procedures--- it is not easily enforceable to prevent facilities from performing procedures currently allowed to perform.
- Therapeutic procedures are performed in hospitals and/or outpatient units throughout the state.
- These procedures are not discretionary.

However, it is recommended that NEWTAC revisit the topic in three years.

Summary: Therefore, NEWTAC recommends that interventional neuroradiology should not be regulated under CON standards. This topic should be reviewed again three years, in order to assess whether the clinical practices have significantly changed accordingly.

SELECTED INTERVENTIONAL NEURORADIOLGY PROCEDURES INCURRED IN 2006

SELECTED INTERVENTIONAL NEURORADIOLOGY PROCEDURES INCURRED IN 2006

PROCEDURE	DESCRIPTION	Inpatient	Outpatient	ALL
36215	SELECT CATH PLACE ARTERIAL 1ST ORDER THORACIC	1,555	2,830	4,385
36216	INITIAL 2ND ORDER THORACIC OR BRACHEOCEPHALIC	2,126	3,275	5,401
36217	INITIAL 3RD ORDER OR MORE SELECT	1,083	1,200	2,283
36218	ADDL 2ND 3RD ETC THOR/BRACH BRANCH	771	1,123	1,894
61623	endovascular temporary balloon arterial occlusion head or neck	7	3	10
61624	transcather permanent occlusion or embolization cns	303	67	370
61626	transcather permanent occlusion or embolization non cns	49	52	101
61630	PTA INTRACRANIAL	10		10
61635	STENT INTRACRANIAL	23	6	29
61640	PTA HEAD VASOSPASM INITIAL	2		2
61641	PTA HEAD VASOSPASM ADDITIONAL	2		2
75650	ANGIOGRAPHY CERVI COCEREBRAL S & I	958	1,777	2,735
75660	ANGIOGRAPHY EXT CAROTID UNI SEL S & I	80	75	155
75662	ANGIOGRAPHY EXT CAROTID BILAT S & I	102	145	247
75665	ANGIO CAROTID CEREBRAL UNI S & I	602	404	1,006
75671	ANGIO CAROTID CEREBRAL BIL S & I	1,216	1,943	3,159
75676	ANGIOGRAPHY CAROTID CERVICAL UNI S & I	516	260	776
75680	ANGIOGRAPHY CAROTID CERVICAL BILAT	963	1,841	2,804
75685	ANGIOGRA VERT/CERV/INTRO CRAN S&I	1,523	1,968	3,491
75705	ANGIOGRAPHY SPINAL S & I	123	453	576
TOTAL		12,014	17,422	29,436

Total Procedures: 29,436

Total Therapeutic Procedures: 524

CERTIFICATE OF NEED
Compliance Activity Report to the CON Commission
December 11, 2007

This quarterly report is designed to update the Commission on the Department's activity in monitoring compliance with all Certificates of Need issued as required by Section 22247 of the Public Health Code. This report details activities from July 1, 2007 through September 30, 2007.

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 performs follow up checks on approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222 of the Code. For the 4th quarter of FY2007, the following actions have occurred since the last quarterly report:

- 259 follow up letters mailed
- 118 projects deemed 100% complete and operational
- 12 CON approvals expired due to noncompliance with Part 222 (not meeting required time frames to implement projects)

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 in accordance with Part 222 of the Code. For the 4th quarter of FY2007, the following action has occurred since the last quarterly report:

- Surveys were mailed to hospitals approved to perform primary PCI (percutaneous coronary intervention) without onsite open heart surgery. To date, 12 hospitals have been approved to perform this service. Seven (7) of the 12 programs are due for their first volume check; three (3) are due in 2008; and one (1) has voluntarily withdrawn from the program. The survey is designed to: 1) Verify 48 required cases have been performed annually; 2) Participation in the data collection system is ongoing; and 3) Only emergency PCI procedures are being performed at these sites. The survey findings will be presented in the next quarterly report.

Duplication Rates and Factors using Hospital and Registry Reporting Sources

Planning Area	Duplication Rate	Duplication Factor
1	0.21085	0.78915
2	0.23517	0.76483
3	0.11219	0.88781
4	0.25664	0.74336
5	0.21849	0.78151
6	0.34615	0.65385
7	0.21865	0.78135
8	0.12314	0.87686

Data based on Michigan Cancer Registry including records processed through November 30, 2007 for cases first diagnosed in 2005.

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

12/10/2007

Treatment Visit Category	Statewide Percent
Simple	1.6%
Intermediate	0.8%
Complex	73.4%
Intensity Modulated Radiation Therapy	24.2%

Source: 2006 Annual Hospital Statistical Survey

Preliminary Projected NH/LTC Bed Need 2010 (Planning Year)

HSA	County Name	UseRate Age 0-64	UseRate Age 65-74	UseRate Age 75-84	UseRate Age 85+	NEW BED NEED	ADC Adjustment Factor
7	ALCONA	170	3,126	10987	37368	88	90
8	ALGER	170	3,126	10987	37368	68	90
4	ALLEGAN	170	3,126	10987	37368	426	95
7	ALPENA	170	3,126	10987	37368	173	95
7	ANTRIM	170	3,126	10987	37368	142	95
6	ARENAC	170	3,126	10987	37368	112	95
8	BARAGA	170	3,126	10987	37368	50	90
3	BARRY	170	3,126	10987	37368	252	95
6	BAY	170	3,126	10987	37368	552	95
7	BENZIE	170	3,126	10987	37368	118	95
3	BERRIEN	170	3,126	10987	37368	790	95
3	BRANCH	170	3,126	10987	37368	222	95
3	CALHOUN	170	3,126	10987	37368	651	95
3	CASS	170	3,126	10987	37368	234	95
7	CHARLEVOIX	170	3,126	10987	37368	152	95
7	CHEBOYGAN	170	3,126	10987	37368	181	95
8	CHIPPEWA	170	3,126	10987	37368	189	95
6	CLARE	170	3,126	10987	37368	163	95
2	CLINTON	170	3,126	10987	37368	268	95
7	CRAWFORD	170	3,126	10987	37368	104	95
8	DELTA	170	3,126	10987	37368	234	95
8	DICKINSON	170	3,126	10987	37368	174	95
2	EATON	170	3,126	10987	37368	472	95
7	EMMET	170	3,126	10987	37368	172	95
5	GENESEE	170	3,126	10987	37368	1938	95
6	GLADWIN	170	3,126	10987	37368	170	95
8	GOGEBIC	170	3,126	10987	37368	114	95
7	GRANDTRAVERS	170	3,126	10987	37368	410	95
6	GRATIOT	170	3,126	10987	37368	255	95
2	HILLSDALE	170	3,126	10987	37368	218	95
8	HOUGHTON	170	3,126	10987	37368	168	95
6	HURON	170	3,126	10987	37368	226	95
2	INGHAM	170	3,126	10987	37368	1161	95
4	IONIA	170	3,126	10987	37368	258	95
6	IOSCO	170	3,126	10987	37368	207	95
8	IRON	170	3,126	10987	37368	101	95
6	ISABELLA	170	3,126	10987	37368	244	95
2	JACKSON	170	3,126	10987	37368	794	95
3	KALAMAZOO	170	3,126	10987	37368	1069	95
7	KALKASKA	170	3,126	10987	37368	81	90
4	KENT	170	3,126	10987	37368	2388	95
4	LAKE	170	3,126	10987	37368	83	90
5	LAPEER	170	3,126	10987	37368	352	95
7	LEELANAU	170	3,126	10987	37368	136	95
2	LENAWEE	170	3,126	10987	37368	487	95
1	LIVINGSTON	170	3,126	10987	37368	592	95
8	LUCE	170	3,126	10987	37368	46	90

HSA	County Name	UseRate Age 0-64	UseRate Age 65-74	UseRate Age 75-84	UseRate Age 85+	NEW BED NEED	ADC Adjustment Factor
8	MACKINAC	170	3,126	10987	37368	79	90
1	MACOMB	170	3,126	10987	37368	4305	95
7	MAINISTEE	170	3,126	10987	37368	154	95
8	MARQUETTE	170	3,126	10987	37368	282	95
4	MASON	170	3,126	10987	37368	166	95
4	MECOSTA	170	3,126	10987	37368	212	95
8	MEONMINEE	170	3,126	10987	37368	140	95
6	MIDLAND	170	3,126	10987	37368	395	95
7	MISSAUKEE	170	3,126	10987	37368	91	90
1	MONROE	170	3,126	10987	37368	645	95
4	MONTCALM	170	3,126	10987	37368	253	95
7	MONTMORENCY	170	3,126	10987	37368	99	90
4	MUSKEGON	170	3,126	10987	37368	779	95
4	NEWAYGO	170	3,126	10987	37368	219	95
1	OAKLAND	170	3,126	10987	37368	5326	95
4	OCEANA	170	3,126	10987	37368	124	95
6	OGEMAW	170	3,126	10987	37368	144	95
8	ONTONAGON	170	3,126	10987	37368	48	90
4	OSCEOLA	170	3,126	10987	37368	106	95
7	OSCODA	170	3,126	10987	37368	85	90
7	OTSEGO	170	3,126	10987	37368	139	95
4	OTTAWA	170	3,126	10987	37368	1060	95
7	PRESQUE ISLE	170	3,126	10987	37368	115	95
6	ROSCOMMON	170	3,126	10987	37368	186	95
6	SAGINAW	170	3,126	10987	37368	1039	95
1	ST CLAIR	170	3,126	10987	37368	754	95
3	ST JOSEPH	170	3,126	10987	37368	289	95
7	SANILAC	170	3,126	10987	37368	231	95
8	SCHOOLCRAFT	170	3,126	10987	37368	58	90
5	SHIAWASSEE	170	3,126	10987	37368	350	95
6	TUSCOLA	170	3,126	10987	37368	270	95
3	VAN BUREN	170	3,126	10987	37368	325	95
1	WASHTENAW	170	3,126	10987	37368	1146	95
1	NW Wayne	170	3,126	10987	37368	2563	95
1	SW Wayne	170	3,126	10987	37368	1732	95
1	Detroit	170	3,126	10987	37368	4435	95
7	WEXFORD	170	3,126	10987	37368	168	95

CERTIFICATE OF NEED

Quarterly Program Section Activity Report to the CON Commission

July 1, 2007 through September 30, 2007 (FY 2007)

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

Measures

Administrative Rule 325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	162	582
Letters of Intent Processed within 15 days	160	579

Administrative Rule 325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	96	320
Applications Processed within 15 Days	96	320
Applications Incomplete/More Information Needed	57	248

Administrative rules 325.9206 and 325.9207 requires 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	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	42	0	150	2
Substantive Applications	27	3	158	4
Comparative Review Applications	5	0	15	0

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.

Administrative Rule 325.9227 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	Most Recent Quarter	Year-to-Date
Emergency Applications Received	1	5
Decisions Issued within 10 workings Days	1	5

Measures – continued

Administrative Rule 325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	12	1	60	1

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 other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	35	154
FOIA Requests Processed on Time	35	154
Number of Applications Viewed Onsite	10	136

FOIA – Freedom of Information Act.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(12/03/07)

Case Name	*Date Opened*	*Case Description*	*Status*
Unity Health, LLC, Court of Claims Docket No: 05-224-MK	03/13/06	Lawsuit filed in the Court of Claims, seeking damages based on violations of civil rights in relation to the attempt by Unity Health to obtain a CON and/or a change in the review standards to allow it to obtain a CON to establish a hospital on the eastside of Detroit.	Case #05-000224-MK-C30 and 05-536754-CK are joined---Wayne County CC will have jurisdiction of the Court of Claims case.
Unity Health, LLC, Wayne County Circuit Court	05/02/06		Hearing on Motion for Summary Disposition set for 12/07/07.
Mobile Diagnostic Docket No: 2007-1870 CON	03/14/07	Appeal of denial of CON application # 06-0031 to expand mobile MRI Network No. 79 by adding a second MRI unit.	Motions for Summary Disposition and response briefs filed. Awaiting final proposed decision.
Regency on the Lake-Novi, LLC Administrative Tribunal Docket No.: 2007-1988 CON	04/02/07	Appeal of Denial of CON application. Comparative Review decision including Maple Drake Real Estate, Maple Manor Rehabilitation Center Status.	Proposed Decision granting Department's request for summary disposition issued 10/11/07. Awaiting final decision.
Maple Drake Real Estate, LLC Administrative Tribunal Docket No: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Comparative Review proposed decision including Maple Manor Rehabilitation Center and Regency on the Lake.	Proposed Decision granting Department's request for summary disposition issued 10/11/07. Awaiting final decision.
Maple Manor Rehabilitation Center Administrative Tribunal Docket No.: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Approval with Regency on the Lake and Maple Drake Real Estate.	Proposed Decision granting Department's request for summary disposition issued 10/11/07. Awaiting final decision.
MediLodge of Milford, LLC (AG#20073000935) DLEG Office of Administrative Hearings & Rules Docket No.: 2007-3545 CON	07/17/07	Appeal of denial of CON application.	Pre-Hearing Conference held 11/13/08. Awaiting scheduling Order.

CERTIFICATE OF NEED LEGAL ACTION

(12/03/07)

Case Name	***Date Opened***	***Case Description***	***Status***
MediLodge of Montrose, Inc. (AG#20073002174) DLEG Office of Administrative Hearings & Rules Docket No.: 2007-4038 CON	08/21/07	Comparative Review - includes Heartland HCC-Briarwood, CON Application No. 07-0008 Heartland HCC-Fostrain, CON Application No.07-0009. The latter two received a proposed approval.	Pre-Hearing conference held on 11/29/07. Awaiting scheduling Order.
Metron of Kalamazoo (2007-3000872-A)	07/13/07	Appeal of Certificate of Need. Appeal of Department's Proposed Decision denying Petitioner its request to acquire an existing nursing home.	Pre-hearing conference and Order entered 11/2/07. Respondent's Summary Disposition Brief due 1/04/08; Petitioner's response due 2/04/08; Respondent's reply due 2/19/08.

s: chd; assign control; special; CON Leg Action; report 12-03-07

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

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	J	F	M*	A	M	J*	J	A	S*	O*	N	D*	J*	F	M*	A	M	J*	J	A	S*	O*	N	D*
Air Ambulance Services	PH		D R	•	•	• —	P		▲						F									
Cardiac Catheterization Services	▮	▮	▮	▮	▮	▮	▮		—	P PH		▲ F	D R											
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	P		▲ F									
Hospital Beds (Includes LTACSs Beg. 1/07)	•	•	•	•	•	• R				PH			D R											
Megavoltage Radiation Therapy (MRT) Services/Units										PH		R	D R											
Nursing Home and Hospital Long-term Care Unit Beds	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	P		▲ F									
Open Heart Surgery Services	▮	▮	▮	▮	▮	▮	▮	•	• —	• P PH	•	• ▲ F	D R											
Positron Emission Tomography (PET) Scanner Services										PH			D R											
Psychiatric Beds and Services	•	•	• R	•	•	• R	•	•	• —	P		▲ F												
Surgical Services										PH			D R											
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	PH		D R	•	•	• R	•	•	• —	P		▲ F												
FY2007 Annual Activity Report												R												
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R A	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval December 11, 2007

Updated December 6, 2007

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 Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	June 4, 2004	2008
Computed Tomography (CT) Scanner Services	December 27, 2006	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2008
Magnetic Resonance Imaging (MRI) Services	November 13, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2008
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds, Addendum for Special Population Groups, and Addendum for New Design Model Pilot Program	December 3, 2004	2010
Open Heart Surgery Services	June 4, 2004	2008
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2008
Psychiatric Beds and Services	October 17, 2005	2009
Surgical Services	June 5, 2006	2008
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 4, 2004	2010

*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 Hearing 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.