MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services . The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. For purposes of these standards:

(a) "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.

(b) "Burn care" 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.

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

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

(e) "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) “Dedicated endoscopy or cystoscopy operating room” means a room used exclusively for endoscopy or cystoscopy cases.

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

(i) “Emergency Room” means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(j) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

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

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

(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 and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.

(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) "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.

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

~~(r) "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.~~

~~(s) "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.~~

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

(~~u~~s) "Operating room" or "OR" 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.

(~~v~~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.

(~~w~~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.

(~~x~~v) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor.

(~~y~~w) "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, or acquisition of a surgical service or one or more operating rooms.

~~(z) "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 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.~~

(~~aa~~x) "Sterile corridor" 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~~y) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

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

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

(~~cc~~z) "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.

(~~dd~~aa) "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) Terms defined in the Code have the same meanings when used in 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 the number of surgical cases, 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, 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, and precludes the use of the room in subsection (2)(a)(v).

(v) 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, and precludes the use of the room in subsection (2)(a)(iv).

(vi) A hybrid ORCCL shall have 0.5 excluded for each room meeting the requirements of section of these standards. A surgical facility will not be limited to the number of hybrid ORCCLS within a single licensed facility.

(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).

(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 to initiate a surgical service

Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not offered surgical services within the 12-month period immediately preceding the date an application is submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the following, as applicable to the proposed project.

(1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation.

(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) 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 to replace a surgical service

Sec. 5. To 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 operated by an applicant at the same site as the operating room(s) to be replaced. This also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes relocating an existing surgical facility or one or more operating rooms to a new geographic location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services. The term does not include the renovation of an existing surgical service or one or more operating rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant proposing to replace shall demonstrate:

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

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room 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, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,125 hours of use in a 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.

(3) 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.

(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 an 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).

(6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(a) The proposed new site 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 metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or micropolitan statistical area county.

(b) 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:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room 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.)

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

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,125 hours of use in a 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.)

(7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.

(8) 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 or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation,.

(9) 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), (2), (6), and (8).

Section 6. Requirements to expand an existing surgical service

Sec. 6. To 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. An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following as applicable, to the proposed project.

(1) An applicant shall demonstrate the following:

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

(i) 1,216 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room 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 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to 438/1,750 + 985/1,313 = 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 1,750 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases would equate to 438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00 OR.)

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

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, 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 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 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 ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 979 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,400 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, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation.

(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.

(4) 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 subsections (1) and (2).

Section 7. Requirements to acquire an existing surgical service

Sec. 7. 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. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

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

(2) For the first application proposing to acquire an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in compliance with the applicable volume requirements set forth in these standards. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition.

(3) For any application proposing to acquire an existing surgical service except the first application, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall be required to be in compliance with the applicable volume requirements on the date the application is submitted to the Department.

(4) Subsection (3) 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 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)

Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current con review standards for open heart surgery services.

(2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the facility, the applicant is in compliance with Section 6 of these standards.

(3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in compliance with the provisions of Section 5, if applicable.

(4) The applicant meets the applicable requirements of the CON review standards for cardiac catheterization services.

(5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

Section 9. Requirements for Medicaid Participation

Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 10. Project delivery requirements terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(i) The designation of ORs as defined by the standards shall not be changed without prior notification to the Department.

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

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

(iv) 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.

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

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

(vii) 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.

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

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

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

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

(xii) 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.

(B) For purposes of evaluating subsection (A), 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.

(C) 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) Compliance with the following access to care requirements:

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

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

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

(d) 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.

(e) 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.

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

(a) Existing operating rooms shall perform an average of at least:

(i) 1,042 surgical cases per year per operating room verifiable by the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room verifiable by the Department, or

(iii) Be in compliance using the applicable weighted averages under Section 5.

(b) Existing operating rooms, located in a rural or micropolitan county, or within 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 in a surgical service that has three, four, or five OR'S shall perform an average of at least:

(i) 839 surgical cases per year per operating room verifiable by the Department or

(ii) 1,200 hours of use per year per operating room verifiable by the Department.

(c) The applicant shall participate in a data collection System 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.

(d) The surgical service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

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

Section 11. Documentation of projections

Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume projections were developed and shall include only those surgical cases performed in an OR.

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

(2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical cases, or hours of use, performed at 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 continue to be in compliance with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation, expansion, or replacement 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 replacement 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 12. Effect on prior CON review standards; comparative reviews

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

APPENDIX A

CON REVIEW STANDARDS FOR SURGICAL SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget