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

Tuesday, December 13, 2005

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 10:12 a.m.

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO
Roger G. Andrzejewski
Bradley N. Cory (left at 3:30 p.m.)
James Delaney (left at 2:47 p.m.)
Dorothy E. Deremo
James E. Maitland (via teleconference from 1:02 p.m. to 2:03 p.m.)
Michael A. Sandler, MD
Renee Turner-Bailey (left at 2:47 p.m.)
Michael W. Young, DO

B. Members Absent:

None.

C. Department of Attorney General Staff:

Ronald J. Styka (left at 3:42 p.m.)

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Jan Christensen
Tom Freebury
Mary Greco
William Hart
Larry Horvath
John Hubinger
Matt Jordan
Joette Laseur
Bruce Matkovich
Andrea Moore
Stan Nash
Brenda Rogers
Gaye Tuttle
Matt Weaver

II. Review of Agenda.

The Commission requested that the Department move the final language for both Surgical Services – Part 1 and MRT to the Governor and the Joint Legislative Commitee today, if at all possible.

Motion by Commissioner Sandler, seconded by Commissioner Delaney, to accept the Agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest.

No conflicts were noted.

IV. Review of Minutes of September 13, 2005.

Motion by Commissioner Ajluni, seconded by Commissioner Young, to accept the Minutes of September 13, 2005, as presented. Motion Carried.

V. Hospital Beds (Define Cancer Hospital) – tabled from the June 22, 2005 Meeting (Attachment A).

A. Discussion.

Motion by Commissioner Goldman, seconded by Commissioner Dermo, to place the CON Review Standards for Hospital Beds on the Agenda as an active item. Motion Carried.

B. Public Comment.

William Blaul, Karmanos Cancer Hospital

C. Commission Final Action.

Motion by Commissioner Goldman, seconded by Commissioner Sandler, to disapprove the proposed changes to the Standards. Motion Carried.

VI. Megavoltage Radiation Therapy (MRT) Services/Units (Attachment B).

A. Discussion.

Ms. Rogers provided an overview of the proposed changes and the status.

B. Public Comment.

Larry Horwitz, Economic Alliance

C. Commission Final Action.

Motion by Commissioner Sandler, seconded by Commissioner Delaney, to accept the proposed language as final and move the Standards to the Governor and Joint Legislative Committee for the 45-day review period. Motion Carried.

VII. Surgical Services - Part 1 (Attachment C).

A. Discussion.

Ms. Rogers provided an overview.

B. Public Comment.

Dr. Robert Frank, Wayne State University
Terrance O'Rourke, Hackley Hospital
Brad Willoughby, Holland Surgery Center
Dr. Walter Whitehouse, St. Joseph Mercy Hospital
James Ball, General Motors
Walt Wheeler
Matt LeGault, POH
Jeff Recknagel, Orthopaedic Associates of Muskegan
Amy Barkholz, Michigan Hospital Association
Dale Steiger, Blue Cross and Blue Shield of Michigan
Dale Sowders, Holland Hospital
John Flack, Wayne State University
Julie Greene, Grand Valley Surgery Center
John Fox, Priority Health
Larry Horwitz, Economic Alliance
Mark Hutchinson, St. Mary's Health Care
Robert Meeker, Spectrum Health

Lunch Break from 11:50 a.m. to 1:02 p.m.

Discussion - continued.

Mr. Horvath provided an overview of pending CON applications.

C. Commission Final Action.

Motion by Commissioner Deremo, seconded by Commissioner Turner-Bailey, to accept the proposed language as final. Motion Carried.

Motion by Commissioner Goldman, seconded by Commissioner Delaney, to move the language to the Governor and Joint Legislative Committee for the 45-day review period today. Motion Carried.

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to make the Standards effective on March 10, 2006. Motion Failed.

VIII. Surgical Services SAC Report and Proposed Language – Part 2.

A. Discussion.

Chairperson Miller provided written (Attachment D) and oral overview of the recommended changes to the Standards (Attachment E) from the Surgical Services SAC. Discussion followed.

B. Public Comment.

Robert Meeker, Spectrum Health

Barbara Jackson, Economic Alliance
Dr. Walter Whitehouse, St. Joseph Mercy Hospital
Julie Greene, Grand Valley Surgery Center

C. Commission Proposed Action.

Motion by Commissioner Deremo, seconded by Commissioner Goldman, to accepted the Standards as proposed and move forward for Public Hearing and submission to the Joint Legislative Committee. Motion Carried.

IX. Re-Calculation of the Hospital Bed Need Numbers.

A. Discussion.

Ms. Rogers gave an overview of the Commission's responsibility to re-calculate the numbers.

B. Commission Action.

Motion by Commissioner Goldman, seconded by Commissioner Andrzejewski, to re-calculate the Hospital Bed Need using 2003 or more recent data should it become available as the base year and 5 years for the planning year. Motion Carried.

X. Nursing Home Special Population Groups Bed Numbers.

A. Discussion.

Ms. Rogers gave an overview of the Commission's responsibility to redistribute Nursing Home Special Pool Beds and the number of beds available for redistribution.

B. Commission Action.

Motion by Commissioner Cory, seconded by Commissioner Deremo, to have the Department post a notice on the web to receive input on the redistribution of the beds. Motion Carried.

XI. New Medical Technology.

Ms. Rogers reported no new medical technology.

XII. Legislative Report.

Mr. Christensen reported no current legislative activity.

XIII. Compliance Report.

Mr. Christensen gave an overview of the Department's compliance activities. Discussion followed.

XIV. Future Meeting Dates.

March 21, 2006
June 21, 2006
September 19, 2006
December 12, 2006

XV. Public Comment.

Jim Foresman, Miller Canfield
Lody Zwarensteyn, Alliance for Health
Amy Barkholz, Michigan Hospital Association
Larry Horwitz, Economic Alliance of Michigan
Ghabi Kaspo, DDS
Sharon Brooks, University of Michigan
Patrick O'Donovan, Beaumont Hospitals
Dr. Adil Akhtar, Beaumont Hospitals
Robert Meeker, Spectrum Health
James Flickema, Northern Michigan Hospital

XVI. Review of Commission Work Plan.

Ms. Rogers gave an overview of the draft Work Plan, adding a Hospital Bed LTACH Workgroup (Commissioner Goldman as liaison) and the issue of Dental CT (Commissioner Sandler as liaison).

Motion by Commissioner Maitland, seconded by Commissioner Delaney, to approve the Work Plan as drafted. Motion Carried.

XVII. Administrative Update

Mr. Hart gave an overview of the organization of the CON Policy Section.

Chairperson Hagenow announced the members of the Hospital Beds SAC.

XVIII. Adjournment.

Meeting adjourned at 4:14 p.m. due to loss of quorum.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.22217, 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 that involve (a) increasing licensed beds in a hospital licensed under Part 215 or (b) physically relocating hospital beds from one licensed site to another geographic location or (c) replacing beds in a hospital or (d) acquiring a hospital or (e) beginning operation of a new hospital.

(2) A hospital licensed under Part 215 is a covered health facility for purposes of Part 222 of the Code.

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

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

(5) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

(6) The Department shall use sections 3, 4, 5, 6, 7, 8, 10, and 15 of these standards and Section 2 of the Addendum for Projects for HIV Infected Individuals, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(7) The Department shall use Section 9 of these standards and Section 3 of the Addendum for Projects for HIV Infected Individuals, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a hospital with a valid license and which does not involve a change in bed capacity.

(b) "Alcohol and substance abuse hospital," for purposes of these standards, means a licensed hospital within a long-term (acute) care hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by DRGs 433 - 437.

(c) "Base year" means the most recent year that final MIDB data is available to the Department unless a different year is determined to be more appropriate by the Commission.

(d) "CANCER HOSPITAL" MEANS A HOSPITAL THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE) PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT HOSPITAL IN ACCORDANCE WITH SECTION 1886 (D)(1)(B)(V) OF THE SOCIAL SECURITY ACT, AS AMENDED.

(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.

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

(~~f~~G) "Department" means the Michigan Department of Community Health (MDCH).

(~~g~~H) "Department inventory of beds" means the current list maintained for each hospital subarea on a continuing basis by the Department of (i) licensed hospital beds and (ii) hospital beds approved by a valid CON issued under either Part 221 or Part 222 of the Code that are not yet licensed. The term does not include hospital beds certified for long-term-care in hospital long-term care units.

(~~h~~I) "Discharge relevance factor" (%R) means a mathematical computation where the numerator is the inpatient hospital discharges from a specific zip code for a specified hospital subarea and the denominator is the inpatient hospital discharges for any hospital from that same specific zip code.

(~~i~~J) "Existing hospital beds" means, for a specific hospital subarea, the total of all of the following: (i) hospital beds licensed by the Department; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that are part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final Department decision.

(~~j~~K) "Health service area" OR "HSA" means the groups of counties listed in Section 17.

(~~k~~L) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code and (ii) unlicensed newborn bassinets.

(~~l~~M) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

(~~m~~N) "Hospital long-term-care unit" or "HLTCU" means a nursing care unit, owned or operated by and as part of a hospital, licensed by the Department, and providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(~~n~~O) "Hospital subarea" or "subarea" means a cluster or grouping of hospitals and the relevant portion of the state's population served by that cluster or grouping of hospitals. For purposes of these standards, hospital subareas and the hospitals assigned to each subarea are set forth in Appendix A.

(~~o~~P) "Host hospital," for purposes of these standards, means an existing licensed hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a long-term (acute) care hospital, or alcohol and substance abuse hospital, to begin operation.

(Q) "LICENSED CANCER HOSPITAL SITE" MEANS SPACE WITHIN THE LICENSED SITE OF THE HOST HOSPITAL, AS WELL AS SPACE ADJACENT TO OR CONNECTED TO THE HOST HOSPITAL FOR WHICH CON APPROVAL HAS BEEN SECURED AND A CERTIFICATE OF LICENSURE HAS BEEN ISSUED.

(~~p~~R) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(~~q~~S) "Long-term (acute) care hospital," ~~for purposes of these standards,~~ means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412.

(~~r~~T) "Market forecast factors" (%N) means a mathematical computation where the numerator is the number of total inpatient discharges indicated by the market survey forecasts and the denominator is the base year MIDB discharges.

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

(~~t~~V) "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 B.

(~~u~~W) "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.

(~~v~~X) "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 B.

(~~w~~Y) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation in a different subarea as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(~~x~~Z) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital subarea as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(~~y~~AA) "Overbedded subarea" means a hospital subarea in which the total number of existing hospital beds in that subarea exceeds the subarea needed hospital bed supply as set forth in Appendix C.

(~~z~~BB) "Planning year" means five years beyond the base year, established by the CON Commission, for which hospital bed need is developed, unless a different year is determined to be more appropriate by the Commission.

(~~aa~~CC) "Relevance index" or "market share factor" (%Z) means a mathematical computation where the numerator is the number of inpatient hospital patient days provided by a specified hospital subarea from a specific zip code and the denominator is the total number of inpatient hospital patient days provided by all hospitals to that specific zip code using MIDB data.

(~~bb~~DD) "Relocate existing licensed hospital beds" for purposes of Section 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital subarea. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(~~cc~~EE) "Replacement beds in a hospital" means hospital beds that meet all of the following conditions; (i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently licensed; (ii) the hospital beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.); and (iii) the hospital beds to be replaced will be located in the replacement zone.

(~~dd~~FF) "Replacement zone" means a proposed licensed site that is (i) in the same subarea as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(~~ee~~GG) "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 B.

(~~ff~~HH) "Utilization rate" or "use rate" means the number of days of inpatient care per 1,000 population during a one-year period.

(~~gg~~II) "Zip code population" means the latest population estimates for the base year and projections for the planning year, by zip code.

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

Section 3. Hospital subareas

Sec. 3. (1)(a) Each existing hospital is assigned to a hospital subarea as set forth in Appendix A which is incorporated as part of these standards, until Appendix A is revised pursuant to this subsection.

(i) These hospital subareas, and the assignments of hospitals to subareas, shall be updated, at the direction of the Commission, starting in May 2003, to be completed no later than November 2003. Thereafter, at the direction of the Commission, the updates shall occur no later than two years after the official date of the federal decennial census, provided that:

(A) Population data at the federal zip code level, derived from the federal decennial census, are available; and final MIDB data are available to the Department for that same census year.

(b) For an application involving a proposed new licensed site for a hospital (whether new or replacement), the proposed new licensed site shall be assigned to an existing hospital subarea utilizing a market survey conducted by the applicant and submitted with the application. The market survey shall provide, at a minimum, forecasts of the number of inpatient discharges for each zip code that the proposed new licensed site shall provide service. The forecasted numbers must be for the same year as the base year MIDB data. The market survey shall be completed by the applicant using accepted standard statistical methods. The market survey must be submitted on a computer media and in a format specified by the Department. The market survey, if determined by the Department to be reasonable pursuant to Section 14, shall be used by the Department to assign the proposed new site to an existing subarea based on the methodology described by "The Specification of Hospital Service Communities in a Large Metropolitan Area" by J. William Thomas, Ph.D., John R. Griffith, and Paul Durance, April 1979 as follows:

(i) For the proposed new site, a discharge relevance factor for each of the zip codes identified in the application will be computed. Zip codes with a market forecast factor of less than .05 will be deleted from consideration.

(ii) The base year MIDB data will be used to compute discharge relevance factors (%Rs) for each hospital subarea for each of the zip codes identified in step (i) above. Hospital subareas with a %R of less than .10 for all zip codes identified in step (i) will be deleted from the computation.

(iii) The third step in the methodology is to calculate a population-weighted average discharge relevance factor $\overline{R}_j$ for the proposed hospital and existing subareas. Letting:

P_i = Population of zip code i.

d_{ij} = Number of patients from zip code i treated at hospital j.

$D_i = \sum_j d_{ij}$ = Total patients from zip code i.

$I_j = \{i \mid (d_{ij}/D_i) \geq \alpha\}$, set of zip codes for which the individual relevance factor [%R from (i) and (ii) above) values (d_{ij}/D_i) of hospital j exceeds or equals α, where α is specified $0 \leq \alpha \geq 1$.

$$\text{then } \overline{R}_j = \frac{\sum_{i \in Ij} P_i (d_{ij}/D_i)}{\sum_{i \in Ij} P_i}$$

(iv) After $\overline{R}_j$ is calculated for the applicant(s) and the included existing subareas, the hospital/subarea with the smallest $\overline{R}_j$ ($S\overline{R}_j$) is grouped with the hospital/subarea having the greatest individual discharge relevance factor in the $S\overline{R}_j$'s home zip code. $S\overline{R}_j$'s home zip code is defined as the zip code from $S\overline{R}_j$'s with the greatest discharge relevance factor.

(v) If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (iii), and (iv) must be repeated until all applicants have been assigned to an existing subarea.

(2) The Commission shall amend Appendix A to reflect: (a) approved new licensed site(s) assigned

to a specific hospital subarea; (b) hospital closures; and (c) licensure action(s) as appropriate.

(3) As directed by the Commission, new sub-area assignments established according to subsection (1)(a)(i) shall supersede Appendix A and shall be included as an amended appendix to these standards effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

Sec. 4. (1) The determination of the needed hospital bed supply for a hospital subarea for a planning year shall be made using the MIDB and population estimates and projections by zip code in the following methodology:

(a) All hospital discharges for normal newborns (DRG 391) and psychiatric patients (ICD-9-CM codes 290 through 319 as a principal diagnosis) will be excluded.

(b) For each hospital subarea, calculate the number of patient days (take the patient days for each discharge and accumulate it within the respective age group) for the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older. Data from non-Michigan residents are to be included for each specific age group. Data from non-Michigan residents are to be included for each specific age group.

(c) For each hospital subarea, calculate the relevance index (%Z) for each zip code and for each of the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 THROUGH 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older.

(d) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective base year zip code and age group specific year population. The result will be the zip code allocations by age group for each subarea.

(e) For each hospital subarea, calculate the subarea base year population by age group by adding together all zip code population allocations calculated in (d) for each specific age group in that subarea. The result will be six population age groups for each subarea.

(f) For each hospital subarea, calculate the patient day use rates for ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 THROUGH 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older by dividing the results of (b) by the results of (e).

(g) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective planning year zip code and age group specific year population. The results will be the projected zip code allocations by age group for each subarea.

(h) For each hospital subarea, calculate the subarea projected year population by age group by adding together all projected zip code population allocations calculated in (g) for each specific age group. The result will be six population age groups for each subarea.

(i) For each hospital subarea, calculate the subarea projected patient days for each age group by multiplying the six projected populations by age group calculated in step (h) by the age specific use rates identified in step (f).

(j) For each hospital subarea, calculate the adult medical/surgical subarea projected patient days by adding together the following age group specific projected patient days calculated in (i): ages 15 through 44, ages 45 through 64, ages 65 through 74, and ages 75 and older. The 0 (excluding normal newborns) through 14 (pediatric) and female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges) age groups remain unchanged as calculated in (i).

(k) For each hospital subarea, calculate the subarea projected average daily census (ADC) for three age groups: Ages 0 (excluding normal newborns) through 14 (pediatric), female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), and adult medical surgical by dividing the results calculated in (j) by 365 (or 366 if the planning year is a leap year). Round each ADC to a whole number. This will give three ADC computations per subarea.

(l) For each hospital subarea and age group, select the appropriate subarea occupancy rate from the occupancy rate table in Appendix D.

(m) For each hospital subarea and age group, calculate the subarea projected bed need number of

hospital beds for the subarea by age group by dividing the ADC calculated in (k) by the appropriate occupancy rate determined in (l). To obtain the total hospital bed need, add the three age group bed projections together. Round any part of a bed up to a whole bed.

Section 5. Bed Need

Sec. 5. (1) The bed-need numbers incorporated as part of these standards as Appendix C shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Commission shall direct the Department, effective November 2004 and every two years thereafter, to re-calculate the acute care bed need methodology in Section 4, within a specified time frame.

(3) The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).

(4) When the Department is directed by the Commission to apply the methodology pursuant to subsection (2), the effective date of the bed-need numbers shall be established by the Commission.

(5) As directed by the Commission, new bed-need numbers established by subsections (2) and (3) shall supersede the bed-need numbers shown in Appendix C and shall be included as an amended appendix to these standards.

Section 6. Requirements for approval -- new beds in a hospital

Sec. 6. (1) An applicant proposing new beds in a hospital, except an applicant meeting the requirements of subsection 2, 3, or 4, shall demonstrate that it meets all of the following:

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(b) The total number of existing hospital beds in the subarea to which the new beds will be assigned does not currently exceed the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

(c) Approval of the proposed new beds in a hospital shall not result in the total number of existing hospital beds, in the subarea to which the new beds will be assigned, exceeding the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

(2) An applicant proposing to begin operation as a new long-term (acute) care hospital, CANCER HOSPITAL, or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:

(a) If the long-term (acute) care hospital OR CANCER HOSPITAL applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as a long-term (acute) care hospital OR CANCER HOSPITAL within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as a long-term (acute) care hospital within the 12 or 18-month period, then the CON granted pursuant to this section, INCLUDING CONS APPROVED FOR THE ESTABLISHMENT OF A CANCER HOSPITAL AND FOR SERVICES DESCRIBED IN SUBSECTION (6)(2)(C), shall expire automatically.

(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement between the applicant and the host hospital, AS WELL AS OTHER ARRANGEMENT FOR A CANCER HOSPITAL. The initial, renewed, or any subsequent lease OR OTHER

ARRANGEMENT shall specify at least all of the following:

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital.

(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital, OR IN SPACE IN A LICENSED CANCER HOSPITAL SITE, OR BOTH.

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

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the long-term (acute) care hospital OR CANCER HOSPITAL. In the event that the host hospital applies for a CON to acquire CANCER HOSPITAL OR the long-term (acute) care hospital [including the beds leased by the host hospital to the long-term (acute) care hospital] within six months following the termination of the lease with the long-term (acute) care hospital OR OTHER ARRANGEMENT WITH A CANCER HOSPITAL, it shall not be required to be in compliance with the hospital bed supply set forth in Appendix C if the host hospital proposes to add the beds of the long-term (acute) care hospital OR CANCER HOSPITAL to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

(B) Delicensure of the hospital beds; or

(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services [EXCEPT CON APPROVAL SOUGHT BY A CANCER HOSPITAL FOR THE FOLLOWING COVERED CLINICAL SERVICES: (I) BONE MARROW TRANSPLANTATION; (II) COMPUTED TOMOGRAPHY (CT); (III) MAGNETIC RESONANCE IMAGING (MRI); (IV) MEGAVOLTAGE RADIATION THERAPY (MRT); (V) POSITRON EMISSION TOMOGRAPHY (PET); (VI) SURGICAL SERVICES]; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

(d) The new licensed hospital shall remain within the host hospital OR, IN THE CASE OF A CANCER HOSPITAL, WITHIN THE LICENSED CANCER HOSPITAL SITE.

(e) The new hospital shall be assigned to the same subarea as the host hospital.

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(3) of these standards.

(g) The lease OR OTHER ARRANGEMENT will not result in an increase in the number of licensed hospital beds in the subarea.

(h) Applica~~tio~~n T~~t~~s proposing a new hospital under this subsection shall not be subject to comparative review.

(3) An applicant proposing to add new hospital beds, as the receiving licensed hospital under Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The approval of the proposed new hospital beds shall not result in an increase in the number of licensed hospital beds in the subarea.

(b) The proposed project to add new hospital beds, under this subsection, shall constitute a change in bed capacity under Section 1(3) of these standards.

(c) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(4) As a pilot program, an applicant may apply for the addition of new beds if all of the following subsections are met. Further, an applicant proposing new beds at an existing licensed hospital site shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The beds are being added at the existing licensed hospital site.

(b) The hospital at the existing licensed hospital site has operated as follows for the previous, consecutive 12 months based on its existing licensed hospital bed capacity as documented on the most recent reports of the "Annual Hospital Statiscal Questionnaire" or more current verifiable data:

Number of Licensed Hospital Beds	Average Occupancy
Fewer than 300	80% and above
300 or more	85% and above

(c) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the occupancy rate for the hospital to 80 percent for hospitals with licensed beds of 300 or more and to 75 percent for hospitals with licensed beds of fewer than 300. The number of beds shall be calculated as follows:

(i) Divide the actual number of patient days of care provided during the most recent, consecutive 12-month period for which verifiable data are available to the department by .80 for hospitals with licensed beds of 300 or more and by .75 for hospitals with licensed beds of fewer than 300 to determine licensed bed days at 80 percent occupancy or 75 percent occupancy as applicable;

(ii) Divide the result of step (i) by 365 (or 366 for leap years) and round the result up to the next whole number;

(iii) Subtract the number of licensed beds as documented on the "Department Inventory of Beds" from the result of step (ii) and round the result up to the next whole number to determine the maximum number of beds that may be approved pursuant to this subsection.

(d) The provisions of Section 6(4) 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 deemed complete in accordance with Rule 325.9201 prior to November 30, 2003. The Department shall report to the CON Commission within 180 days following the expiration of Section 6(4) on the number of applications received and approved, the total capital expenditures approved, and the projected cost savings to be realized, if any.

(e) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

Section 7. Requirements for approval -- replacement beds in a hospital in a replacement zone

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing replacement beds in a hospital in the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(2) In order to be approved, the applicant shall propose to (i) replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (ii) that the proposed new licensed site is in the replacement zone.

(3) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

Section 8. Requirements for approval of an applicant proposing to relocate existing licensed hospital beds

Sec 8. (1) The proposed project to relocate beds, under this section, shall constitute a change in bed capacity under Section 1(4) of these standards.

(2) Any existing licensed acute care hospital may relocate all or a portion of its beds to another existing licensed acute care hospital located within the same subarea according to the provisions in this section.

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

(4) The relocated beds shall continue to be counted in the inventory for the subarea but licensed to the recipient hospital.

(5) The relocation of beds from any other licensed acute care hospital within the subarea to any licensed acute care hospital within the subarea, shall not be subject to a mileage limitation.

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

Sec. 9. (1) An applicant shall agree that, if approved, the project 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 applicant shall provide the Department with a notice stating the date the hospital beds are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(ii) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(iii) 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 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 on a separate basis for each licensed site; in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(A) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.

(iv) 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) Not deny services to any individual based on ability to pay or source of payment.

(ii) Maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.

(iii) Provide services to any individual based on clinical indications of need for the services.

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

Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties

Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for purposes of these standards, are incorporated as part of these standards as Appendix B. The Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the

office of information and regulatory affairs of the United States office of management and budget.

Section 11. Department inventory of beds

Sec. 11. The Department shall maintain and provide on request a listing of the Department inventory of beds for each subarea.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on ~~June 10, 2003~~ MARCH 9, 2004 and effective ~~August 4, 2003~~JUNE 4, 2004.

(2) Projects reviewed under these standards shall be subject to comparative review except those projects meeting the requirements of Section 7 involving the replacement of beds in a hospital within the replacement zone and projects involving acquisition (including purchase, lease, donation or comparable arrangements) of a hospital.

Section 13. Additional requirements for applications included in comparative reviews

Sec. 13. (1) Any application subject to comparative review under Section 22229 of the Code being Section 333.22229 of the Michigan Compiled Laws or these standards shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order the Department determines the projects most fully promote the availability of quality health services at reasonable cost.

Section 14. Documentation of market survey

Sec. 14. An applicant required to conduct a market survey under Section 3 shall specify how the market survey was developed. This specification shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method(s) used. Based on this documentation, the Department shall determine if the market survey is reasonable.

Section 15. Requirements for approval -- acquisition of a hospital

Sec. 15. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C for the subarea in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition,

(c) the project is limited solely to the acquisition of a hospital with a valid license, and

(d) if the application is to acquire a hospital, which was proposed in a prior application to be established as a long-term (acute) care hospital (LTAC) and which received CON approval, the applicant also must meet the requirements of Section 6(2). Those hospitals that received such prior approval are so identified in Appendix A.

Section 16. Requirements for approval – all applicants

Sec. 16. 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 17. Health service areas

Sec. 17. Counties assigned to each of the health service areas are as follows:

HSA	COUNTIES		
1 - Southeast	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2 - Mid-Southern	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3 - Southwest	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4 - West	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5 - GLS	Genesee	Lapeer	Shiawassee
6 - East	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7 - Northern Lower	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8 - Upper Peninsula	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

CON REVIEW STANDARDS FOR HOSPITAL BEDS

HOSPITAL SUBAREA ASSIGNMENTS

Health Service Area	Sub Area	Hospital Name	City
1 - Southeast			
	1A	North Oakland Med Centers (Fac #63-0110)	Pontiac
	1A	Pontiac Osteopathic Hospital (Fac #63-0120)	Pontiac
	1A	St. Joseph Mercy – Oakland (Fac #63-0140)	Pontiac
	1A	Select Specialty Hospital - Pontiac (LTAC - FAC #63-0172)*	Pontiac
	1A	Crittenton Hospital (Fac #63-0070)	Rochester
	1A	Huron Valley – Sinai Hospital (Fac #63-0014)	Commerce Township
	1A	Wm Beaumont Hospital (Fac #63-0030)	Royal Oak
	1A	Wm Beaumont Hospital – Troy (Fac #63-0160)	Troy
	1A	Providence Hospital (Fac #63-0130)	Southfield
	1A	Great Lakes Rehabilitation Hospital (Fac #63-0013)	Southfield
	1A	Straith Hospital for Special Surg (Fac #63-0150)	Southfield
	1A	The Orthopaedic Specialty Hospital (Fac #63-0060)	Madison Heights
	1A	St. John Oakland Hospital (Fac #63-0080)	Madison Heights
	1A	Southeast Michigan Surgical Hospital (Fac #50-0100)	Warren
	1B	Bi-County Community Hospital (Fac #50-0020)	Warren
	1B	St. John Macomb Hospital (Fac #50-0070)	Warren
	1C	Oakwood Hosp And Medical Center (Fac #82-0120)	Dearborn
	1C	Garden City Hospital (Fac #82-0070)	Garden City
	1C	Henry Ford –Wyandotte Hospital (Fac #82-0230)	Wyandotte
	1C	Select Specialty Hosp Wyandotte (LTAC - Fac #82-0272)*	Wyandotte
	1C	Oakwood Annapolis Hospital (Fac #82-0010)	Wayne
	1C	Oakwood Heritage Hospital (Fac #82-0250)	Taylor
	1C	Riverside Osteopathic Hospital (Fac #82-0160)	Trenton
	1C	Oakwood Southshore Medical Center (Fac #82-0170)	Trenton
	1C	Kindred Hospital – Detroit (Fac #82-0130)	Lincoln Park
	1D	Sinai-Grace Hospital (Fac #83-0450)	Detroit
	1D	Rehabilitation Institute of Michigan (Fac #83-0410)	Detroit
	1D	Harper University Hospital (Fac #/83-0220)	Detroit
	1D	St. John Detroit Riverview Hospital (Fac #83-0034)	Detroit
	1D	Henry Ford Hospital (Fac #83-0190)	Detroit
	1D	St. John Hospital & Medical Center (Fac #83-0420)	Detroit
	1D	Children's Hospital of Michigan (Fac #83-0080)	Detroit
	1D	Detroit Receiving Hospital & Univ Hlth (Fac #83-0500)	Detroit
	1D	St. John Northeast Community Hosp (Fac #83-0230)	Detroit
	1D	Kindred Hospital–Metro Detroit (Fac #83-0520)	Detroit
	1D	SCCI Hospital-Detroit (LTAC - Fac #83-0521)*	Detroit
	1D	Greater Detroit Hosp–Medical Center (Fac #83-0350)	Detroit
	1D	Renaissance Hosp & Medical Centers (Fac #83-0390)	Detroit
	1D	United Community Hospital (Fac #83-0490)	Detroit

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

Health Service Area	Sub Area	Hospital Name	City
1 – Southeast (continued)			
	1D	Harper-Hutzel Hospital (Fac #83-0240)	Detroit
	1D	Select Specialty Hosp–NW Detroit (LTAC - Fac #83-0523)*	Detroit
	1D	Bon Secours Hospital (Fac #82-0030)	Grosse Pointe
	1D	Cottage Hospital (Fac #82-0040)	Grosse Pointe Farm
	1E	Botsford General Hospital (Fac #63-0050)	Farmington Hills
	1E	St. Mary Mercy Hospital (Fac #82-0190)	Livonia
	1F	Mount Clemens General Hospital (Fac #50-0060)	Mt. Clemens
	1F	Select Specialty Hosp – Macomb Co. (FAC #50-0111)*	Mt. Clemens
	1F	St. John North Shores Hospital (Fac #50-0030)	Harrison Twp.
	1F	St. Joseph's Mercy Hosp & Hlth Serv (Fac #50-0110)	Clinton Township
	1F	St. Joseph's Mercy Hospital & Health (Fac #50-0080)	Mt. Clemens
	1G	Mercy Hospital (Fac #74-0010)	Port Huron
	1G	Port Huron Hospital (Fac #74-0020)	Port Huron
	1H	St. Joseph Mercy Hospital (Fac #81-0030)	Ann Arbor
	1H	University Of Michigan Health System (Fac #81-0060)	Ann Arbor
	1H	Select Specialty Hosp–Ann Arbor (Ltac - Fac #81-0081)*	Ann Arbor
	1H	Chelsea Community Hospital (Fac #81-0080)	Chelsea
	1H	Saint Joseph Mercy Livingston Hosp (Fac #47-0020)	Howell
	1H	Saint Joseph Mercy Saline Hospital (Fac #81-0040)	Saline
	1H	Forest Health Medical Center (Fac #81-0010)	Ypsilanti
	1H	Brighton Hospital (Fac #47-0010)	Brighton
	1I	St. John River District Hospital (Fac #74-0030)	East China
	1J	Mercy Memorial Hospital (Fac #58-0030)	Monroe
2 - Mid-Southern			
	2A	Clinton Memorial Hospital (Fac #19-0010)	St. Johns
	2A	Eaton Rapids Medical Center (Fac #23-0010)	Eaton Rapids
	2A	Hayes Green Beach Memorial Hosp (Fac #23-0020)	Charlotte
	2A	Ingham Reg Med Cntr (Greenlawn) (Fac #33-0020)	Lansing
	2A	Ingham Reg Med Cntr (Pennsylvania) (Fac #33-0010)	Lansing
	2A	Edward W. Sparrow Hospital (Fac #33-0060)	Lansing
	2A	Sparrow – St. Lawrence Campus (Fac #33-0050)	Lansing
	2B	Carelink of Jackson (Ltac Fac #38-0030)*	Jackson
	2B	W. A. Foote Memorial Hospital (Fac #38-0010)	Jackson
	2C	Hillsdale Community Health Center (Fac #30-0010)	Hillsdale
	2D	Emma L. Bixby Medical Center (Fac #46-0020)	Adrian
	2D	Herrick Memorial Hospital (Fac #46-0030)	Tecumseh

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
3 – Southwest			
	3A	Borgess Medical Center (Fac #39-0010)	Kalamazoo
	3A	Bronson Methodist Hospital (Fac #39-0020)	Kalamazoo
	3A	Borgess-Pipp Health Center (Fac #03-0031)	Plainwell
	3A	Lakeview Community Hospital (Fac #80-0030)	Paw Paw
	3A	Bronson – Vicksburg Hospital (Fac #39-0030)	Vicksburg
	3A	Pennock Hospital (Fac #08-0010)	Hastings
	3A	Three Rivers Area Hospital (Fac #75-0020)	Three Rivers
	3A	Sturgis Hospital (Fac #75-0010)	Sturgis
	3A	Sempercare Hospital at Bronson (LTAC - Fac #39-0032)*	Kalamazoo
	3B	Fieldstone Ctr of Battle Crk. Health (Fac #13-0030)	Battle Creek
	3B	Battle Creek Health System (Fac #13-0031)	Battle Creek
	3B	Select Spec Hosp–Battle Creek (Ltac - Fac #13-0111)*	Battle Creek
	3B	SW Michigan Rehab. Hosp. (Fac #13-0100)	Battle Creek
	3B	Oaklawn Hospital (Fac #13-0080)	Marshall
	3C	Community Hospital (Fac #11-0040)	Watervliet
	3C	Lakeland Hospital, St. Joseph (Fac #11-0050)	St. Joseph
	3C	Lakeland Specialty Hospital (LTAC - Fac #11-0080)*	Berrien Center
	3C	South Haven Community Hospital (Fac #80-0020)	South Haven
	3D	Lakeland Hospital, Niles (Fac #11-0070)	Niles
	3D	Lee Memorial Hospital (A) (Fac #14-0010)	Dowagiac
	3E	Community Hlth Ctr Of Branch Co (Fac #12-0010)	Coldwater
4 – WEST			
	4A	Memorial Medical Center Of West MI (Fac #53-0010)	Ludington
	4B	Kelsey Memorial Hospital (Fac #59-0050)	Lakeview
	4B	Mecosta County General Hospital (Fac #54-0030)	Big Rapids
	4C	Spectrum Hlth-Reed City Campus (Fac #67-0020)	Reed City
	4D	Lakeshore Community Hospital (Fac #64-0020)	Shelby
	4E	Gerber Memorial Hospital (Fac #62-0010)	Fremont
	4F	Carson City Hospital (Fac #59-0010)	Carson City
	4F	Gratiot Community Hospital (Fac #29-0010)	Alma
	4G	Hackley Hospital (Fac #61-0010)	Muskegon
	4G	Mercy Gen Hlth Partners–(Sherman) (Fac #61-0020)	Muskegon
	4G	Mercy Gen Hlth Partners–(Oak) (Fac #61-0030)	Muskegon
	4G	Lifecare Hospitals of Western MI (LTAC - Fac #61-0052)*	Muskegon

	4G	Select Spec Hosp–Western MI (LTAC - Fac #61-0051)*	Muskegon

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
4 – West (continued)			
	4G	North Ottawa Community Hospital (Fac #70-0010)	Grand Haven
	4H	Spectrum Hlth–Blodgett Campus (Fac #41-0010)	E. Grand Rapids
	4H	Spectrum Hlth–Butterworth Campus (Fac #41-0040)	Grand Rapids
	4H	Spectrum Hlth–Kent Comm Campus (Fac #41-0090)	Grand Rapids
	4H	Mary Free Bed Hospital & Rehab Ctr (Fac #41-0070)	Grand Rapids
	4H	Metropolitan Hospital (Fac #41-0060)	Grand Rapids
	4H	Saint Mary's Mercy Medical Center (Fac #41-0080)	Grand Rapids
	4I	Sheridan Community Hospital (A) (Fac #59-0030)	Sheridan
	4I	United Memorial Hospital & LTCU (Fac #59-0060)	Greenville
	4J	Holland Community Hospital (Fac #70-0020)	Holland
	4J	Zeeland Community Hospital (Fac #70-0030)	Zeeland
	4K	Ionia County Memorial Hospital (Fac #34-0020)	Ionia
	4L	Allegan General Hospital (Fac #03-0010)	Allegan
5 – GLS			
	5A	Memorial Healthcare (Fac #78-0010)	Owosso
	5B	Genesys Reg Med Ctr–Hlth Park (Fac #25-0072)	Grand Blanc
	5B	Hurley Medical Center (Fac #25-0040)	Flint
	5B	Mclaren Regional Medical Center (Fac #25-0050)	Flint
	5B	Select Specialty Hospital-Flint (LTAC - Fac #25-0071)*	Flint
	5C	Lapeer Regional Hospital (Fac #44-0010)	Lapeer
6 – East			
	6A	West Branch Regional Medical Cntr (Fac #65-0010)	West Branch
	6A	Tawas St Joseph Hospital (Fac #35-0010)	Tawas City
	6B	Central Michigan Community Hosp (Fac #37-0010)	Mt. Pleasant
	6C	Mid-Michigan Medical Center-Clare (Fac #18-0010)	Clare
	6D	Mid-Michigan Medical Cntr - Gladwin (Fac #26-0010)	Gladwin
	6D	Mid-Michigan Medical Cntr - Midland (Fac #56-0020)	Midland

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

(A) Licensed sites with less than 15 acute care med/surg beds and up to 10 med/surg beds designated for short-term nursing care program ("swing beds"). These hospitals have state/federal critical access hospital designation.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
6 – East (continued)			
	6E	Bay Regional Medical Center (Fac #09-0050)	Bay City
	6E	Bay Regional Medical Ctr-West (Fac #09-0020)	Bay City
	6E	Samaritan Health Center (Fac #09-0051)	Bay City
	6E	Bay Special Care (LTAC - Fac #09-0010)*	Bay City
	6E	Standish Community Hospital (A) (Fac #06-0020)	Standish
	6F	Select Specialty Hosp–Saginaw (LTAC - Fac #73-0062)*	Saginaw
	6F	Covenant Medical Centers, Inc (Fac #73-0061)	Saginaw
	6F	Covenant Medical Cntr–N Michigan (Fac #73-0030)	Saginaw
	6F	Covenant Medical Cntr–N Harrison (Fac #73-0020)	Saginaw
	6F	Healthsource Saginaw (Fac #73-0060)	Saginaw
	6F	St. Mary's Medical Center (Fac #73-0050)	Saginaw
	6F	Caro Community Hospital (Fac #79-0010)	Caro
	6F	Hills And Dales General Hospital (Fac #79-0030)	Cass City
	6G	Harbor Beach Community Hosp (A) (Fac #32-0040)	Harbor Beach
	6G	Huron Medical Center (Fac #32-0020)	Bad Axe
	6G	Scheurer Hospital (A) (Fac #32-0030)	Pigeon
	6H	Deckerville Community Hospital (A) (Fac #76-0010)	Deckerville
	6H	Mckenzie Memorial Hospital (A) (Fac #76-0030)	Sandusky
	6I	Marlette Community Hospital (Fac #76-0040)	Marlette
7 - Northern Lower			
	7A	Cheboygan Memorial Hospital (Fac #16-0020)	Cheboygan
	7B	Charlevoix Area Hospital (Fac #15-0020)	Charlevoix
	7B	Mackinac Straits Hospital (A) (Fac #49-0030)	St. Ignace
	7B	Northern Michigan Hospital (Fac #24-0030)	Petoskey
	7C	Rogers City Rehabilitation Hospital (Fac #71-0030)	Rogers City
	7D	Otsego Memorial Hospital (Fac #69-0020)	Gaylord
	7E	Alpena General Hospital (Fac #04-0010)	Alpena
	7F	Kalkaska Memorial Health Center (A) (Fac #40-0020)	Kalkaska
	7F	Leelanau Memorial Health Center (A) (Fac #45-0020)	Northport
	7F	Munson Medical Center (Fac #28-0010)	Traverse City
	7F	Paul Oliver Memorial Hospital (A) (Fac #10-0020)	Frankfort

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

(A) Licensed sites with less than 15 acute care med/surg beds and up to 10 med/surg beds designated for short-term nursing care program ("swing beds"). These hospitals have state/federal critical access hospital designation.

Health Service Area	Sub Area	Hospital Name	City
7 - Northern Lower (continued)			
	7G	Mercy Hospital - Cadillac (Fac #84-0010)	Cadillac
	7H	Mercy Hospital - Grayling (Fac #20-0020)	Grayling
	7I	West Shore Medical Center (Fac #51-0020)	Manistee
8 - UPPER PENINSULA			
	8A	Grand View Hospital (Fac #27-0020)	Ironwood
	8B	Ontonagon Memorial Hospital (A) (Fac #66-0020)	Ontonagon
	8C	Iron County General Hospital (Fac #36-0020)	Iron River
	8D	Baraga County Memorial Hospital (A) (Fac #07-0020)	L'anse
	8E	Keweenaw Memorial Medical Center (Fac #31-0010)	Laurium
	8E	Portage Health System (Fac #31-0020)	Hancock
	8F	Dickinson County Memorial Hospital (Fac #22-0020)	Iron Mountain
	8G	Bell Memorial Hospital (Fac #52-0010)	Ishpeming
	8G	Marquette General Hospital (Fac #52-0050)	Marquette
	8H	St. Francis Hospital (Fac #21-0010)	Escanaba
	8I	Munising Memorial Hospital (A) (Fac #02-0010)	Munising
	8J	Schoolcraft Memorial Hospital (A) (Fac #77-0010)	Manistique
	8K	Helen Newberry Joy Hospital (A) (Fac #48-0020)	Newberry
	8L	Chippewa Co. War Memorial Hosp (Fac #17-0020)	Sault Ste Marie

(A) Licensed sites with less than 15 acute care med/surg beds and up to 10 med/surg beds designated for short-term nursing care program (“swing beds”). These hospitals have state/federal critical access hospital designation.

APPENDIX B

CON REVIEW STANDARDS FOR HOSPITAL BEDS

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

APPENDIX C

CON REVIEW STANDARDS FOR HOSPITAL BEDS

The hospital bed need for purposes of these standards until otherwise changed by the Commission are as follows:

Health Service Area	SA No.	Bed Need	Bed Inventory 12-01-03*
1 - SOUTHEAST			
	1A	2693	3408
	1B	415	551
	1C	1372	2143
	1D	3098	4828
	1E	451	578
	1F	636	770
	1G	275	282
	1H	1431	1773
	1I	50	68
	1J	149	217
2 - MID-SOUTHERN			
	2A	866	1143
	2B	293	390
	2C	48	65
	2D	98	180
3 - SOUTHWEST			
	3A	763	1080
	3B	282	341
	3C	261	431
	3D	85	89
	3E	59	102
4 - WEST			
	4A	57	81
	4B	63	126
	4C	17	42
	4D	11	24
	4E	38	61
	4F	136	191
	4G	391	568
	4H	1240	1738
	4I	47	65
	4J	153	250
	4K	21	77
	4L	24	54

***Applicants must contact the Department to obtain the current number of beds in the Department inventory of beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.**

Health Service Area	SA No.	Bed Need	Bed Inventory 12-01-03*
5 - GLS			
	5A	79	115
	5B	1120	1241
	5C	119	183
6 - EAST			
	6A	99	148
	6B	55	118
	6C	47	64
	6D	216	272
	6E	299	443
	6F	765	1091
	6G	43	64
	6H	13	40
	6I	24	48
7 - NORTHERN LOWER			
	7A	43	46
	7B	203	273
	7C	0	36
	7D	27	53
	7E	99	124
	7F	349	354
	7G	62	97
	7H	53	90
	7I	40	75
8 - UPPER PENINSULA			
	8A	24	54
	8B	7	25
	8C	21	36
	8D	11	24
	8E	50	85
	8F	88	96
	8G	228	358
	8H	57	110
	8I	4	25
	8J	7	25
	8K	9	25
	8L	52	82

***Applicants must contact the Department to obtain the current number of beds in the Department inventory of beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.**

APPENDIX D

OCCUPANCY RATE TABLE

ADC >=	ADC <	Occup	Beds	ADC >=	ADC <	Occup	Beds
	50.000	**0.60**	83	101.475	102.225	0.75	136
50.000	51.423	0.61	84	102.225	102.975	0.75	137
51.423	52.886	0.62	85	102.975	103.725	0.75	138
52.886	53.506	0.62	86	103.725	104.475	0.75	139
53.506	54.999	0.63	87	104.475	105.225	0.75	140
54.999	55.629	0.63	88	105.225	107.388	0.76	141
55.629	56.259	0.63	89	107.388	108.148	0.76	142
56.259	57.792	0.64	90	108.148	108.908	0.76	143
57.792	58.432	0.64	91	108.908	109.668	0.76	144
58.432	59.072	0.64	92	109.668	110.428	0.76	145
59.072	60.645	**0.65**	93	110.428	111.188	0.76	146
60.645	61.295	0.65	94	111.188	111.948	0.76	147
61.295	61.945	0.65	95	111.948	112.708	0.76	148
61.945	63.558	0.66	96	112.708	113.468	0.76	149
63.558	64.218	0.66	97	113.468	114.228	0.76	150
64.218	65.861	0.67	98	114.228	116.501	0.77	151
65.861	66.531	0.67	99	116.501	117.271	0.77	152
66.531	67.201	0.67	100	117.271	118.041	0.77	153
67.201	68.884	0.68	101	118.041	118.811	0.77	154
68.884	69.564	0.68	102	118.811	119.581	0.77	155
69.564	70.244	0.68	103	119.581	120.351	0.77	156
70.244	71.967	0.69	104	120.351	121.121	0.77	157
71.967	72.657	0.69	105	121.121	121.891	0.77	158
72.657	73.347	0.69	106	121.891	122.661	0.77	159
73.347	75.110	**0.70**	107	122.661	123.431	0.77	160
75.110	75.810	0.70	108	123.431	124.201	0.77	161
75.810	76.510	0.70	109	124.201	124.971	0.77	162
76.510	78.313	0.71	110	124.971	127.374	0.78	163
78.313	79.023	0.71	111	127.374	128.154	0.78	164
79.023	79.733	0.71	112	128.154	128.934	0.78	165
79.733	80.443	0.71	113	128.934	129.714	0.78	166
80.443	82.296	0.72	114	129.714	130.494	0.78	167
82.296	83.016	0.72	115	130.494	131.274	0.78	168
83.016	83.736	0.72	116	131.274	132.054	0.78	169
83.736	84.456	0.72	117	132.054	132.834	0.78	170
84.456	85.176	0.72	118	132.834	133.614	0.78	171
85.176	87.089	0.73	119	133.614	134.394	0.78	172
87.089	87.819	0.73	120	134.394	135.174	0.78	173
87.819	88.549	0.73	121	135.174	135.954	0.78	174
88.549	89.279	0.73	122	135.954	136.734	0.78	175
89.279	90.009	0.73	123	136.734	137.514	0.78	176
90.009	90.739	0.73	124	137.514	140.067	0.79	177
90.739	91.469	0.73	125	140.067	140.857	0.79	178
91.469	93.462	0.74	126	140.857	141.647	0.79	179
93.462	94.202	0.74	127	141.647	142.437	0.79	180
94.202	94.942	0.74	128	142.437	143.227	0.79	181
94.942	95.682	0.74	129	143.227	144.017	0.79	182
95.682	96.422	0.74	130	144.017	144.807	0.79	183
96.422	97.162	0.74	131	144.807	145.597	0.79	184
97.162	97.902	0.74	132	145.597	146.387	0.79	185
97.902	99.975	**0.75**	133	146.387	147.177	0.79	186
99.975	100.725	0.75	134	147.177	147.967	0.79	187

100.725	101.475	0.75	135	147.967	148.757	0.79	188

APPENDIX D (Continued)

ADC >=	ADC <	Occup	Beds
148.757	149.547	0.79	189
149.547	152.240	**0.80**	190
152.240	153.040	0.80	191
153.040	153.840	0.80	192
153.840	154.640	0.80	193
154.640	155.440	0.80	194
155.440	156.240	0.80	195
156.240	157.040	0.80	196
157.040	157.840	0.80	197
157.840	160.623	0.81	198
160.623	161.433	0.81	199
161.433	162.243	0.81	200
162.243	163.053	0.81	201
163.053	163.863	0.81	202
163.863	164.673	0.81	203
164.673	165.483	0.81	204
165.483	166.293	0.81	205
166.293	169.166	0.82	206
169.166	169.986	0.82	207
169.986	170.806	0.82	208
170.806	171.626	0.82	209
171.626	172.446	0.82	210
172.446	173.266	0.82	211
173.266	174.086	0.82	212
174.086	174.906	0.82	213
174.906	175.726	0.82	214
175.726	178.699	0.83	215
178.699	179.529	0.83	216
179.529	180.359	0.83	217
180.359	181.189	0.83	218
181.189	182.019	0.83	219
182.019	182.849	0.83	220
182.849	183.679	0.83	221
183.679	184.509	0.83	222
184.509	185.339	0.83	223
185.339	186.169	0.83	224
186.169	189.252	0.84	225
189.252	190.092	0.84	226
190.092	190.932	0.84	227
190.932	191.772	0.84	228
191.772	192.612	0.84	229
192.612	193.452	0.84	230
193.452	194.292	0.84	231
194.292	195.132	0.84	232
195.132	195.972	0.84	233
195.972	196.812	0.84	234
196.812	197.652	0.84	235
197.652	198.492	0.84	236
198.492	199.332	0.84	237
199.332	200.172	0.84	238
200.172		**0.85**	

1070

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH AND MEDICAL AFFAIRS

CON REVIEW STANDARDS FOR HOSPITAL BEDS
-- ADDENDUM FOR PROJECTS FOR HIV INFECTED INDIVIDUALS --

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.2217, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Hospital Beds and may be used for determining the need for projects established to meet the needs of HIV infected individuals.

(2) Except as provided by sections 2 and 3 below, these standards supplement and do not supercede the requirements and terms of approval required by the CON Review Standards for Hospital Beds.

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

(4) "HIV infected" means that term as defined in Section 5101 of the Code.

(5) Planning area for projects for HIV infected individuals means the State of Michigan.

Section 2. Requirements for approval; change in bed capacity

Sec. 2. (1) A project which, if approved, will increase the number of licensed hospital beds in an overbedded subarea or will result in the total number of existing hospital beds in a subarea exceeding the needed hospital bed supply as determined under the CON Review Standards for Hospital Beds may, nevertheless, be approved pursuant to subsection (3) of this addendum.

(2) Hospital beds approved as a result of this addendum shall be included in the Department inventory of existing beds in the subarea in which the hospital beds will be located. Increases in hospital beds approved under this addendum shall cause subareas currently showing a current surplus of beds to have that surplus increased.

(3) In order to be approved under this addendum, an applicant shall demonstrate all of the following:
(a) The Director of the Department has determined that action is necessary and appropriate to meet the needs of HIV infected individuals for quality, accessible and efficient health care.
(b) The hospital will provide services only to HIV infected individuals.
(c) The applicant has obtained an obligation, enforceable by the Department, from existing licensed hospital(s) in any subarea of this state to voluntarily delicense a number of hospital beds equal to the number proposed in the application. The effective date of the delicensure action will be the date the beds approved pursuant to this addendum are licensed. The beds delicensed shall not be beds already subject to delicensure under a bed reduction plan.
(d) The application does not result in more than 20 beds approved under this addendum in the State.

(4) In making determinations under Section 22225(2)(a) of the Code, for projects under this addendum, the Department shall consider the total cost and quality outcomes for overall community health systems for services in a dedicated portion of an existing facility compared to a separate aids facility and has determined that there exists a special need, and the justification of any cost increases in terms of important quality/access improvements or the likelihood of future cost reductions, or both.

Section 3. Project delivery requirements--additional terms of approval for projects involving HIV infected individuals approved under this addendum.

Sec. 3. (1) An applicant shall agree that, if approved, the services provided by the beds for HIV infected individuals shall be delivered in compliance with the following terms of CON approval:

(a) The license to operate the hospital will be limited to serving the needs of patients with the clinical spectrum of HIV infection and any other limitations established by the Department to meet the purposes of this addendum.

(b) The hospital shall be subject to the general license requirements of Part 215 of the Code except as waived by the Department to meet the purposes of this addendum.

(c) The applicant agrees that the Department shall revoke the license of the hospital if the hospital provides services to inpatients other than HIV infected individuals.

Section 4. Comparative reviews

Sec. 4. (1) Projects proposed under Section 3 shall be subject to comparative review.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

(By authority conferred on the ~~Certificate of Need~~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 that involve ~~megavoltage radiation therapy (~~MRT~~)~~ services/units.

(2) A ~~megavoltage radiation therapy~~MRT service/unit is a covered clinical service for purposes of Part 222 of the Code. A ~~megavoltage radiation therapy~~MRT service/unit previously approved pursuant to Section ~~8~~ 7 of these standards now seeking approval to operate pursuant to sections 4, 5, 6, ~~7~~8, 9, or 10 shall be considered as a person requesting ~~certificate of need~~CON approval to begin or expand, as applicable, operation of an MRT service/unit. A ~~megavoltage radiation therapy~~MRT unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting ~~certificate of need~~CON approval to begin or expand, as applicable, operation of a non-special MRT service/unit.

(3) The Department shall use sections 4, 5, 6, ~~7~~8, 9, and 10, 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 15, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(5)(a) These standards shall apply to the review of all CON applications for megavoltage radiation therapy services for which the Director of the Department of Community Health has not made a final decision under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws, as of the effective date of these standards.~~

~~(b) In the case of an application that has been deemed submitted but that has not received a final decision by the Director on the effective date of these standards, the applicant may request and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.~~

~~(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8) of the Code, being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection and shall consider the results of that hearing before a final decision is made.~~

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of aN EXISTING MRT service OR EXISTING MRT unit(S)" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an EXISTING MRT service OR EXISTING MRT unit(S) ~~listed on the Department Inventory of MRT Units~~.

(b) "Begin operation of an MRT service ~~/unit~~" means the establishment of a non-special MRT

~~service/~~unit at a geographic location where an MRT service~~/unit~~ is not currently provided ~~that will result in an increase in the number of non-special MRT units listed on the Department Inventory of MRT Units~~. ~~The relocation of an MRT unit, meeting the requirements of Section 10, to a geographic location within the same planning area shall not be considered as beginning operation of an MRT service/unit.~~ THE TERM DOES NOT INCLUDE THE ACQUISITION OR RELOCATION OF AN EXISTING MRT SERVICE AND/OR UNIT(S) OR THE RENEWAL OF A LEASE.

(c) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus~~,~~; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, and Iridium-192.

(d) "Cancer treatment program" means a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability~~,~~ and, either on-site or through written agreements with other providers, all of the following services: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) ~~megavoltage radiation therapy~~MRT capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.

(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) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(h) "Computer based treatment planning system" means a computer system capable of displaying radiation doses and dose distributions within a patient using anatomical data from that patient and using measured radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a brachytherapy package.

(i) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(j) "CYBER KNIFE" MEANS, FOR PURPOSES OF THESE STANDARDS, A TREATMENT DEVICE THAT IS A FRAMELESS SPECIAL STEREOTACTIC RADIOSURGERY UNIT THAT CONSISTS OF THREE KEY COMPONENTS: (I) AN ADVANCED, LIGHTWEIGHT LINEAR ACCELERATOR (LINAC) (THIS DEVICE IS USED TO PRODUCE A HIGH ENERGY MEGAVOLTABE OF RADIATION), (II) A ROBOT WHICH CAN POINT THE LINEAR ACCELERATOR FROM A WIDE VARIETY OF ANGLES, AND (III) SEVERAL X-RAY CAMERAS (IMAGING DEVICES) THAT ARE COMBINED WITH SOFTWARE TO TRACK PATIENT POSITION. THE CAMERAS OBTAIN FREQUENT PICTURES OF THE PATIENT DURING TREATMENT AND USE THIS INFORMATION TO TARGET THE RADIATION BEAM EMITTED BY THE LINEAR ACCELERATOR.

(K) "Department" means the Michigan Department of Community Health (MDCH).

~~(k) "Department Inventory of Megavoltage Radiation Therapy Units" means the list maintained by the Department of (i) the licensed MRT units operating pursuant to a valid certificate of need issued under Part 222 or former Part 221; (ii) licensed, operating MRT units for which the operation of the unit did not require a certificate of need; and (iii) the MRT units that are not yet operational but have a valid certificate of need issued under Part 222 or former Part 221. The list will not include those units approved pursuant to Section 8 of these standards. The list will identify non-special and special purpose MRT units separately.~~

(l) "Dosimetrist" means a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(m) "Driving miles" means the number of miles from the ADDRESS OF~~city in which~~ the proposed

MRT ~~unit will be located~~SERVICE to the ~~closest~~ ADDRESS OF THE ~~city in which an~~CLOSEST existing MRT unit ~~is located~~. Driving miles is the number of miles from ~~center-of-city~~ADDRESS to ~~center-of-city~~ADDRESS ~~shown on the Michigan Department of Transportation map~~AS IDENTIFIED BY USE OF MAPPING SOFTWARE THAT IS VERIFIABLE BY THE DEPARTMENT.

(n) "Duplication factor" means the number derived by subtracting the duplication rate from 1.

(o) "Duplication rate" means the percent of new cancer cases in each planning area determined by the DEPARTMENT, VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, ~~Office of the State Registrar and Center for Health Statistics~~ that have been reported more than one time to the Michigan Cancer Surveillance Program.

(p) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit, that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit. Section 12 sets forth how ETVs shall be calculated.

(q) "Existing ~~megavoltage radiation therapy~~MRT service" means ~~the~~ A CON APPROVED AND OPERATIONAL facility and equipment ~~at one geographic location~~ used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all EXISTING MRT units AT ~~that are listed on the Department Inventory of MRT Units~~A GEOGRAPHIC LOCATION(S).

(R) "EXISTING MRT UNIT" MEANS A CON APPROVED AND OPERATIONAL EQUIPMENT USED TO PROVIDE MRT SERVICES.

(~~r~~S) "Expand an existing MRT service" means ADDING ONE ADDITIONAL MRT UNIT TO ~~increasing~~ the number of EXISTING MRT units ~~(second, third, etc.) at the same geographic location of an existing MRT service~~.

(~~s~~T) ~~"F.T.E." or~~ "Full time equivalent" OR "FTE" means an individual(s) with normally scheduled working hours of 40 hours per week.

(~~t~~U) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(~~u~~V) "Geographic location" means either (i) the geographic location of a licensed health facility as defined in the ~~Certificate of Need~~CON Review Standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location.

(~~v~~W) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, or heavy ions with masses greater than that of an electron.

(~~w~~X) "IMAGE GUIDED RADIATION THERAPY" OR "IGRT" MEANS THE USE OF IN-ROOM IMAGING TO ALLOW PRECISE TARGET LOCALIZATION USING ULTRASOUND, IMPLANTED FIDUCIAL MARKERS OR IMAGE RECONSTRUCTION USING KV OR MEGAVOLTAGE BEAMS. TWO-DIMENSIONAL PORT FILMS USING PATIENT ANATOMY FOR LOCALIZATION DO NOT CONSTITUTE IGRT.

(~~x~~Y) "Immediately available" means continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.

(~~x~~Z) "INTENSITY MODULATED RADIATION THERAPY" OR "IMRT" MEANS A VISIT UTILIZING ONLY THE COMPUTER CONTROLLED MULTI-LEAF COLLIMATOR PART OF THE CMS DEFINITION FOR IMRT.

(~~z~~AA) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(~~y~~BB) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site USING A DEDICATED UNIT.

(~~z~~CC) ~~"IRB" or "institutional~~ Institutional review board" OR "IRB" means an institutional review board, as defined by Public Law 93-348, that is regulated by Title 45 CFR 46.

(DD) "ISOCENTER" MEANS THE VIRTUAL POINT IN SPACE ABOUT WHICH THE MRT UNIT OPERATES AND IS PLACED AT THE CENTER OF THE TUMOR FOR THE DELIVERY OF THE RADIATION TREATMENT.

(~~aa~~EE) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a

hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(~~bb~~FF) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission (NRC) or REGISTERED BY the Michigan Department of ~~Consumer & Industry Services~~COMMUNITY HEALTH, Division of Health Facilities and Services, Radiation Safety Section.

(GG) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND1396R-8 TO 1396V.

(~~cc~~HH) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board certified or board qualified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics.

(~~dd~~II) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by a ~~megavoltage radiation therapy~~MRT unit.

(~~ee~~JJ) "~~Megavoltage radiation therapy~~MRT program" means one or more MRT services operated at one or more geographic locations under the same administrative unit.

(~~ff~~KK) "~~Megavoltage radiation therapy~~MRT service" means ~~providing~~ THE CON APPROVED~~megavoltage radiation therapy~~MRT ~~and/or the~~ utilization of a ~~megavoltage radiation therapy~~MRT unit(s) at one geographic location.

(~~gg~~LL) ~~"Megavoltage radiation therapy unit" or~~ "MRT unit" or "unit" means a CON APPROVED linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(MM) "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 C.

(~~hh~~NN) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the ~~Michigan~~ Department~~, of Community Health, Division of the Registrar and Health Statistics,~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(OO) "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 C.

(~~ii~~PP) "Multi-disciplinary cancer committee" means a standing committee that (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation; (ii) meets at least on a quarterly basis; and (iii) is responsible for (a) establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility; (b) monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and (c) oversight of the applicant's tumor registry for quality control, staging, and abstracting.

(~~jj~~QQ) "New cancer case," for purposes of these standards, means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.

(~~kk~~RR) ~~"Non-special megavoltage radiation therapy unit" or~~ "~~non~~Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose ~~megavoltage~~

radiation therapyMRT unit.

(llSS) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(mmTT) "Patient care evaluation studies" means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; hospital wide quality assurance activities; and ongoing monitoring, evaluating, and action planning.

(nnUU) "Planning area" means the groups of counties shown in Section 16.

(ooVV) "Relocation of an existing MRT service AND/OR MRT unit(S)" means a change in the geographic location within the same planning area of an MRT unit listed on the Department Inventory of MRT Units.

(ppWW) "Replace/upgrade AN EXISTING megavoltage radiation therapyMRT unit" means an equipment change proposed by an applicant that results in the AN applicant operating the same number of non-special and the same number and type of special purpose megavoltage radiation therapyMRT units before and after the equipment change.

(qqXX) "Rural county" means a county not located in a metropolitan STATISTICAL area OR MICROPOLITAN STATISTICAL AREAS as THOSE that termS ARE is defined UNDER pursuant to the "revised standards Standards for defining Defining metropolitan AND MICROPOLITAN STATISTICAL areas in the 1990's" by the statistical policy office of the office of information and regulatory affairs of the united United states States office of management and budget, 55 65 F.R., p. 82238 12154 (DECEMBER March 3027, 19902000) AND AS SHOWN IN APPENDIX C.

(rrYY) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(ssZZ) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(ttAAA) "Special purpose megavoltage radiation therapyMRT unit" or "special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) heavy particle accelerator, (ii) gamma knife, (iii) dedicated stereotactic radiosurgery unit, (iv) dedicated total body irradiator (TBI), or (v) an OR-based IORT unit, OR (VI) CYBER KNIFE.

(uuBBB) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the destruction of a precisely defined intracranial AND/OR EXTRACRANIAL tumor or lesion.

(vvCCC) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

(wwDDD) "Treatment site" means the anatomical location of the MRT treatment.

(xxEEE) "Treatment visit" means one patient encounter during which megavoltage radiation therapyMRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(yyFFF) "Tumor registry," for the purposes of these standards, means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program As As required pursuant to Public Act 82 of 1984, as amended.

(zzGGG) "Very complex treatment visit" means those visits listed in Section 12 which THATinvolve special techniques in the performance of the MRT.

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

Section 3. Modification of the Appendices

Sec. 3. (1) The Commission may modify the Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program presented to the Commission by the Department.

(2) The Commission may periodically modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data provided by MRT providers as part of a Department survey presented to the Commission by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) ~~The Department shall modify the Department Inventory of MRT Units set forth in Appendix C based on decisions made on certificates of need and certificate of need applications.~~

~~(5)~~ Modifications made by the Commission pursuant to subsections (1) or (2) shall not require ~~ad hoc~~STANDARD advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 4. ~~Department Inventory of Megavoltage Radiation Therapy (MRT) Units~~

~~Sec 4. Appendix C sets forth the MRT units included in the Department Inventory of MRT Units as of the effective date of these standards. Modification to Appendix C shall be made by the Department pursuant to Section 3.~~

~~Section 5.~~ Requirements for approval - applicants proposing to begin operation of a ~~megavoltage radiation therapy~~MRT ~~unit~~SERVICE

Sec. ~~5~~4. (1) An applicant proposing to begin operation of a ~~megavoltage radiation therapy~~**MRT** ~~unit(s)~~SERVICE shall demonstrate that:

(a) a minimum of 8,000 equivalent treatment visits (ETVs) for each proposed unit results from application of the methodology described in Section 11 and

(b) the proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):

(a) The site of the proposed MRT ~~unit~~ SERVICE is located in a rural OR MICROPOLITAN STATISTICAL AREA county.

(b) ~~The site of the proposed MRT unit is a licensed hospital site that has 90 or more licensed hospital beds.~~

~~(c)~~ The site of the proposed MRT ~~unit~~ SERVICE is 60 driving miles or more from the nearest ~~existing megavoltage radiation therapy~~MRT service.

(~~d~~C) The proposed MRT ~~unit~~/service projects a minimum of 5,500 equivalent treatment visits (ETVs) for each proposed unit based on the application of the methodology described in Section 11.

(~~e~~D) The proposed MRT unit is not a special purpose MRT unit.

(3) ALL APPLICANTS UNDER THIS SECTION SHALL DEMONSTRATE, AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT, THAT THE FOLLOWING STAFF, AT A MINIMUM, WILL BE PROVIDED:

(A) 1 F.T.E. BOARD-CERTIFIED OR BOARD-QUALIFIED PHYSICIAN TRAINED IN RADIATION ONCOLOGY.

(B) 1 BOARD-CERTIFIED OR BOARD-QUALIFIED RADIATION PHYSICIST CERTIFIED IN THERAPEUTIC RADIOLOGIC PHYSICS.

(C) 1 DOSIMETRIST OR PHYSICS ASSISTANT.

(D) 2 RADIATION THERAPY TECHNOLOGISTS [REGISTERED OR ELIGIBLE BY THE AMERICAN REGISTRY OF RADIOLOGICAL TECHNOLOGISTS (ARRT)], AND

(E) 1 PROGRAM DIRECTOR WHO IS A BOARD-CERTIFIED PHYSICIAN TRAINED IN RADIATION ONCOLOGY WHO MAY ALSO BE THE PHYSICIAN REQUIRED UNDER SUBSECTION (3)(A).

Section ~~65~~. Requirements for approval - applicants proposing to expand an existing ~~megavoltage radiation therapy~~MRT service

Sec. ~~65~~. (1) An applicant proposing to expand an existing MRT service with an additional non-special MRT unit shall demonstrate:

(A) ~~that~~ an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units, AND

(B) ~~listed on the Department Inventory of MRT Units at~~ the ~~location where the~~ADDITIONAL unit ~~is to~~SHALL be ~~added~~LOCATED AT THE SAME SITE, UNLESS THE REQUIREMENTS OF SECTION 9(2) ALSO HAVE BEEN MET.

(2) An applicant proposing to expand an existing MRT ~~program~~ SERVICE with a special purpose MRT unit shall demonstrate each of the following, as applicable:

(a) An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units ~~listed on the Department Inventory of MRT Units~~ at the location where the special purpose unit is to be located. ~~If the special purpose unit will not be located at the same location as the existing MRT program, compliance with this subsection shall be determined based on the average number of ETVs performed on each of the non-special MRT units listed on the Department Inventory of MRT Units for the existing MRT program being expanded.~~

(b) An applicant proposing to ~~acquire~~ EXPAND BY ADDING a dedicated total body irradiator shall have either (i) a valid CON ~~issued under former Part 221 or Part 222~~ to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON ~~issued under former Part 221 or Part 222~~ to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(c) An applicant proposing to ~~acquire~~ EXPAND BY ADDING a heavy particle accelerator shall have available, either on-site or through written agreement(s), 3-dimensional imaging and 3-dimensional treatment planning capabilities. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(d) An applicant proposing to ~~acquire~~ EXPAND BY ADDING and ~~operate~~ operatING a dedicated stereotactic radiosurgery unit (including a gamma knife AND CYBER KNIFE) shall demonstrate that (i) the applicant has, at the time the application is filed, a ~~formal~~ CONTRACTUAL relationship with a BOARD-ELIGIBLE OR BOARD-CERTIFIED neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.

(e) An applicant proposing to ~~operate~~ EXPAND BY ADDING an operating room based intraoperative ~~megavoltage radiation therapy~~MRT unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.

Section ~~76~~. Requirements for approval - applicants proposing to replace/upgrade AN EXISTING ~~megavoltage radiation therapy~~MRT unit(s)

Sec. ~~76~~. An applicant requesting to replace/upgrade aN EXISTING MRT unit(s) shall demonstrate each of the following, as applicable.

(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only unit at that geographic location, shall demonstrate each of the following:

(a) ~~The unit is listed on the current Department Inventory of MRT Units.~~

~~(b) The unit was listed on the Department Inventory of MRT Units as of the effective date of these standards.~~

~~(c)~~ The unit performed at least 5,500 ETVs in the most recent 12-month period.

(~~d~~B) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section ~~10~~ 9 ~~also~~ have been met.

(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service which is the only MRT service in the planning area shall demonstrate each of the following:

(a) ~~The unit is listed on the current Department Inventory of MRT Units.~~

~~(b)~~ Each unit at the geographic location of the unit to be replaced operated at an average of at least 5,500 ETVs in the most recent 12-month period.

(~~e~~B) The replacement unit will be located at the same geographic location as the unit to be replaced, UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 9 HAVE BEEN MET.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:

(a) ~~The unit is listed on the current Department Inventory of MRT Units.~~

~~(b)~~ Each non-special unit at the geographic location of the unit to be replaced operated at a~~n average~~ TOTAL of at least ~~7~~13,000 ETVs FOR TWO UNITS AND AN ADDITIONAL 5,500 ETVS FOR EACH ADDITIONAL UNIT (I.E., 13,000 ETVS + 5,500 ETVS = 18,500 ETVS FOR THREE UNITS, 13,000 + 5,500 ETVS + 5,500 ETVS = 24,000 ETVS FOR FOUR UNITS, ETC.) in the most recent 12-month period.

(~~e~~B) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section ~~10~~ 9 ~~also~~ have been met.

(4) An applicant requesting to replace/upgrade an existing special purpose unit shall demonstrate each of the following, as applicable:

(a) ~~The unit is listed on the current Department Inventory of MRT Units as a special purpose MRT unit.~~

~~(b)~~ The special purpose unit to be replaced operated at the following level of utilization during the most recent 12-month period, as applicable:

(i) an average of 7,000 ETVs for each heavy particle accelerator;

(ii) an average of 1,000 ETVs for each OR-based IORT unit, gamma knife, CYBER KNIFE, dedicated stereotactic radiosurgery unit, or dedicated total body irradiator.

(~~e~~B) The replacement special purpose unit will be located at the same geographic location as the special purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements of sections ~~6~~ 5 and ~~10~~ 9 ~~also~~ have been met.

(~~d~~C) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON ~~issued under former Part 221 or Part 222~~ to operate a bone marrow transplantation program.

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

(6) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED OF OR RENDERED CONSIDERABLY INOPERABLE WITHIN 30 DAYS OF THE REPLACEMENT EQUIPMENT BECOMING OPERATIONAL.

Section ~~8~~7. Requirements for approval - applicants proposing to use ~~megavoltage radiation therapy~~MRT units exclusively for research

Sec. ~~8~~7. (1) An applicant proposing a ~~megavoltage radiation therapy~~MRT unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(b) The ~~megavoltage radiation therapy~~MRT unit shall operate under a protocol approved by the applicant's ~~institutional review board~~IRB.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 15(1)(c)(v), (viii), (xiii)~~, (xiv)~~; 15(2); 15(3); and 15(4).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 4, 5; 6; ~~7;~~ and 15(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of these standards.

(3) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED OF OR RENDERED CONSIDERABLY INOPERABLE WITHIN 30 DAYS OF THE REPLACEMENT EQUIPMENT BECOMING OPERATIONAL.

Section ~~9~~8. Requirements for approval - applicants proposing to acquire an existing MRT service~~/~~ OR AN EXISTING MRT unit(S)

Sec. ~~9~~8. (1) An applicant proposing to acquire an existing MRT service~~/~~ AND ITS MRT unit(S) shall demonstrate that it meets all of the following:

(~~1~~A) The project is limited solely to the acquisition of an existing MRT service~~/~~ AND ITS MRT unit(S).

(~~2~~B) The project will not change the number or type (special, non-special) of MRT units ~~listed on the Department Inventory of MRT Units~~ at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 OR 5~~ or 6~~, as applicable.

(~~3~~C) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section ~~7~~ 6, AS APPLICABLE, ~~also~~ have been met.

~~(4) All MRT units at the service to be acquired are currently listed on the Department Inventory of MRT Units.~~

~~(5) The applicant agrees to operate the MRT service in accord with all applicable project delivery requirements set forth in Section 15 of these standards.~~

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING MRT UNIT(S) OF AN EXISTING MRT SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(A) THE PROJECT IS LIMITED SOLELY TO THE ACQUISITION OF AN EXISTING MRT UNIT(S) OF AN EXISTING MRT SERVICE.

(B) THE PROJECT WILL NOT CHANGE THE NUMBER OR TYPE (SPECIAL, NON-SPECIAL) OF MRT UNITS AT THE GEOGRAPHIC LOCATION OF THE MRT SERVICE BEING ACQUIRED UNLESS THE APPLICANT DEMONSTRATES THAT THE PROJECT IS IN COMPLIANCE WITH THE REQUIREMENTS OF SECTION 4 OR 5, AS APPLICABLE.

(C) THE PROJECT WILL NOT RESULT IN THE REPLACEMENT/UPGRADE OF AN EXISTING MRT UNIT(S) TO BE ACQUIRED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 6, AS APPLICABLE, ALSO HAVE BEEN MET.

(D) THE REQUIREMENTS OF SECTION 4(3) HAVE BEEN MET.

Section ~~10~~9. Requirements for approval - applicants proposing to relocate an existing MRT

service AND/OR MRT unit(S)

Sec. ~~10~~9. (1) An applicant proposing to relocate an existing MRT service AND/~~OR~~ ITS MRT unit(S) shall demonstrate that it meets all of the following:

(~~1~~A) ~~The MRT unit(s) to be relocated is listed on the Department Inventory of MRT Units.~~

~~(2)~~ The relocation of the EXISTING MRT SERVICE AND ITS MRT unit(S) will not change the number or type (special, non-special) of MRT units in the planning area, UNLESS SUBSECTIONS (C) AND/OR (D), AS APPLICABLE, HAVE BEEN MET.

(~~3~~B) The new geographic location will be in the same planning area as the existing geographic location.

(~~4~~C) The project will not result in the replacement/upgrade of the EXISTING MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section ~~7~~6, as applicable, ~~also~~ have been met.

(D) THE PROJECT WILL NOT RESULT IN THE EXPANSION OF AN EXISTING MRT SERVICE UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5, AS APPLICABLE, HAVE BEEN MET.

(2) AN APPLICANT PROPOSING TO RELOCATE AN MRT UNIT(S) OF AN EXISTING MRT SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(A) THE RELOCATION OF THE MRT UNIT(S) WILL NOT CHANGE THE NUMBER OR TYPE (SPECIAL, NON-SPECIAL) OF MRT UNITS IN THE PLANNING AREA, UNLESS SUBSECTIONS (C) AND/OR (D), AS APPLICABLE, HAVE BEEN MET.

(B) THE NEW GEOGRAPHIC LOCATION WILL BE IN THE SAME PLANNING AREA AS THE EXISTING GEOGRAPHIC LOCATION.

(C) THE PROJECT WILL NOT RESULT IN THE REPLACEMENT/UPGRADE OF THE EXISTING MRT (UNIT)S TO BE RELOCATED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 6, AS APPLICABLE, HAVE BEEN MET.

(D) THE PROJECT WILL NOT RESULT IN THE EXPANSION OF AN EXISTING MRT SERVICE UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5, AS APPLICABLE, HAVE BEEN MET.

(~~5~~E) ~~The unit to be relocated is not a special purpose unit unless the location to which the special purpose unit is to be relocated meets the requirements of Section 6, as applicable.~~FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED TO THE ORIGINAL SITE FOR A MINIMUM OF THREE YEARS.

(~~6~~F) ~~The applicant agrees to all applicable project delivery requirements set forth in Section 15 of these standards.~~ FOR A MICROPOLITAN STATISTICAL AREA OR RURAL COUNTY, EACH EXISTING MRT UNIT AT THE GEOGRAPHIC LOCATION OF THE MRT UNIT TO BE RELOCATED OPERATED AT AN AVERAGE OF AT LEAST 5,500 ETVS IN THE MOST RECENT 12-MONTH PERIOD. FOR A METROPOLITAN STATISTICAL AREA COUNTY, EACH EXISTING MRT UNIT AT THE GEOGRAPHIC LOCATION OF THE MRT UNIT TO BE RELOCATED OPERATED AT AN AVERAGE OF AT LEAST 8,000 ETVS IN THE MOST RECENT 12-MONTH PERIOD.

(G) THE REQUIREMENTS OF SECTION 4(3) HAVE BEEN MET.

(H) A SPECIAL PURPOSE UNIT CANNOT BE RELOCATED TO A SITE THAT DOES NOT HAVE AN EXISTING NON-SPECIAL PURPOSE UNIT.

Section 10. Requirements for approval -- all applicants

Sec. 10. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL PROVIDE A SIGNED AFFIDAVIT STATING 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. 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 11. Methodology for computing the projected number of equivalent treatment visits

Sec. 11. The applicant being reviewed under Section ~~5~~ 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).

(1) Identify the number of new cancer cases documented in accord with the requirements of Section 14.

(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.

(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.

(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.

(5) Determine the number of estimated simple, intermediate, ~~and~~ complex, AND IMRT treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.

(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.

(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.

(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.

(9) MULTIPLY THE ESTIMATED NUMBER OF TREATMENT VISITS IN THE IMRT CATEGORY PRODUCED IN SUBSECTION (5) BY 2.5.

(~~9~~10) Sum the numbers produced in subsections (6) through (~~8~~9) to determine the total number of estimated ETVs.

Section 12. Equivalent treatment visits

Sec. 12. For purposes of these standards, equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable section(s) of these standards, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding ETV weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) ~~To determine the ETV for intraoperative treatment visits, whether performed on a MRT unit in the radiation oncology department or an OR-based IORT unit, divide the actual, documented number of minutes required to perform each intraoperative treatment visit by 15. The product of this division,~~

~~rounded up to the next whole number, is the ETV for intraoperative treatment visits. Documentation shall be submitted as part of the CON application and/or on a Department form developed for reporting MRT equivalent treatment visits. If a facility performs intraoperative treatment visits on both a unit located in the radiation oncology department and an OR-based IORT unit, the facility shall maintain separate records for the utilization of each separate unit.~~

~~(4)~~ The number of ETVs for each category determined pursuant to subsection~~s~~ (2) ~~and (3)~~ shall be summed to determine the total ETVs for the time period specified in the applicable section(s) of these standards.

TABLE 1

Equivalent TreatmentS

Treatment Visit Category	NON-SPECIAL Visit Weight	SPECIAL VISIT WEIGHT
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.50	
Very Complex:		
Total Body Irradiation	~~5.00~~	5.00
Hemi Body Irradiation	~~4.00~~	4.00
~~Patient under 5 years of age~~	~~2.00~~	
Heavy Particle Accelerator	~~5.00~~	5.00
Stereotactic radio-surgery/RADIO-THERAPY*	~~12.00~~	8.00
(non-gamma knife AND CYBER KNIFE**)		
Gamma Knife**	~~8.00 plus 4 additional ETVs for each iso-center after the first.~~	8.00
DEDICATED OR-BASED IORT		20.00

ALL PATIENTS UNDER 5 YEARS OF AGE RECEIVE A 2.00 ADDITIVE FACTOR.

*AFTER THE FIRST VISIT, EACH ADDITIONAL VISIT RECEIVES 2.5 ADDITIONAL ETVS WITH A MAXIMUM OF FIVE VISITS PER COURSE OF THERAPY.

**AFTER THE FIRST ISOCENTER, EACH ADDITIONAL ISOCENTER RECEIVES 4 ADDITIONAL ETVS.

Section 13. Commitment of new cancer cases

Sec. 13. (1) An applicant proposing to use new cancer cases shall demonstrate all of the following:

(a) Each entity contributing new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.

(b) The geographic locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT SERVICE~~unit(s)~~.

~~(c) Any entity contributing new cancer case data is not listed on the Department Inventory of MRT Units.~~

(2) An entity currently operating or approved to operate a MRT ~~unit~~SERVICE ~~listed on the~~

~~Department Inventory of MRT Units~~ shall not contribute new cancer cases to ~~support~~ INITIATE any MRT ~~unit~~/service.

Section 14. Documentation of new cancer case data

Sec. 14. (1) An applicant required to document volumes of new cancer cases shall submit, as part of its application, documentation from the DEPARTMENT, VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, ~~Office of the State Registrar~~ verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available from the State Registrar.

(2) New cancer case data supporting an application under these standards shall be submitted to the MICHIGAN CANCER SURVEILLANCE PROGRAM ~~Office of the State Registrar~~ using a format and media specified in instructions from the State Registrar.

Section 15. Project delivery requirements - terms of approval for all applicants

Sec. 15. (1) An applicant shall agree that, if approved, ~~megavoltage radiation therapy~~MRT services shall be delivered in compliance with the following applicable terms of ~~certificate of need~~CON approval FOR EACH GEOGRAPHICAL LOCATION WHERE THE APPLICANT OPERATES AN MRT UNIT:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards:

(i)(A)The non-special ~~megavoltage radiation therapy~~MRT units and heavy particle accelerators approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by ~~megavoltage radiation therapy~~MRT units approved exclusively for research pursuant to Section ~~8~~7.

(B) The non-special ~~megavoltage radiation therapy~~MRT units and heavy particle accelerators approved pursuant to Section ~~(5~~4~~)~~(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by ~~megavoltage radiation therapy~~MRT units approved exclusively for research pursuant to Section ~~8~~7.

(ii) An applicant shall establish a mechanism to assure that (a) the ~~megavoltage radiation therapy~~MRT service is staffed so that the ~~megavoltage radiation therapy~~MRT unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapy technologist certified 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 and operates a satisfactory quality assurance mechanism to assure that the ~~megavoltage radiation therapy~~MRT unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.

(iii) At a minimum, the following staff shall be provided: (a) 1 F~~.~~T~~.~~E~~.~~ BOARD-CERTIFIED OR BOARD-QUALIFIED physician trained in radiation oncology for each 250 patients treated with ~~megavoltage radiation therapy~~MRT annually, (b) 1 BOARD-CERTIFIED OR BOARD-QUALIFIED radiation physicist, CERTIFIED IN THERAPEUTIC RADIOLOGIC PHYSICS, immediately available during hours of operation,

(c) 1 dosimetrist or physics assistant for every 300 patients treated with ~~megavoltage radiation therapy~~MRT annually, (d) 2 F~~.~~T~~.~~E~~.~~ radiation therapy technologists [REGISTERED OR ELIGIBLE BY THE AMERICAN REGISTRY OF RADIOLOGICAL TECHNOLOGISTS (ARRT)] for every MRT unit per shift of operation (not including supervisory time), and (e) 1 F~~.~~T~~.~~E~~.~~ program director who is a BOARD-CERTIFIED physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(iv) All ~~megavoltage radiation therapy~~MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during the operation of the unit(s).

(v) The applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. ~~Megavoltage radiation therapy~~MRT facility staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the ~~megavoltage radiation therapy~~MRT unit at all times when patients are treated. A physician shall be on-site in or immediately available to the ~~megavoltage radiation therapy~~MRT unit at all times when patients are treated.

(vi) An applicant shall operate a cancer treatment program. For purposes of evaluating this subsection, the department shall consider it prima facie evidence of meeting this requirement if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. However, the applicant may submit and the Department may accept other evidence that the applicant operates a cancer treatment program as defined in these standards.

(vii) A ~~megavoltage radiation therapy~~MRT service will have simulation capability at the same geographic location of the ~~megavoltage radiation therapy~~MRT service/unit.

(viii) An applicant shall participate in the Michigan Cancer Surveillance Program.

(ix) An applicant required to document new cancer cases shall agree to pay the State Registrar's costs for verification of the new cancer case data.

(x) The applicant shall accept referrals for ~~megavoltage radiation therapy~~MRT services from all appropriately licensed health care practitioners.

(xi) The applicant, to assure that the ~~megavoltage radiation therapy~~MRT unit will be utilized by all segments of the Michigan population, shall: (a) not deny ~~megavoltage radiation therapy~~MRT services to any individual based on ability to pay or source of payment, (b) provide ~~megavoltage radiation therapy~~MRT services to an 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.

(xii)(A) 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, and the volume of care provided to patients from all payor sources and other data requested by the Department OR ITS DESIGNEE, and approved by the ~~Certificate of Need~~CON Commission. The applicant shall provide the required data on a separate basis for each separate and distinct geographic location or unit, and separately for non-special MRT units and each type of special purpose MRT 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.

(B) If the applicant intends to include research treatment visits conducted by a ~~megavoltage radiation therapy~~MRT unit other than an MRT unit approved exclusively for research pursuant to Section ~~8~~ 7 in its utilization statistics, the applicant shall submit to the department a copy of the research protocol with evidence of approval by the ~~institutional review board~~IRB. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall not report to the Department any treatment visits conducted by an MRT unit approved pursuant to Section ~~8~~7.

~~(xiii) Equipment that is replaced shall be removed from service.~~

(~~xiv~~xiii) The applicant shall ~~notify~~ PROVIDE the Department ~~in writing within 10 days of the~~WITH A NOTICE STATING THE FIRST date ~~when any~~ON WHICH THE MRT SERVICE AND ITS unit(s) ~~begins~~

BECAME operationAL, AND SUCH NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(xIv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved and to seek approval under a separate CON application to operate the unit as a non-special MRT unit.

(xvi) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification as a total body irradiator. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator shall meet any requirements specified by the Department of Consumer & Industry Services, Division of Health Facilities and Services, Radiation Safety Section.

(XVI) 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) An applicant for a megavoltage radiation therapyMRT unit under Section 8 7 shall agree that the services provided by the megavoltage radiation therapyMRT unit approved pursuant to Section 8 7 shall be delivered in compliance with the following terms of certificate of needCON approval:

(a) The capital and operating costs relating to the research use of the megavoltage radiation therapyMRT unit approved pursuant to Section 8 7 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The megavoltage radiation therapyMRT unit approved pursuant to Section 8 7 shall not be used for any purposes other than as approved by the institutional review boardIRB unless the applicant has obtained certificate of needCON approval for the megavoltage radiation therapyMRT unit pursuant to Part 222 and these standards, other than Section 87.

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

(4) The applicable agreements and assurances required by this section shall be in the form of a certification authorized by the owner or governing body of the applicant or its authorized agent.

Section 16. Planning areas

Sec. 16. 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 17. Effect on prior ~~planning policies~~CON REVIEW STANDARDS; comparative reviews

Sec. 17. (1) These ~~certificate of need~~CON review standards supersede and replace the ~~Certificate of Need~~CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units approved by the ~~Certificate of Need~~CON Commission on ~~September 22, 1998~~MARCH 14, 2000 and effective ~~December 10, 1998~~APRIL 28, 2000.

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

APPENDIX A

DUPLICATION RATES AND FACTORS

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.~~04553~~14181	0.~~95458~~582
2	0.~~08451022~~283	0.~~91557~~772
3	0.~~06147~~21565	0.~~93857~~843
4	0.~~06597~~126412	0.~~93407~~359
5	0.~~09252~~127394	0.~~90757~~261
6	0.~~09687~~026836	0.~~9031~~7316
7	0.~~13080~~118583	0.~~8692~~8142
8	0.~~08903~~620748	0.~~9110~~7925

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

Treatment Visit Category	Statewide Percent
Simple	~~12~~1.9%
Intermediate	~~26~~.8%
Complex	~~62~~86.2%
IMRT	11.1%

Source: ~~Special Survey of Megavoltage Radiation Services, Michigan Department of Community Health, June 1991~~2003 ANNUAL HOSPITAL STATISTICAL QUESTIONNAIRE

~~APPENDIX C~~

~~DEPARTMENT INVENTORY OF MEGAVOLTAGE RADIATION THERAPY UNITS~~

~~PLANNING AREA 1~~	~~NO. OF NON-SPECIAL MRT UNITS~~	~~NO. OF SPECIAL MRT UNITS~~
~~North Oakland Medical Center Pontiac~~	~~1~~	
~~Mercy Hospital Port Huron~~	~~1~~	
~~St. Joseph Mercy Hospital Ann Arbor~~	~~4~~	
~~University of Michigan Hospitals Ann Arbor~~	~~4~~	
~~St. Mary's Hospital Livonia~~	~~1~~	
~~Oakwood Hospital~~		
~~Dearborn~~	~~2~~	
~~Southgate~~	~~1~~	
~~William Beaumont Hospital Royal Oak~~	~~3~~	
~~William Beaumont Hospital Troy~~	~~1~~	
~~Grace Hospital Division (Outer Drive) Detroit~~	~~2~~	
~~PHMC Cancer Center~~		
~~Southfield~~	~~1~~	
~~Novi~~	~~1~~	
~~Sinai Hospital Detroit~~	~~2~~	
~~St. John Macomb Hospital Warren~~	~~2~~	

APPENDIX C continued

PLANNING AREA 1 continued	NO. OF NON-SPECIAL MRT UNITS	NO. OF SPECIAL MRT UNITS
American Oncologic Associates (MI Institute for Radiation Oncology - MIRO)		
Pontiac	2	
Downriver Center for Oncology		
Brownstown Township	1	
Garden City Radiation Therapy Association		
Garden City	1	
Grosse Pointe Physicians X-Ray Center		
Grosse Pointe Woods	1	
Harper Hospital		
Detroit	4	3
Rochester	1	
Henry Ford Hospital		
Detroit	3	
Henry Ford Hospital		
West Bloomfield	1	
Huron Valley Hospital		
Milford	1	
RADS, PC		
Monroe	1	
Farmington Hills	1	
Clarkston Cancer Treatment Ctr.	1	
Radiation Oncologists		
Rochester Hills	1	
Mt. Clemens	1	
St. John Hospital		
Detroit	2	
St. Joseph Mercy of Macomb		
Clinton Township	1	
X-Ray Treatment Ctr., P.C.		
East Detroit	1	
St. Clair Shores	1	

APPENDIX C continued

PLANNING AREA 2	NO. OF NON-SPECIAL MRT UNITS	NO. OF SPECIAL MRT UNITS
Edward W. Sparrow Hospital Lansing	3	
Emma L. Bixby Hospital Adrian	1	
WA Foote Hospital Jackson	2	
Radiation Oncology Alliance Lansing	1	
PLANNING AREA 3		
Battle Creek Health System Battle Creek	1	
Borgess Medical Center/Bronson Methodist Hospital Kalamazoo (joint)	2	
Mercy Memorial Medical Center St. Joseph	2	
PLANNING AREA 4		
Hackley Hospital Muskegon	2	
Blodgett Memorial Medical Center dba Spectrum Health E. Grand Rapids	1	
Butterworth Hospital dba Spectrum Health Grand Rapids	2	
Big Rapids (NW Radiation Oncology Center)	1	
Lakeshore Area Rad. Oncology Ctr. Holland	1	
St. Mary's Hospital Grand Rapids	1	

~~APPENDIX C continued~~

~~PLANNING AREA 5~~	~~NO. OF NON-SPECIAL MRT UNITS~~	~~NO. OF SPECIAL MRT UNITS~~
~~Genesys Health System~~		
~~Grand Blanc~~	~~2~~	
~~Hurley Medical Center~~		
~~Flint~~	~~2~~	
~~McLaren General Hospital~~		
~~Flint~~	~~2~~	
~~PLANNING AREA 6~~		
~~Bay Medical Center~~		
~~Bay City~~	~~1~~	
~~Saginaw (Saginaw Radiation Oncology Center~~	~~1~~	
~~Mid-Michigan Medical Center~~		
~~Midland~~	~~1~~	
~~Alma~~	~~1~~	
~~St. Mary's Medical Center~~		
~~Saginaw~~	~~2~~	~~1~~
~~Central Michigan Comp. Oncology Ctr (West Branch)~~	~~1~~	
~~PLANNING AREA 7~~		
~~Munson Medical Center~~		
~~Traverse City~~	~~2~~	
~~Northern Michigan Hospital~~		
~~Petoskey~~	~~2~~	
~~PLANNING AREA 8~~		
~~Marquette General Hospital~~	~~2~~	
~~Marquette~~		

APPENDIX C

CON REVIEW STANDARDS FOR MRT 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

CERTIFICATE OF NEED REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the Certificate of Need 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 the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgical center, or a hospital licensed under Part 215 of the Code performing inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Section 9, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(6)(a) These standards shall apply to the review of all Certificate of Need applications for surgical services for which the Director of the Department of Community Health has not made a final decision under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.

(b) In the case of an application which has been deemed submitted, but which has not received a final decision by the Director on the effective date of these standards, an applicant may request, and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.

(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8), being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.

Section 2. Definitions

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

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(c) "Burn care," for purposes of these standards, means surgical services provided to burn patients in a

licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(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) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) "Department" means the Michigan Department of Community Health.

(h) “Emergency Room,” for purposes of Section 6(2)(b) of these standards only, means a designated area in a licensed hospital and recognized by the Department of Consumer and Industry Services as having met the staffing and equipment requirements for the treatment of emergency patients.

(i) "Endoscopy" means visual inspection of any cavity of the body by means of an endoscope.

(j) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(k) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is licensed as part of a licensed hospital site or a freestanding surgical outpatient facility, or that is certified as an ambulatory surgical center.

(l) "Expand a surgical service" means the addition of one or more operating rooms at an existing surgical service.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned by, operated, and licensed as a part of a hospital at a licensed hospital site.

(n) "Hospital" means a health facility licensed under Part 215 of the Code.

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Initiate a surgical service" means to begin operation of a surgical facility at a site that does not perform surgical services as of the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(q) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(r) "Offer" means to perform surgical services.

(s) "Operating room" or "OR," for purposes of these standards, means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases.

(t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(v) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different site within the relocation zone.

(w) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a nonrural

county, or a 20-mile radius if an existing surgical service is located in a rural county.

(x) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(y) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. The term does not include the renovation of an existing surgical service or one or more operating rooms.

(z) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "Revised standards for defining metropolitan areas in the 1990's" by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 55 F.R. p. 12154 (March 30, 1990).

(aa) "Sterile corridor," for purposes of these standards, means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(bb) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(cc) "Surgical facility" means either:

(i) a licensed freestanding surgical outpatient facility;

(ii) a certified ambulatory surgical center; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(dd) "Surgical service" means performing surgery in a surgical facility.

(ee) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

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

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms pursuant to subsection (2) and the number of surgical cases, or hours of use, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision.

(v) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(v), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), (iii), and (iv).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least 1,200 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural county that does not offer surgical services as of the date an application is submitted to the Department.

(3) ~~If the number of surgical cases projected under subsection (1) includes surgical cases performed at an existing surgical facility(s), an~~ AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES PROJECTED UNDER SUBSECTION (1).

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200 surgical cases PER YEAR PER OPERATING ROOM FOR THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT or

(ii) in a hospital, 1,600 hours of use or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data ~~is~~ ARE available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

(i) 1,200 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER or

(ii) in a hospital, 1,600 hours of use or in an FSOF OR ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural county that currently has only one operating room.

(3) ~~If the number of surgical cases, or hours of use, projected under subsection (1) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an~~ AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (1).

SECTION 6. REQUIREMENTS FOR APPROVAL FOR FACILITIES PROPOSING TO REPLACE A SURGICAL SERVICE OR ONE OR MORE OPERATING ROOMS

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200 surgical cases PER YEAR PER OPERATING ROOM FOR THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT or

(ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data ~~is~~ ARE available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

(i) 1,200 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER or

(ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2)(a) Subsection (1) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural county and has one or two operating rooms.

(b) Subsection (1) shall not apply if the proposed project involves replacing one or two operating rooms at the same licensed hospital site if the surgical facility is a hospital that:

(i) is located in a nonrural county;

(ii) has an emergency room at the same licensed hospital site as the operating rooms;

(iii) has exactly two operating rooms; and

(iv) has performed at least 1,200 surgical cases, or at least 1,600 hours of use, per year for the most recent 12-month period for which verifiable data is available to the Department.

Section 7. Requirements for approval for applicants proposing to relocate a surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate a surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility to be relocated have performed an average

of at least:

(a) 1,200 surgical cases PER YEAR PER OPERATING ROOM FOR THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT or

(b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data ~~is~~ ARE available to the Department.

(4) All operating rooms, existing and proposed, are projected to perform an average of at least:

(a) 1,200 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER or

(b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(5) ~~If the number of surgical cases projected under subsection (4) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an~~ AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (4).

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:

(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, after the effective date of these standards, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

(6) Subsection (5) shall not apply if the proposed project involves the acquisition of both of the operating rooms of an existing surgical service of a hospital if the hospital from which the service being acquired is: (A) located in a nonrural county, (b) has an emergency room at the same licensed hospital site as the operating rooms, (c) has exactly two operating rooms, and (d) has performed at least 1,200 surgical cases or at least 1,600 hours of use per year for the most recent 12-month period for which verifiable data is available to the department. The operating rooms acquired under this subsection must remain part of a surgical service of a licensed hospital.

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

Sec. 9. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with

the following terms of Certificate of Need approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following terms of approval, as applicable:

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

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

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

(B) provide surgical services to any individual based on the clinical indications of need for the service.

(C) maintain information by payer 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.

(iii) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, 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 payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) Within 10 days after initiation of the service, an applicant shall provide the Department with a notice stating the first date on which the approved service was initiated.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint

Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

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

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

Section 10. Documentation of projections

Sec. 10. (1) An applicant required to project volumes of service under the applicable sections of these standards shall specify how the volume projections were developed AND SHALL INCLUDE ONLY THOSE SURGICAL CASES PERFORMED IN AN OR. 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 if the projections are reasonable.

(2) If a projected number of surgical cases, or hours of use, UNDER SUBSECTION (1) includes surgical cases, or hours of use, performed at ~~an~~ANOTHER existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will be in compliance with the volume requirements applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 11. Effect on prior Certificate of Need review standards; comparative reviews

Sec. 11. (1) These Certificate of Need review standards supercede and replace the Certificate of Need Review Standards for Surgical Facilities approved by the Certificate of Need Commission on ~~December 12~~SEPTEMBER 22, ~~1995~~ 1998 and effective on ~~January 27~~DECEMBER 10, ~~1996~~1998.

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

TESTIMONY
Report to the CON Commission
Final Recommendations of the
Surgical Services Standard Advisory Committee
December 13th, 2005

Good morning! I am Cheryl Miller, Director of Strategic Planning at Trinity Health's home office in Novi and I had the privilege of chairing the Surgical Services Standard Advisory Committee (SSSAC). I am very pleased to provide you with an overview of the final recommendations from the SSSAC. My comments will focus on the Committee's work since my last update to you on September 13th.

The SSSAC's last meeting was on October 20th in compliance with the 6-month statutory limitation established under PA 619. I am very pleased to report that we completed our charge with the SSSAC's final recommendations in the form of proposed revised language that Brenda will review with everyone in greater detail following my comments.

Just as a reminder, to facilitate more in-depth analyses, the SAC formed two informal work groups to provide a deeper dive into several of many of the very complex issues. At the June Commission meeting, i reported on the early efforts of the first informal Work Group who picked up where Commissioner Hagenow's previous work group left off – namely, the definition of a surgical procedure for CON purposes. At the September Commission meeting, I reported on the Committee's subsequent work that resulted in a recommendation that pledged surgical volume must be procedures done in an operating room without dropping that facility below the compliance threshold. Today, my comments will center on the work of the second Informal Work Group charged with evaluating the specific issues related to minimum volume requirements, an appropriate need methodology and other related issues. After several meetings, the following recommendations were made by this Work Group and endorsed by the SSSAC:

1) The need approach used by the 1995 Ad Hoc Advisory Committee was endorsed and updated. Two significant improvements were introduced:
   a) Separate determinations of need for inpatient and outpatient surgical services, regardless of setting; and
   b) Separate requirements for maintenance of current surgical capacity and for expansion of new surgical capacity.

   All planning assumptions used in the original approach were examined and updated. New CON requirements were developed based on review of best practices and professional literature related to management of surgical facilities; on the professional experience of individual Work Group members; and on consideration of data derived from the special survey of surgical facilities conducted by MDCH.

2) A "blended method" of determining hospital-based operating room need was endorsed, whereby a hospital could employ the hours-based standard for inpatient surgical capacity and the cases-based standard for outpatient surgical capacity. Because the proposed new volume requirements take into account the differences between inpatient and outpatient surgical services, there is no need to define physically distinct inpatient and outpatient surgical departments in a hospital.

3) A separate need standard was developed for rural, micropolitan or like areas for

hospitals with surgical services taking into account the unique difficulties of operating a surgical service in these areas.

4) The validity of special exemptions for hospitals with Burn Center and Trauma Center designations was reaffirmed, and the specifics of these exemptions were simplified. A similar exemption for open-heart surgery programs was rejected.

5) The status of dedicated cystoscopy and endoscopy rooms was clarified and the CON review process for those specialized operating rooms was specified.

Because these issues are complex and so important in understanding how the final proposed language was derived, I'd like to review in detail the evaluation process and considerations behind these recommendations.

Minimum Volume Requirements

The Work Group reviewed the planning model employed by the 1995 Advisory Committee and agreed that the 1995 model included the relevant variables in determining need for surgical facilities, as follows:

1.	Annual days of operation	(days/year)
2.	Daily hours of operation	(hours/day)
3.	Utilization percentage	(utilization %)
4.	Average length of case	(case length)

The formulae for calculating volume requirements for surgical facilities are as follows:

Hours/OR/year = (days) x (hours/day) x (utilization %)

Cases/OR/year = (hours/OR/year) / (case length)

In a departure from the 1995 effort, the Work Group determined that there should be differential volume requirements to expand surgical capacity, as opposed to maintaining existing capacity. In other words, the project delivery requirements to maintain the existing complement of operating rooms should be less rigorous than the requirement to initiate a new surgical facility or to expand an existing one. This approach is consistent with other CON Review Standards that include higher thresholds for expansion than for replacement. The Work Group calculated different volume requirements by varying the utilization percentages in the planning model.

The Work Group focused much attention on the concept of "utilization percentage." The previous advisory committee called this factor "efficiency level," and considered it to account for unavoidable down time in a surgical facility due to scheduling problems, cancellations, and other delays. As used in the contemporary literature, and also by the Work Group, "utilization percentage" takes into account all of the preceding considerations, plus turn-around time (set-up and clean-up) between surgical cases. Professional literature reviewed found an average utilization of 63% for the best-performing quartile of hospital-based surgery departments surveyed. The Work Group recognized that utilization percentage, like occupancy percentage for hospital beds, is a critical factor in calculating need for licensed operating rooms.

In a further departure from the 1995 effort, the Work Group determined that there should be different volume requirements for inpatient surgical services and outpatient (regardless of setting) surgical services. As a result, hospitals would separately calculate their inpatient

and outpatient need for operating rooms, and sum them to produce the facility need for surgical capacity.

The Work Group evaluated different values for each of the planning variables, separately for inpatient and outpatient surgical services. In addition to the work of the previous advisory group and materials distributed to the SAC, the Work Group drew information from supplemental literature related to management of surgical facilities from professional experience of individual Work Group members, and from data derived from the special survey of surgical facilities conducted by MDCH. After considerable discussion and review, the Work Group determined the most appropriate values to be as follows:

1. Annual days of operation 250 days per year
2. Scheduled daily hours of operation:
   Inpatient – 10 hours; Outpatient – 7.5 hours
3. Utilization percentage Maintenance – 60%; Expansion – 65%
4. Average length of case Inpatient – 2.2 hours; Outpatient – 1.08 hour

The Work Group further considered these results. For inpatient services, where the use of surgical hours generally produces the most appropriate estimate of operating room need, the resulting minimum requirements measured by surgical cases, were determined to be unreasonably low. Therefore, the Work Group recommended that hospitals wishing to use cases as an indicator of need for their inpatient volume should use the same standard as applied to outpatient services. Therefore, the Work Group recommended that the minimum volume requirements per operating room per year should be as follows:

❖ Maintain existing capacity, replace, renovate, relocate

Measure per OR per yr	Proposed Inpatient Requirement	Proposed Outpatient Requirement	Current Requirements
Hours	1,500	1,125	1,600 hospital 1,800 FSOF
Cases	1,042	1,042	1,200

❖ Expand existing capacity, initiate new service

Measure per OR per yr	Proposed Inpatient Requirement	Proposed Outpatient Requirement	Current Requirements
Hours	1,625	1,219	1,600 hospital 1,800 FSOF
Cases	1,128	1,128	1,200

"Blended Method" for Hospital-Based Surgical Departments

The approach endorsed by the Work Group included separate need determinations for inpatient and outpatient surgery, regardless of site. The original blended method proposed to the SAC would have allowed mixing measures (i.e., hours and cases) for hospital-based surgical departments. The Work Group recommended that, in addition to using either hours or cases to determine the need for

operating rooms, hospitals should be allowed to combine the inpatient operating room need indicated using inpatient hours with the outpatient operating room need using outpatient cases to determine the total need for surgical capacity at the facility.

Physical Distinctness of Hospital-Based Inpatient and Outpatient Surgical Departments

Since the recommendations for revised volume requirements distinguish between need for inpatient and outpatient surgical capacity, the Work Group recommended that there is no need to define physically distinct inpatient and outpatient surgical departments at a hospital for CON purposes.

Rural and Like Areas Issues

Representatives of rural hospitals made a compelling case to the SAC about the unique difficulties of operating surgical departments in rural hospitals. The Work Group reviewed the data from the MDCH special surgical survey related to rural facilities. The Group acknowledged the particular difficulties of rural hospitals in scheduling longer than eight (8) hours per day. They also determined that the difference between inpatient and outpatient cases at rural hospitals is less significant than at urban hospitals. Therefore, the Work Group determined that the most appropriate values in the need methodology for rural surgical services to be as follows:

1. Annual days of operation — 250 days per year
2. Scheduled daily hours of operation — 8 hours
3. Utilization percentage — Maintenance – 60%; Expansion – 65%
4. Average length of case — 1.43 hours

As a result, the Work Group recommended that the minimum volume requirements per operating room per year for rural surgical facilities should be as follows:

- Maintain existing capacity, replace, renovate, relocate

Measure per OR per yr	Proposed Requirements	Current Requirements
Hours	1,200	1,600 hospital 1,800 FSOF
Cases	839	1,200

- Expand existing capacity, initiate new service

Measure per OR per yr	Proposed Requirements	Current Requirements
Hours	1,300	1,600 hospital 1,800 FSOF
Cases	909	1,200

Exemptions for Special Purpose Operating Rooms

The Work Group reviewed the rationale for exemptions for surgical rooms designated for burn patients and trauma patients. They determined that an exemption for these purposes continues to be justified, but that it should be simplified. Therefore, the Work Group recommended that qualified burn and trauma centers should receive a credit of .5 operating rooms, each, without any adjustment in their case/hours count.

They also considered the justification for a similar exemption for open-heart surgery programs. Because most open-heart procedures are scheduled, rather than emergent, and that there is no requirement to dedicate a specific room for heart surgery, the Work Group determined that no exemption is warranted for open-heart surgery.

Dedicated Cystoscopy and Endoscopy Rooms

The Work Group acknowledged that surgical facilities should be permitted to designate specific operating rooms on the sterile corridor as dedicated cystoscopy and/or endoscopy rooms. However, they determined that such designation should be formalized through the CON process. The Work Group recommended that any change in a hospital's licensed complement of operating rooms that changes the designation of a general-purpose operating room to a dedicated endoscopy and/or cystoscopy room should require non-substantive CON approval. The proposed language offered today allows this to occur with Departmental notification. Furthermore, any change in a hospital's licensed complement of operating rooms that changes the designation of a dedicated endoscopy and/or cystoscopy room to a general-purpose operating room should be considered an expansion of the surgical capacity of that facility and, hence, require substantive CON approval.

Specific language reflecting these recommendations has been developed and endorsed by the SSSAC for the Commission's consideration and forwarding on for public comment.

It should be noted that the proposed recommendations from the SAC also include technical changes suggested by the Department to comply with P.A. 619 of 2002 and other various issues, such as Medicaid participation and defining micropolitan and metropolitan areas.

I want to sincerely thank the Department staff for their tireless efforts, especially Brenda, Larry, Matt, Gaye, Stan and Andrea as well as the wonderful members/alternates who served on the SSSAC. We also were blessed to have a dedicated band of SSSAC groupies who provided an enormous amount of input and guidance along the way.

Thank you again for the opportunity to serve as chairperson of this distinguished and hard-working group, and I would be delighted to answer any questions you may have.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(BY AUTHORITY CONFERRED ON THE ~~CERTIFICATE OF NEED~~ 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~~ THAT involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgi~~cal~~ERY center CERTIFIED UNDER TITLE XVIII, or a SURGICAL DEPARTMENT OF A hospital licensed under Part 215 of the Code ~~performing~~ AND OFFERING inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, and ~~10~~11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Section ~~9~~10, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(6)(a) These standards shall apply to the review of all Certificate of Need applications for surgical services for which the Director of the Department of Community Health has not made a final decision under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.~~

~~(b) In the case of an application which has been deemed submitted, but which has not received a final decision by the Director on the effective date of these standards, an applicant may request, and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.~~

~~(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8), being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.~~

Section 2. Definitions

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

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical

services to patients not requiring hospitalization.

(c) "Burn care~~,~~" ~~for purposes of these standards,~~ means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(D) "CERTIFICATE OF NEED COMMISSION" OR "COMMISSION" MEANS THE COMMISSION CREATED PURSUANT TO SECTION 22211 OF THE CODE, BEING SECTION 333.22211 OF THE MICHIGAN COMPILED LAWS.

(~~d~~E) "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~~E) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(~~f~~G) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(H) "DEDICATED ENDOSCOPY OR CYSTOSCOPY OPERATING ROOM" MEANS A ROOM USED EXCLUSIVELY FOR ENDOSCOPY OR CYSTOSCOPY CASES.

(~~g~~I) "Department" means the Michigan Department of Community Health (MDCH).

(~~h~~J) "Emergency Room~~,~~" ~~for purposes of Section 6(2)(b) of these standards only,~~ means a designated area in a licensed hospital and recognized by the Department ~~of Consumer and Industry Services~~ as having met the staffing and equipment requirements for the treatment of emergency patients.

(~~i~~K) "Endoscopy" means visual inspection of any ~~cavity~~ **PORTION** of the body by means of an endoscope.

(~~j~~L) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(~~k~~M) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is ~~licensed as~~ part of a licensed hospital site~~. or~~ a LICENSED freestanding surgical outpatient facility, or ~~that is~~A certified ~~as an ambulatory surgical center~~ASC.

(~~l~~N) "Expand a surgical service" means the addition of one or more operating rooms at an existing surgical service. **THIS TERM ALSO INCLUDES THE CHANGE FROM A DEDICATED ENDOSCOPY OR CYSTOSCOPY OR TO A NON-DEDICATED OR.**

(~~m~~O) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned ~~by,~~AND operated~~, and licensed~~ as a part of a ~~hospital at a~~ licensed hospital site.

(~~n~~P) "Hospital" means a health facility licensed under Part 215 of the Code.

(~~o~~Q) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(~~p~~R) "Initiate a surgical service" means to begin operation of a surgical facility at a site that ~~does~~ HAS not ~~perform~~ OFFERED surgical services WITHIN THE 12-MONTH PERIOD IMMEDIATELY PRECEDING ~~as of~~ the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(~~q~~S) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(T) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND1396R-8 TO 1396V.

(U) "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.

(V) "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.

(~~r~~W) "Offer" means to perform surgical services.

(~~s~~X) "Operating room" or "OR~~,~~" ~~for purposes of these standards,~~ means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. THIS TERM DOES NOT INCLUDE PROCEDURE ROOMS.

(~~t~~Y) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(~~u~~Z) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(AA) "PROCEDURE ROOM" MEANS A ROOM IN A SURGICAL FACILITY CONSTRUCTED AND EQUIPPED TO PERFORM SURGICAL PROCEDURES AND NOT LOCATED ON A STERILE CORRIDOR.

(~~v~~BB) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different **LOCATION CURRENTLY OFFERING SURGICAL SERVICES** ~~site~~ within the relocation zone.

(~~w~~CC) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a ~~nonrural~~ METROPOLITAN STATISTICAL AREA county, or a 20-mile radius if an existing surgical service is located in a rural OR MICROPOLITAN STATISTICAL AREA county.

(~~x~~DD) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(~~y~~EE) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. **THIS TERM ALSO INCLUDES DESIGNATING AN OR AS A DEDICATED ENDOSCOPY OR CYSTOSCOPY OR.** The term does not include the renovation of an existing surgical service or one or more operating rooms.

(~~z~~FF) "Rural county" means a county not located in a metropolitan STATISTICAL area OR MICROPOLITAN STATISTICAL AREAS as ~~that~~ THOSE terms ~~is~~ ARE defined ~~pursuant~~ UNDER ~~to~~ the "~~Revised~~ standards for defining metropolitan AND MICROPOLITAN STATISTICAL areas ~~in the 1990's~~" by the ~~Statistical~~ STATISTICAL ~~Policy~~ POLICY ~~Office~~ OFFICE of the ~~Office~~ OFFICE of ~~Information~~ Information and ~~Regulatory~~ Regulatory ~~Affairs~~ Affairs of the United States Office of ~~Management~~ MANAGEMENT and ~~Budget~~BUDGET, ~~55~~ 65 F.R. p. ~~12154~~ 82238 (~~March~~ DECEMBER 27~~30~~, ~~1990~~2000) AND AS SHOWN IN APPENDIX A.

(~~aa~~GG) "Sterile corridor~~,~~" ~~for purposes of these standards,~~ means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a

surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(~~bb~~HH) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(~~cc~~II) "Surgical facility" means either:

(i) a licensed ~~freestanding surgical outpatient facility~~FSOF;

(ii) a certified ~~ambulatory surgical center~~ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(~~dd~~JJ) "Surgical service" means performing surgery in a surgical facility.

(~~ee~~KK) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(LL) "VERIFIABLE DATA" MEANS SURGICAL DATA (CASES AND/OR HOURS) FROM THE MOST RECENT ANNUAL SURVEY OR MORE RECENT DATA THAT CAN BE VALIDATED BY THE DEPARTMENT.

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

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms AND VERIFIABLE DATA pursuant to subsection (2) TO DETERMINE ~~and~~ the number of surgical cases, ~~or~~ hours of use, OR BOTH, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. COMPLIANCE WITH CON MINIMUM VOLUME REQUIREMENTS ESTABLISHED BY THESE STANDARDS SHALL BE DETERMINED BASED ON THE AVERAGE NUMBER OF SURGICAL CASES, HOURS OF USE, OR BOTH, PER OPERATING ROOM OF THE SURGICAL SERVICE AS PERMITTED BY THESE STANDARDS.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) ~~An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision.~~

~~(v)~~ An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(Iv),

but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), AND (iii)~~, and (iv)~~.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least ~~1,200~~ 1,128 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural OR MICROPOLITAN STATISTICAL AREA county that does not offer surgical services as of the date an application is submitted to the Department.

(3) ~~*If the number of surgical cases projected under subsection (1) includes surgical cases performed at an existing surgical facility(s), a*~~An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) *FOR THE NUMBER OF SURGICAL CASES PROJECTED UNDER SUBSECTION (1)*.

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:

(i) ~~1,200~~1,128 surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, or

(ii) ~~in a hospital, 1,600~~1,219 hours of use ~~or~~ in a~~n FSOF or ASC, 1,800 hours of use~~FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room for ~~the most recent 12-month period for~~ which verifiable data is available to the Department, OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,625 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,219. (FOR EXAMPLE: USING 410 INPATIENT HOURS AND 915 OUTPATIENT HOURS WOULD EQUATE TO 410/1,625 + 915/1,219 = 0.25 + 0.75 = 1.00 OR.), OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,625 PLUS THE OUTPATIENT CASES DIVIDED BY 1,128. (FOR EXAMPLE: USING 410 INPATIENT HOURS AND 850 OUTPATIENT CASES WOULD EQUATE TO 410/1,625 + 850/1,128 = 0.25 + 0.75 = 1.00 OR.)~~.~~

(b) All PROPOSED operating rooms~~, existing and proposed,~~ are projected to perform an average of at

least:

(i) ~~1,200~~1,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, or

(ii) ~~in a hospital, 1,600~~1,125 hours of use ~~or~~ in a~~n FSOF OR ASC, 1,800 hours of use~~ FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter, OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.). OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1, 042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)~~.~~

(2) AN APPLICANT PROPOSING TO ADD ONE OR MORE OPERATING ROOMS AT A **LICENSED HOSPITAL** AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) THE APPLICANT HAS **TWO, THREE, OR** FOUR OR**S** AT THE LICENSED HOSPITAL.

(B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:

(I) 909 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(II) 1,300 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.

(C) All PROPOSED OPERATING ROOMS ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:

(I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR

(II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural OR MICROPOLITAN STATISTICAL AREA county that currently has only one operating room.

(~~34~~) ~~*If the number of surgical cases, or hours of use, projected under subsection (1) includes surgical cases, or hours of use, performed at an existing surgical facility(s), a*~~An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) *FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (1)*.

Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or more operating rooms

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) ~~1,200~~1,042 surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, or

(ii) ~~in a hospital, 1,600~~1,125 hours of use~~, or~~ in a~~n FSOF or ASC, 1,800 hours of use~~ FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room for ~~the most recent 12-month period for~~ which verifiable data is available to the Department. OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.). OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM **FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:**

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.).~~.~~

(b) All operating rooms, existing and replaced~~proposed~~, are projected to perform an average of at least:

(i) ~~1,200~~1,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER,or

(ii) ~~in a hospital, 1,600~~1,125 hours of use~~, or~~ in a~~n FSOF or ASC, 1,800 hours of use~~ FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter~~.~~. OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.). OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) AN APPLICANT PROPOSING TO REPLACE ONE OR MORE OPERATING ROOMS AT A LICENSED HOSPITAL AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE

FOLLOWING:

(A) THE APPLICANT HAS THREE, **FOUR**, OR **FIVE** ORS AT THE LICENSED HOSPITAL.

(B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:

(I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.

(C) All OPERATING ROOMS, EXISTING AND REPLACED, ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:

(I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR

(II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(~~23~~)~~(a)~~ SubsectionS (1) AND (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural OR MICROPOLITAN STATISTICAL AREA county and has one or two operating rooms.

~~(b) Subsection (1) shall not apply if the proposed project involves replacing one or two operating rooms at the same licensed hospital site if the surgical facility is a hospital that:~~

~~(i) is located in a nonrural county;~~

~~(ii) has an emergency room at the same licensed hospital site as the operating rooms;~~

~~(iii) has exactly two operating rooms; and~~

~~(iv) has performed at least 1,200 surgical cases, or at least 1,600 hours of use, per year for the most recent 12-month period for which verifiable data is available to the Department.~~

(4) SUBSECTIONS (1) AND (2) SHALL NOT APPLY TO THOSE HOSPITALS LICENSED UNDER PART 215 OF PA 368 OF 1978, AS AMENDED THAT HAD FEWER THAN 70 LICENSED BEDS ON DECEMBER 1, 2002 PROVIDED THE NUMBER OF ORS AT THE SURGICAL SERVICE HAS NOT INCREASED AS OF MARCH 31, 2003, AND THE LOCATION DOES NOT CHANGE.

(5) AN APPLICANT PROPOSING TO DESIGNATE A**N OR AS A DEDICATED** ENDOSCOPY OR CYSTOSCOPY **OR** SHALL SUBMIT NOTIFICATION TO THE DEPARTMENT ON A FORM PROVIDED BY THE DEPARTMENT. **AN APPLICANT UNDER THIS SUBSECTION SHALL NOT BE REQUIRED TO COMPLY WITH SUBSECTIONS (1) AND (2).**

Section 7. Requirements for approval for applicants proposing to relocate aN EXISTING surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate aN EXISTING surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility **FROM WHICH ONE OR MORE ORS ARE PROPOSED** to be relocated have performed an average of at least:

(a) ~~1,200~~1,042 surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(b) ~~in a hospital, 1,600~~1,125 hours of use~~, or~~ in a~~n FSOF or ASC, 1,800 hours of use~~ FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR~~for the most recent 12-month period for which verifiable~~

~~data is available to the Department:~~**.**

(C) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:**

(I) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.). OR

(D) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM **FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS**:

(I) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(4) All operating rooms, existing and ~~proposed~~**RELOCATED**, are projected to perform an average of at least:

(a) ~~1,200~~ 1,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.~~or~~

(b) ~~in a hospital, 1,600~~1,125 hours of use~~, or~~ in a~~n FSOF or ASC, 1,800 hours of use~~ FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter~~.~~**.**

(C) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:**

(I) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.) OR

(D) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(I) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(5) AN APPLICANT PROPOSING TO RELOCATE ONE OR MORE OPERATING ROOMS **FROM** ONE LICENSED HOSPITAL **SITE TO ANOTHER LICENSED HOSPITAL SITE** AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) THE APPLICANT HAS, THREE, **FOUR,** OR **FIVE** ORS AT THE LICENSED HOSPITAL.

(B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:

(I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.

(C) All OPERATING ROOMS, EXISTING AND RELOCATED, ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:

(I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR

(II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(~~5~~6) ~~*If the number of surgical cases projected under subsection (4) includes surgical cases, or hours of use, performed at an existing surgical facility(s), a*~~An applicant shall demonstrate that it meets the requirements of Section ~~10~~11(2) *FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (4)*.

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:

(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, ON OR after ~~the effective date of these standards~~JANUARY 27, 1996, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

~~(6) Subsection (5) shall not apply if the proposed project involves the acquisition of both of the operating rooms of an existing surgical service of a hospital if the hospital from which the service being acquired is: (A) located in a nonrural county, (b) has an emergency room at the same licensed hospital site as the operating rooms, (c) has exactly two operating rooms, and (d) has performed at least 1,200 surgical cases or at least 1,600 hours of use per year for the most recent 12-month period for which verifiable data is available to the department. The operating rooms acquired under this subsection must remain part of a surgical service of a licensed hospital.~~

(6) SUBSECTION (**5**) SHALL NOT APPLY TO THOSE HOSPITALS LICENSED UNDER PART 215 OF PA 368 OF 1978, AS AMENDED THAT HAD FEWER THAN 70 LICENSED BEDS ON DECEMBER 1, 2002 PROVIDED THE NUMBER OF ORS AT THE SURGICAL SERVICE HAS NOT INCREASED AS OF MARCH 31, 2003, AND THE LOCATION DOES NOT CHANGE.

Section 9. Requirements for approval -- all applicants

Sec. 9. AN APPLICANT SHALL PROVIDE **EVIDENCE OF PARTICIPATION IN MEDICAID OR IN MEDICAID MANAGED CARE PRODUCTS OR ATTESTATION THAT THE APPLICANT HAS BEEN UNABLE TO CONTRACT AT CURRENT MEDICAID RATES** AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. **BY PROVIDING A SIGNED AFFIDAVIT,** AN APPLICANT THAT IS AN ASC **OR ESOF** SHALL DEMONSTRATE A WILLINGNESS TO PARTICIPATE WHEN ACCEPTED BY MEDICAID. AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL PROVIDE A SIGNED AFFIDAVIT STATING 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. 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 ~~9~~10. Project delivery requirements -- terms of approval for all applicants

Sec. ~~9~~10. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of ~~Certificate of Need~~CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following terms of approval, as applicable:

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

(II) THE DESIGNATION OF ORS AS DEFINED BY THE STANDARDS SHALL NOT BE CHANGED WITHOUT PRIOR NOTIFICATION TO THE DEPARTMENT.

(ii<u>I</u>) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

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

(B) provide surgical services to any individual based on the clinical indications of need for the service.

(C) maintain information by payer 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.

(~~iii~~IV) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, 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 payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~iv~~) ~~Within 10 days after initiation of the service, an~~THE applicant shall provide the Department with a notice stating the first date on which the ~~approved~~ service ~~was initiated~~BECAME OPERATIONAL, AND SUCH NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the

surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(F) AN APPLICANT SHALL PARTICIPATE IN MEDICAID **OR IN MEDICAID MANAGED CARE PRODUCTS** AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER **OR ATTEST THAT THE APPLICANT HAS BEEN UNABLE TO CONTRACT WITH MEDICAID MANAGED CARE PRODUCTS AT CURRENT MEDICAID RATES.**

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

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

Section ~~10~~11. Documentation of projections

Sec. ~~10~~11. (1) An applicant required to project volumes of service under the applicable sections of these standards shall specify how the volume projections were developed *AND SHALL INCLUDE ONLY THOSE SURGICAL CASES PERFORMED IN AN OR*. 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 if the projections are reasonable.

(2) If a projected number of surgical cases, or hours of use, *UNDER SUBSECTION (1)* includes surgical cases, or hours of use, performed at an*OTHER* existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will **CONTINUE TO** be in compliance with the volume requirements **(CASES AND/OR HOURS)** applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section ~~11~~12. Effect on prior ~~Certificate of Need~~CON review standards; comparative reviews

Sec. ~~11~~12. (1) These ~~Certificate of Need~~**CON** review standards supercede and replace the ~~Certificate of Need~~**CON** Review Standards for Surgical Facilities approved by the ~~Certificate of Need~~**CON** Commission on ~~December 12, 1995~~SEPTEMBER 22, 1998 and effective on ~~January 27, 1996~~DECEMBER 10, 1998.

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

APPENDIX A

CON REVIEW STANDARDS
FOR SURGICAL 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