MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR
NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, ~~relocation,~~ or acquisition ~~replacement~~ of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. FURTHER, THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL OF THE INITIATION OR ACQUISITION OF SPECIAL CARE NURSERY (SCN) SERVICES. Pursuant to Part 222 of the Code, neonatal intensive care services/beds AND SPECIAL NEWBORN NURSING SERVICES ~~is~~ ARE ~~a~~ 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. (1) As used in these standards:

~~(a) "Acquisition of a NICU" means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.~~

~~(b~~a) ~~"Bassinet" means an unlicensed bassinet in the obstetrical or newborn service that provides care for the uncomplicated newborn.~~

~~(c~~ba) "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~~b) "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~~c) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

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

(~~g~~e) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.

(~~h~~f) "Existing NICU beds" means the total number of all of the following:

(i) licensed hospital beds designated for NICU services;

(ii) NICU beds with valid CON approval but not yet licensed or designated;

(ii) NICU beds under appeal from a final decision of the Department; and

(iii) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision. ~~The term includes those beds designated by the Department as special newborn nursery unit (SNNU) beds.~~

~~(h) "Expansion of NICU services" means increasing the number of hospital beds designated for NICU services at a licensed site.~~

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

~~(j) "Initiation of NICU services" means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a~~

~~NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.~~

(~~l~~h) "Infant" means an individual up to 1 year of age.

(~~m~~i) "Licensed site" means 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 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.

(~~n~~j) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(~~o~~k) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(~~p~~l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6 and1396r-8~~ to ~~1396v~~1396w-5.

~~(q) "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.~~

~~(r) "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.~~

(~~s~~m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, AND/OR LESS THAN 32 WEEKS GESTATION;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) TOTAL parenteral nutrition.

(~~t~~n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include UNLICENSED SCN BEDS ~~bassinets or special newborn care bassinets~~.

(~~u~~o) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(~~v~~p) "Neonate" means an individual up to 28 days of age.

(~~w~~q) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(~~x~~r) "Planning area" means the groups of counties shown in ~~Section 12~~APPENDIX B.

(~~y~~s) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

(~~z~~t) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of 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.

(~~aa~~u) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

~~(bb) "Replacement of NICU beds" means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.~~

~~(cc) "Replacement zone" means a proposed licensed site which is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.~~

(~~dd~~v) "Special ~~newborn~~ care NURSERY ~~bassinet~~SERVICES" OR "SCN SERVICES" means ~~an unlicensed bassinet identified within the hospital obstetrical or newborn service which provides~~ PROVISIONS OF the services identified in subsections (i) through (v~~i~~) for infants WITH PROBLEMS THAT ARE EXPECTED TO RESOLVE RAPIDLY AND who WOULD NOT BE ANTICIPATED TO NEED SUBSPECIALTY SERVICES ON AN URGENT BASIS ~~require minimal care that goes beyond that of the uncomplicated newborn, or transitional care or developmental maturation in preparation for discharge home~~. REFERRAL TO A HIGHER LEVEL OF CARE SHOULD OCCUR FOR ALL INFANTS WHO NEED PEDIATRIC SURGICAL OR MEDICAL SUBSPECIALTY INTERVENTION. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. FOR PURPOSES OF THESE STANDARDS, SCN SERVICES ARE SPECIAL NEWBORN NURSING SERVICES.

(i) Care for low birth weight infants ~~between~~ weighing 1,500 ~~and 2,499~~ grams or more~~;~~ AND/OR GREATER THAN OR EQUAL TO 32 WEEKS GESTATION;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

~~(iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;~~

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v~~i~~) ~~the administration of oxygen by hood or nasal canula~~PROVIDE MECHANICAL VENTILATION ~~FOR BRIEF DURATION (LESS THAN 24 HOURS)~~ OR CONTINUOUS POSITIVE AIRWAY PRESSURE OR BOTH FOR A BRIEF DURATION (NOT TO EXCEED 24 HOURS COMBINED).

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

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

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements ~~for applicants proposing~~ to initiate NICU services

Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(~~1~~a) There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(~~2~~b) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(~~3~~c) A unit of at least 15 beds will be developed and operated.

(~~4~~d) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements ~~for applicants proposing~~ to ~~expand~~ REPLACE NICU services

Sec. 5. Replacement of NICU beds means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.~~replacement zone~~.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section ~~5~~7(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

~~Sec. 5. (1) An applicant proposing to expand NICU services by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.~~

~~(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:~~

~~(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.~~

~~(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.~~

~~(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 √ADC. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.~~

~~**Section 6. Requirements for approval to relocate NICU beds**~~

~~Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:~~

~~(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.~~

~~(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.~~

~~(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.~~

~~(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.~~

~~(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.~~

~~(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.~~

~~(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:~~

~~(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~

~~(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.~~

~~(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:~~

~~(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~

~~(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.~~

~~(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.~~

~~(10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.~~

Section 7. ~~Requirements for approval for replacement of NICU beds~~ REQUIREMENTS FOR APPROVAL TO EXPAND NICU SERVICES

Sec. 7. (1) An applicant proposing to expand NICU services AT A LICENSED SITE by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 √ADC. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.

~~Sec. 7. (1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:~~

~~(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and~~

~~(b) the proposed licensed site is in the replacement zone.~~

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

(1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

SECTION 9. REQUIREMENTS TO INITIATE, ACQUIRE, OR REPLACE, SCN SERVICES

SEC. 9. AN APPLICANT PROPOSING SCN SERVICES SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE, BY VERIFIABLE DOCUMENTATION:

(1) ALL APPLICANTS SHALL DEMONSTRATE THE FOLLOWING:

(a) A BOARD CERTIFIED NEONATOLOGIST SERVING AS THE PROGRAM DIRECTOR

(b) THE HOSPITAL HAS THE FOLLOWING CAPABILITIES AND PERSONNEL CONTINUOSLY AVAILABLE AND ON-SITE:

(i) THE ABILITY TO PROVIDE MECHANICAL VENTILATION AND/OR CONTINUOUS POSITIVE AIRWAY PRESSURE FOR UP TO 24 HOURS;

(ii) PORTABLE X-RAY EQUIPMENT AND BLOOD GAS ANALYZER;

(iii) PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE PRACTITIONERS; AND

(iv) RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, LABORATORY TECHNICIANS AND SPECIALIZED NURSES WITH EXPERIENCE CARING FOR PREMATURE INFANTS.

(2) INITIATION OF SCN SERVICES MEANS THE ESTABLISHMENT OF AN SCN AT A LICENSED SITE THAT HAS NOT HAD IN THE PREVIOUS 12 MONTHS A DESIGNATED SCN OR DOES NOT HAVE A VALID CON TO INITIATE AN SCN.

(a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING TO INITIATE AN SCN SERVICE SHALL HAVE A WRITTEN CONSULTING AGREEMENT WITH A HOSPITAL WHICH HAS AN EXISTING, OPERATIONAL NICU. THE AGREEMENT MUST SPECIFY THAT THE EXISTING SERVICE SHALL, FOR THE FIRST TWO YEARS OF OPERATION OF THE NEW SERVICE, PROVIDE THE FOLLOWING SERVICES TO THE APPLICANT HOSPITAL:

(i) RECEIVE AND MAKE RECOMMENDATIONS ON THE PROPOSED DESIGN OF SCN AND SUPPORT AREAS THAT MAY BE REQUIRED;

(ii) PROVIDE STAFF TRAINING RECOMMENDATIONS FOR ALL PERSONNEL ASSOCIATED WITH THE NEW PROPOSED SERVICE;

(iii) ASSIST IN DEVELOPING APPROPRIATE PROTOCOLS FOR THE CARE AND TRANSFER, IF NECESSARY, OF PREMATURE INFANTS;

(iv) PROVIDE RECOMMENDATIONS ON STAFFING NEEDS FOR THE PROPOSED SERVICE; AND

(v) WORK WITH THE MEDICAL STAFF AND GOVERNING BODY TO DESIGN AND IMPLEMENT A PROCESS THAT WILL ANNUALLY MEASURE, EVALUATE, AND REPORT TO THE MEDICAL STAFF AND GOVERNING BODY THE CLINICAL OUTCOMES OF THE NEW SERVICE, INCLUDING:

(A) MORTALITY RATES;

(B) MORBIDITY RATES INCLUDING INTRAVENTRICULAR HEMORRHAGE (GRADE 3 AND 4), RETINOPATHY OF PREMATURITY (STAGE 3 AND 4), CHRONIC LUNG DISEASE (OXYGEN DEPENDENCY AT 36 WEEKS GESTATION), NECROTIZING ENTEROCOLITIS, PNEUMOTHORAX, NEONATAL DEPRESSION (APGAR SCORE OF LESS THAN 5 AT FIVE MINUTES); AND

(C) INFECTION RATES.

(b) SCN SERVICES SHALL BE PROVIDED IN UNLICENSED SCN BEDS LOCATEDWITHIN THE HOSPITAL OBSTETRICAL DEPARTMENT OR NICU SERVICE. UNLICENSED SCN BEDS ARE NOT INCLUDED IN THE NICU BED NEED.

(3) REPLACEMENT OF SCN SERVICES MEANS NEW PHYSICAL PLANT SPACE BEING DEVELOPED THROUGH NEW CONSTRUCTION OR NEWLY ACQUIRED SPACE (PURCHASE, LEASE OR DONATION), TO HOUSE AN EXISTING SCN SERVICE.

(a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING A REPLACEMENT SCN SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(i) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO REPLACE THE ENTIRE HOSPITAL.

(ii) THE APPLICANT CURRENTLY OPERATES THE SCN SERVICE AT THE CURRENT LICENSED SITE.

(iii) THE PROPOSED LICENSED SITE IS IN THE SAME PLANNING AREA AS THE EXISTING LICENSED SITE.

(4) ACQUISITION OF AN SCN SERVICE MEANS OBTAINING POSSESSION AND CONTROL OF AN EXISTING SCN SERVICE BY CONTRACT, OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT.

(~~i~~a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING TO ACQUIRE AN SCN SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(~~ii~~i) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO ACQUIRE THE ENTIRE HOSPITAL.

(~~iii~~ii) THE LICENSED SITE DOES NOT CHANGE AS A RESULT OF THE ACQUISITION, UNLESS THE APPLICANT MEETS SUBSECTION 3.

Section ~~9~~10. Additional requirements for applications included in comparative reviews.

Sec. 10~~9~~. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(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(1) 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), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded
Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

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

Section ~~10~~11. Requirements for ~~approval for all applicants~~MEDICAID PARTICIPATION

Sec. ~~10~~11. An applicant for NICU SERVICES AND SCN SERVICES 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 ~~11~~12. Project delivery requirements ~~--~~ AND terms of approval ~~for all applicants~~

Sec. ~~11~~12. ~~(1)~~ An applicant shall agree that, if approved, the ~~project~~ NICU AND SCN SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable operating standards.~~

(~~c~~2) Compliance with the following applicable quality assurance standards FOR NICU SERVICES:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(c) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.

(d) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(e) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(f) An applicant shall develop and implement a system for discharge planning.

(g) A board certified neonatologist shall serve as the director of neonatal services.

(h) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.

(i) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(j) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(3) COMPLIANCE WITH THE FOLLOWING APPLICABLE QUALITY ASSURANCE FOR SCN SERVICES:

(a) AN APPLICANT SHALL COORDINATE ITS SERVICES WITH OTHER PROVIDERS OF OBSTETRICAL, PERINATAL, NEONATAL AND PEDIATRIC CARE IN ITS PLANNING AREA, AND OTHER PLANNING AREAS IN THE CASE OF HIGHLY SPECIALIZED SERVICES.

(b) AN APPLICANT SHALL DEVELOP AND IMPLEMENT A SYSTEM FOR DISCHARGE PLANNING.

(c) A BOARD CERTIFIED NEONATOLOGIST SHALL SERVE AS THE SCN PROGRAM DIRECTOR.

(d) THE HOSPITAL CONTINUES TO HAVE THE FOLLOWING CAPABILITIES AND PERSONNEL CONTINUOSLY AVAILABLE AND ON-SITE:

(i) THE ABILITY TO PROVIDE MECHANICAL VENTILATION AND/OR CONTINUOUS POSITIVE AIRWAY PRESSURE FOR UP TO 24 HOURS.

(ii) PORTABLE X-RAY EQUIPMENT AND BLOOD GAS ANALYZER;

(iii) PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE PRACTITIONERS; AND

(iv) RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, LABORATORY TECHNICIANS AND SPECIALIZED NURSES WITH EXPERIENCE CARING FOR PREMATURE INFANTS.

(~~i~~4) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

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

(~~A~~a) THE NICU AND SCN SERVICES shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(~~B~~b) THE NICU AND SCN SERVICES SHALL not deny NICU and SCN services to any individual based on ability to pay or source of payment.~~;~~

(~~B~~c) THE NICU AND SCN SERVICES SHALL provide NICU and SCN services to any individual based on clinical indications of need for the services.~~;~~

(~~C~~d) THE NICU AND SCN SERVICES SHALL maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(~~E~~e) Compliance with selective contracting requirements shall not be construed as a violation of this term.

~~(ii) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.~~

~~(iii) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.~~

~~(iv) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.~~

~~(v) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.~~

~~(vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.~~

~~(vii) An applicant shall develop and implement a system for discharge planning.~~

~~(viii) A board certified neonatologist shall serve as the director of neonatal services.~~

~~(ix) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.~~

~~(x) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.~~

~~(xi) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.~~

(5) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(~~xii~~a) The ~~applicant~~ NICU AND SCN SERVICES 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, 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.

(i) THE SCN SERVICES SHALL PROVIDE DATA FOR THE PERCENTAGE OF TRANSFERS TO A HIGHER LEVEL OF CARE, HOURS OF LIFE AT THE TIME OF TRANSFER TO A HIGHER LEVEL OF CARE, ADMISSIONS TO THE SCN AT LESS THAN 32 WEEKS GESTATION, NUMBER OF ADMISSIONS REQUIRING RESPIRATORY SUPPORT GREATER THAN 24 HOURS IN DURATION, NUMBER OF ADMISSIONS TO SCN, AND RATES OF MORBIDITY INCLUDING: INTRAVENTRICULAR HEMORRHAGE (GRADE 3 AND 4), RETINOPATHY OF PREMATURITY (STAGE 3 AND 4), CHRONIC LUNG DISEASE (OXYGEN DEPENDENCY AT 36 WEEKS GESTATION), NECROTIZING ENTEROCOLITIS, AND PNEUMOTHORAX.

(~~xiii~~b) The ~~applicant~~ NICU AND SCN SERVICES shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

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

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

~~**Section 12. Planning areas**~~

~~Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:~~

~~**Planning Areas** **Counties**~~

~~1 Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne~~

~~2 Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee~~

~~3 Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren~~

~~4 Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa~~

~~5 Genesee, Lapeer, Shiawassee~~

~~6 Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola~~

~~7 Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford~~

~~8 Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft~~

Section 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care ~~and Special Newborn Nursery~~ Services/Beds approved by the Commission on ~~September 18, 2007~~ JUNE 10, 2010 and effective on ~~November 13, 2007~~AUGUST 12, 2010.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section ~~5~~7(2).

(d) SCN SERVICES REQUESTED UNDER SECTION 9.

APPENDIX A

CON REVIEW STANDARDS
FOR NEONATAL INTENSIVE CARE SERVICES/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 B

The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:

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