

1 MICHIGAN DEPARTMENT OF ~~COMMUNITY HEALTH~~ AND HUMAN SERVICES

2  
3 CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR  
4 NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES  
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of  
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)  
9

10 **Section 1. Applicability**

11  
12 Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement,  
13 relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal  
14 intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for  
15 the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222 of  
16 the Code, neonatal intensive care services/beds and special newborn nursing services are covered  
17 clinical services. The Department shall use these standards in applying Section 22225(1) of the Code,  
18 being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being  
19 Section 333.22225(2)(c) of the Michigan Compiled Laws.  
20

21 **Section 2. Definitions**

22  
23 Sec. 2. (1) As used in these standards:

24  
25 (a) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
26 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

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

32 (d) "Department" means the Michigan Department of ~~Community Health~~ AND HUMAN SERVICES  
33 (MDCHMDHHS).

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

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

38 (i) licensed hospital beds designated for NICU services;

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

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

41 (iii) proposed NICU beds that are part of an application for which a proposed decision has been  
42 issued, but is pending final Department decision.

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

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

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

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

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

- 54 (l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.
- 55 (m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following
- 56 services:
- 57 (i) constant nursing care and continuous cardiopulmonary and other support services for severely ill
- 58 infants;
- 59 (ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;
- 60 (iii) ventilatory support beyond that needed for immediate ventilatory stabilization;
- 61 (iv) surgery and post-operative care during the neonatal period;
- 62 (v) pharmacologic stabilization of heart rate and blood pressure; or
- 63 (vi) total parenteral nutrition.
- 64 (n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of
- 65 a hospital which is both capable of providing neonatal intensive care services and is composed of licensed
- 66 hospital beds designated as NICU. This term does not include unlicensed SCN beds.
- 67 (o) "Neonatal transport system" means a specialized transfer program for neonates by means of an
- 68 ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.
- 69 (p) "Neonate" means an individual up to 28 days of age.
- 70 (q) "Perinatal care network," means the providers and facilities within a planning area that provide
- 71 basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.
- 72 (r) "Planning area" means the groups of counties shown in Appendix B.
- 73 (s) "Planning year" means the most recent continuous 12 month period for which birth data is
- 74 available from the Vital Records and Health Data Development Section.
- 75 (t) "Qualifying project" means each application in a comparative group which has been reviewed
- 76 individually and has been determined by the Department to have satisfied all of the requirements of
- 77 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
- 78 applicable requirements for approval in the Code and these standards.
- 79 (u) "Relocation of the designation of beds for NICU services" means a change within the same
- 80 planning area in the licensed site at which existing licensed hospital beds are designated for NICU
- 81 services.
- 82 (v) "Special care nursery services" or "SCN services" means provisions of ~~the services identified in~~
- 83 ~~subsections (i) through (v)~~ for infants with problems that are expected to resolve rapidly and who would
- 84 not be anticipated to need subspecialty services on an urgent basis. THESE SERVICES INCLUDE:
- 85 (i) Care for low birth weight infants BORN greater than or equal to 32 weeks gestation AND/OR
- 86 weighing GREATER THAN OR EQUAL TO 1,500grams or more and/or greater than or equal to 32 weeks
- 87 gestation;
- 88 (ii) enteral tube feedings;
- 89 (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
- 90 (iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring
- 91 ventilatory support; or
- 92 (v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration
- 93 (not to exceed 24 hours combined).
- 94
- 95 Referral to a higher level of care should occur for all infants who need pediatric surgical or medical
- 96 subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation
- 97 may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital.
- 98 For purposes of these standards, SCN services are special newborn nursing services.
- 99 ~~(i) Care for low birth weight infants weighing 1,500grams or more and/or greater than or equal to 32~~
- 100 ~~weeks gestation;~~
- 101 ~~(ii) enteral tube feedings;~~
- 102 ~~(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;~~
- 103 ~~(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring~~
- 104 ~~ventilatory support; or~~
- 105 ~~(v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration~~
- 106 ~~(not to exceed 24 hours combined).~~

107 (w) "WELL NEWBORN NURSERY SERVICES" MEANS PROVIDING THE FOLLOWING SERVICES  
108 AND DOES NOT REQUIRE A CERTIFICATE OF NEED:

- 109 (i) THE CAPABILITY TO PERFORM NEONATAL RESUSCITATION AT EVERY DELIVERY;  
110 (ii) EVALUATE AND PROVIDE POSTNATAL CARE FOR STABLE TERM NEWBORN INFANTS;  
111 (iii) STABILIZE AND PROVIDE CARE FOR INFANTS BORN AT 35 TO 37 WEEKS' GESTATION  
112 WHO REMAIN PHYSIOLOGICALLY STABLE; AND  
113 (iv) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN 35 WEEKS  
114 OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.

115 (2) The definitions in Part 222 shall apply to these standards.  
116

### 117 **Section 3. Bed need methodology**

118  
119 Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following  
120 formula:

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

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

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

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

131 (e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for  
132 the applicable planning area adjusted for the very low birth weight adjustment factor as determined in  
133 subsection (1)(d).  
134

135 (2) The result of subsection (1) is the number of NICU beds needed in the planning area for the  
136 planning year.  
137

### 138 **Section 4. Requirements to initiate NICU services**

139  
140 Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not  
141 had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a  
142 NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of  
143 Section 6 shall not be considered as the initiation of NICU services/beds.  
144

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

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

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

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

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

160  
161 **Section 5. Requirements to replace NICU services**  
162

163 Sec. 5. Replacement of NICU beds means new physical plant space being developed through new  
164 construction or newly acquired space (purchase, lease or donation), to house existing licensed and  
165 designated NICU beds.  
166

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

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

173 (b) the proposed licensed site is in the same planning area as the existing licensed site and in the  
174 area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in  
175 which replacement beds in a hospital are not subject to comparative review.  
176

177 **Section 6. Requirements for approval to relocate NICU beds**  
178

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

181 (1) The applicant is the licensed site to which the relocation of the designation of beds for NICU  
182 services is proposed.  
183

184 (2) The applicant shall provide a signed written agreement that provides for the proposed increase,  
185 and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites  
186 involved in the proposed relocation. A copy of the agreement shall be provided in the application.  
187

188 (3) The existing licensed site from which the designation of beds for NICU services proposed to be  
189 relocated is currently licensed and designated for NICU services.  
190

191 (4) The proposed project does not result in an increase in the number of beds designated for NICU  
192 services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.  
193

194 (5) The proposed project does not result in an increase in the number of licensed hospital beds at the  
195 applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital  
196 Beds have also been met.  
197

198 (6) The proposed project does not result in the operation of a NICU of less than 15 beds at the  
199 existing licensed site from which the designation of beds for NICU services are proposed to be relocated.  
200

201 (7) If the applicant licensed site does not currently provide NICU services, an applicant shall  
202 demonstrate both of the following:  
203

204 (a) the proposed project involves the establishment of a NICU of at least 15 beds; and  
205 (b) for each of the 3 most recent years for which birth data are available from the Vital Records and  
206 Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the  
207 licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the  
208 licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles  
209 from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If  
210 the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the  
211 applicant licensed site was established as the result of the consolidation and closure of 2 or more  
212 obstetrical units, the combined number of live births from the obstetrical units that were closed and

213 relocated to the applicant licensed site may be used to evaluate compliance with this requirement for  
214 those years when the applicant licensed site was not in operation.

215  
216 (8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an  
217 applicant shall demonstrate both of the following:

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

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

227  
228 (9) The project results in a decrease in the number of licensed hospital beds that are designated for  
229 NICU services at the licensed site at which beds are currently designated for NICU services. The  
230 decrease in the number of beds designated for NICU services shall be equal to or greater than the  
231 number of beds designated for NICU services proposed to be increased at the applicant's licensed site  
232 pursuant to the agreement required by this subsection. This subsection requires a decrease in the  
233 number of licensed hospital beds that are designated for NICU services, but does not require a decrease  
234 in the number of licensed hospital beds.

235  
236 (10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the  
237 proposed project involves the relocation of all beds designated for NICU services at the applicant's  
238 licensed site.

239

## 240 **Section 7. Requirements for approval to expand NICU services**

241

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

247

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

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

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

259 (c) Apply the ADC determined in accordance with subsection (b) in the following formula:  $ADC +$   
260  $2.06 \sqrt{ADC}$ . The result is the maximum number of beds that may be approved pursuant to this subsection  
261 [up to 5 beds at each licensed site.](#)

262

## 263 **Section 8. Requirements for approval to acquire a NICU service**

264

265 Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital  
266 beds designated for NICU services by contract, ownership, lease or other comparable arrangement.  
267

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

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

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

276 (c) the project does not involve the initiation, expansion or replacement of a covered clinical service,  
277 a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the  
278 applicant facility, unless the applicant meets other applicable sections.  
279

### 280 **Section 9. Requirements to initiate, acquire, or replace SCN services** 281

282 Sec. 9. An applicant proposing SCN services shall demonstrate each of the following, as applicable,  
283 by verifiable documentation:  
284

285 (1) All applicants shall demonstrate the following:

286 (a) A board certified neonatologist serving as the program director.

287 (b) The hospital has the following capabilities and personnel continuously available and on-site:

288 (i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to  
289 24 hours;

290 (ii) portable x-ray equipment and blood gas analyzer;

291 (iii) pediatric physicians and/or neonatal nurse practitioners; and

292 (iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with  
293 experience caring for premature infants.  
294

295 (2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had  
296 in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.

297 (a) In addition to the requirements of Section 9(1), an applicant proposing to initiate an SCN service  
298 shall have a written consulting agreement with a hospital which has an existing, operational NICU. The  
299 agreement must specify that the existing service shall, for the first two years of operation of the new  
300 service, provide the following services to the applicant hospital:

301 (i) receive and make recommendations on the proposed design of SCN and support areas that may  
302 be required;

303 (ii) provide staff training recommendations for all personnel associated with the new proposed  
304 service;

305 (iii) assist in developing appropriate protocols for the care and transfer, if necessary, of premature  
306 infants;

307 (iv) provide recommendations on staffing needs for the proposed service; and

308 (v) work with the medical staff and governing body to design and implement a process that will  
309 annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of  
310 the new service, including:

311 (A) mortality rates;

312 (B) morbidity rates including intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity  
313 (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing  
314 enterocolitis, pneumothorax, neonatal depression (apgar score of less than 5 at five minutes); and

315 (C) infection rates.

316 (b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical  
317 department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.

318  
 319 (3) Replacement of SCN services means new physical plant space being developed through new  
 320 construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.  
 321 (a) In addition to the requirements of Section 9(1), an applicant proposing a replacement SCN service  
 322 shall demonstrate all of the following:  
 323 (i) The proposed project is part of an application to replace the entire hospital.  
 324 (ii) The applicant currently operates the SCN service at the current licensed site.  
 325 (iii) The proposed licensed site is in the same planning area as the existing licensed site.  
 326

327 (4) Acquisition of an SCN service means obtaining possession and control of an existing SCN service  
 328 by contract, ownership, lease or other comparable arrangement.

329 (a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service  
 330 shall demonstrate all of the following:  
 331 (i) The proposed project is part of an application to acquire the entire hospital.  
 332 (ii) The licensed site does not change as a result of the acquisition, unless the applicant meets  
 333 subsection 3.  
 334

335 **Section 10. Additional requirements for applications included in comparative reviews.**  
 336

337 Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being  
 338 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and  
 339 reviewed comparatively with other applications in accordance with the CON rules.  
 340

341 (2) Each application in a comparative review group shall be individually reviewed to determine  
 342 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section  
 343 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the  
 344 Code and these standards. If the Department determines that one or more of the competing applications  
 345 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The  
 346 Department shall approve those qualifying projects which, taken together, do not exceed the need, as  
 347 defined in Section 22225(1), and which have the highest number of points when the results of subsection  
 348 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the  
 349 Department shall approve those qualifying projects which, taken together, do not exceed the need, as  
 350 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an  
 351 application is submitted to the Department. If 2 or more qualifying projects are determined to have an  
 352 identical number of points and each operates a NICU at the time an application is submitted to the  
 353 Department, the Department shall approve those qualifying projects which, taken together, do not exceed  
 354 the need, as defined in Section 22225(1), in the order in which the applications were received by the  
 355 Department, based on the submission date and time, as determined by the Department when submitted.  
 356

357 (a) A qualifying project will have points awarded based on the geographic proximity to NICU services,  
 358 both operating and CON approved but not yet operational, in accordance with the following schedule:  
 359

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

369

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

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

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

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

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

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

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

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

396

397	Hospital	
398	Indigent	Points
399	<u>Volume</u>	<u>Awarded</u>
400		
401	0 - <6%	0.2
402	6 - <11%	0.4
403	11 - <16%	0.6
404	16 - <21%	0.8
405	21 - <26%	1.0
406	26 - <31%	1.2
407	31 - <36%	1.4
408	36 - <41%	1.6
409	41 - <46%	1.8
410	46% +	2.0

411

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

417

418 (3) Submission of conflicting information in this section may result in a lower point reward. If an  
419 application contains conflicting information which could result in a different point value being awarded in  
420 this section, the Department will award points based on the lower point value that could be awarded from  
421 conflicting information. For example, if submitted information would result in 6 points being awarded, but  
422 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the



423 conflicting information does not affect the point value, the Department will award points accordingly. For  
424 example, if submitted information would result in 12 points being awarded and other conflicting information  
425 would also result in 12 points being awarded, then 12 points will be awarded.

426

### 427 **Section 11. Requirements for Medicaid participation**

428

429 Sec. 11. An applicant for NICU services and SCN services shall provide verification of Medicaid  
430 participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof  
431 of Medicaid participation will be provided to the Department within six (6) months from the offering of  
432 services if a CON is approved.

433

### 434 **Section 12. Project delivery requirements and terms of approval**

435

436 Sec. 12. An applicant shall agree that, if approved, the NICU and SCN services shall be delivered in  
437 compliance with the following terms of approval:

438 (1) Compliance with these standards.

439

440 (2) Compliance with the following applicable quality assurance standards for NICU services:

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

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

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

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

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

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

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

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

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

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

463

464 (3) Compliance with the following applicable quality assurance standards for SCN services:

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

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

468 (c) A board certified neonatologist shall serve as the SCN program director.

469 (d) The hospital continues to have the following capabilities and personnel continuously available and  
470 on-site:

471 (i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to  
472 24 hours;

473 (ii) portable x-ray equipment and blood gas analyzer;

474 (iii) pediatric physicians and/or neonatal nurse practitioners; and

475 (iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with  
476 experience caring for premature infants.

477

478 (4) Compliance with the following access to care requirements:

479 (a) The NICU and SCN services shall participate in Medicaid at least 12 consecutive months within  
480 the first two years of operation and continue to participate annually thereafter.

481 (b) The NICU and SCN services shall not deny NICU and SCN services to any individual based on  
482 ability to pay or source of payment.

483 (c) The NICU and SCN services shall provide NICU and SCN services to any individual based on  
484 clinical indications of need for the services.

485 (d) The NICU and SCN services shall maintain information by payor and non-paying sources to  
486 indicate the volume of care from each source provided annually.

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

489

490 (5) Compliance with the following monitoring and reporting requirements:

491 (a) The NICU and SCN services shall participate in a data collection network established and  
492 administered by the Department or its designee. The data may include, but is not limited to, annual  
493 budget and cost information, operating schedules, through-put schedules, and demographic, diagnostic,  
494 morbidity and mortality information, as well as the volume of care provided to patients from all payor  
495 sources. The applicant shall provide the required data on a separate basis for each licensed site; in a  
496 format established by the Department; and in a mutually agreed upon media. The Department may elect  
497 to verify the data through on-site review of appropriate records.

498 (i) The SCN services shall provide data for the percentage of transfers to a higher level of care,  
499 hours of life at the time of transfer to a higher level of care, admissions to the SCN at less than 32 weeks  
500 gestation, number of admissions requiring respiratory support greater than 24 hours in duration, number  
501 of admissions to SCN, and rates of morbidity including: intraventricular hemorrhage (grade 3 and 4),  
502 retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks  
503 gestation), necrotizing enterocolitis, and pneumothorax.

504 (b) The NICU and SCN services shall provide the Department with timely notice of the proposed  
505 project implementation consistent with applicable statute and promulgated rules.

506

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

509

### 510 **Section 13. Department inventory of beds**

511

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

514

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

516

517 Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for  
518 Neonatal Intensive Care Services/Beds approved by the Commission on [December 12,](#)  
519 [2013SEPTEMBER 25, 2014](#) and effective on [March 3, 2014DECEMBER 22, 2014](#).

520

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

522 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section  
523 333.22229(3) of the Michigan Compiled Laws;

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

526 (c) Beds requested under Section 7(2).

527 (d) SCN services requested under Section 9.

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget

**APPENDIX B**

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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   |