

1 MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

2
3 CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR
4 **NEONATAL INTENSIVE CARE SERVICES/BEDS (NICU) AND SPECIAL NEWBORN NURSING**
5 **SERVICES**
6

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

10
11 **Section 1. Applicability**
12

13 Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement,
14 relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal
15 intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for
16 the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222
17 of the Code, neonatal intensive care services/beds and special newborn nursing services are covered
18 clinical services. The Department shall use these standards in applying Section 22225(1) of the Code,
19 being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being
20 Section 333.22225(2)(c) of the Michigan Compiled Laws.
21

22 **Section 2. Definitions**
23

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

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

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

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

33 (d) "Department" means the Michigan Department of Health and Human Services (MDHHS).

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 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
- 65 of a hospital which is both capable of providing neonatal intensive care services and is composed of
- 66 licensed 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~~ 12-month period for which birth data
- 74 is 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 services for infants with
- 83 problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty
- 84 services on an urgent basis. These services include:
- 85 (i) Care for infants born greater than or equal to 32 weeks gestation and/or weighing greater than or
- 86 equal to 1,500grams;
- 87 (ii) enteral tube feedings;
- 88 (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
- 89 (iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring
- 90 ventilatory support; ~~or~~
- 91 (v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration
- 92 (not to exceed 24 hours combined); OR
- 93 (vi) PROVIDE PHARMACOLOGIC INTERVENTION AND MONITORING FOR NEONATAL
- 94 ABSTINENCE SYNDROME (NAS) INFANTS.
- 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
- 97 maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or
- 98 another hospital. For purposes of these standards, SCN services are special newborn nursing services.
- 99 (w) "Well newborn nursery services" means providing the following services and does not require a
- 100 certificate of need:
- 101 (i) the capability to perform neonatal resuscitation at every delivery;
- 102 (ii) evaluate and provide postnatal care for stable term newborn infants;
- 103 (iii) stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically
- 104 stable; and
- 105 (iv) stabilize newborn infants who are ill and those born less than 35 weeks of gestation until they can
- 106 be transferred to a higher level of care facility.

107
108 (2) The definitions in Part 222 shall apply to these standards.
109

110 **Section 3. Bed need methodology** 111

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

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

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

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

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

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

127
128 (2) The result of subsection (1) is the number of NICU beds needed in the planning area for the
129 planning year.
130

131 **Section 4. Requirements to initiate NICU services** 132

133 Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not
134 had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a
135 NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements
136 of Section 6 shall not be considered as the initiation of NICU services/beds.
137

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

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

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

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

147 (d) For each of the 3 most recent years for which birth data are available from the Vital Records and
148 Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or
149 more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more
150 live births, if the licensed site is located in a rural or micropolitan statistical area county and is located
151 more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON
152 approval to operate NICU services.
153

154 **Section 5. Requirements to replace NICU services** 155

156 Sec. 5. Replacement of NICU beds means new physical plant space being developed through new
157 construction or newly acquired space (purchase, lease or donation), to house existing licensed and
158 designated NICU beds.
159

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

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

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

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

170
171
172 Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate
173 compliance with all of the following:

174
175 (1) The applicant is the licensed site to which the relocation of the designation of beds for NICU
176 services is proposed.

177
178 (2) The applicant shall provide a signed written agreement that provides for the proposed increase,
179 and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites
180 involved in the proposed relocation. A copy of the agreement shall be provided in the application.

181
182 (3) The existing licensed site from which the designation of beds for NICU services proposed to be
183 relocated is currently licensed and designated for NICU services.

184
185 (4) The proposed project does not result in an increase in the number of beds designated for NICU
186 services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

187
188 (5) The proposed project does not result in an increase in the number of licensed hospital beds at the
189 applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital
190 Beds have also been met.

191
192 (6) The proposed project does not result in the operation of a NICU of less than 15 beds at the
193 existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

194
195 (7) If the applicant licensed site does not currently provide NICU services, an applicant shall
196 demonstrate both of the following:

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

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

208
209 (8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an
210 applicant shall demonstrate both of the following:

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

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

220
221 (9) The project results in a decrease in the number of licensed hospital beds that are designated for
222 NICU services at the licensed site at which beds are currently designated for NICU services. The
223 decrease in the number of beds designated for NICU services shall be equal to or greater than the
224 number of beds designated for NICU services proposed to be increased at the applicant's licensed site
225 pursuant to the agreement required by this subsection. This subsection requires a decrease in the
226 number of licensed hospital beds that are designated for NICU services, but services but does not require
227 a decrease in the number of licensed hospital beds.

228
229 (10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the
230 proposed project involves the relocation of all beds designated for NICU services at the applicant's
231 licensed site.

232 233 **Section 7. Requirements for approval to expand NICU services**

234
235 Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating
236 additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase
237 will not result in a surplus of NICU beds based on the difference between the number of existing NICU
238 beds in the planning area and the number of beds needed for the planning year resulting from application
239 of the methodology set forth in Section 3.

240
241 (2) An applicant may apply and be approved for NICU beds in excess of the number determined as
242 needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides
243 NICU services to patients transferred from another licensed and designated NICU. The maximum
244 number of NICU beds that may be approved pursuant to this subsection shall be determined in
245 accordance with the following:

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

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

252 (c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC +$
253 $2.06 \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this
254 subsection.

255 256 **Section 8. Requirements for approval to acquire a NICU service**

257
258 Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital
259 beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

260
261 (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the
262 needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU
263 subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are
264 met:

- 265 (a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds
266 designated for NICU services, at the licensed site to be acquired;
267 (b) the licensed site does not change as a result of the acquisition, unless the applicant meets
268 Section 6; and,
269 (c) the project does not involve the initiation, expansion or replacement of a covered clinical service,
270 a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the
271 applicant facility, unless the applicant meets other applicable sections.
272

273 **Section 9. Requirements to initiate, acquire, or replace SCN services** 274

275 Sec. 9. An applicant proposing SCN services shall demonstrate each of the following, as applicable,
276 by verifiable documentation:
277

278 (1) All applicants shall demonstrate the following:

279 (a) A ~~board-certified~~board-certified neonatologist serving as the program director.

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

281 (i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to
282 24 hours;

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

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

285 (iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with
286 experience caring for premature infants.
287

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

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

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

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

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

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

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

304 (A) mortality rates;

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

308 (C) infection rates.

309 (b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical
310 department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.
311

312 (3) Replacement of SCN services means new physical plant space being developed through new
313 construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.

314 (a) In addition to the requirements of Section 9(1), an applicant proposing a replacement SCN
315 service shall demonstrate all of the following:

316 (i) The proposed project is part of an application to replace the entire hospital.

317 (ii) The applicant currently operates the SCN service at the current licensed site.

- 318 (iii) The proposed licensed site is in the same planning area as the existing licensed site.
- 319
- 320 (4) Acquisition of an SCN service means obtaining possession and control of an existing SCN
- 321 service by contract, ownership, lease or other comparable arrangement.
- 322 (a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service
- 323 shall demonstrate all of the following:
- 324 (i) The proposed project is part of an application to acquire the entire hospital.
- 325 (ii) The licensed site does not change as a result of the acquisition, unless the applicant meets
- 326 subsection 3.
- 327

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

329

330 Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being

331 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and

332 reviewed comparatively with other applications in accordance with the CON rules.

333

334 (2) Each application in a comparative review group shall be individually reviewed to determine

335 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section

336 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the

337 Code and these standards. If the Department determines that one or more of the competing applications

338 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The

339 Department shall approve those qualifying projects which, taken together, do not exceed the need, as

340 defined in Section 22225(1), and which have the highest number of points when the results of subsection

341 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the

342 Department shall approve those qualifying projects which, taken together, do not exceed the need, as

343 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an

344 application is submitted to the Department. If 2 or more qualifying projects are determined to have an

345 identical number of points and each operates a NICU at the time an application is submitted to the

346 Department, the Department shall approve those qualifying projects which, taken together, do not exceed

347 the need, as defined in Section 22225(1), in the order in which the applications were received by the

348 Department, based on the submission date and time, as determined by the Department when submitted.

349 (a) A qualifying project will have points awarded based on the geographic proximity to NICU

350 services, both operating and CON approved but not yet operational, in accordance with the following

351 schedule:

352

<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

364 (b) A qualifying project will have points awarded based on the number of very low birth weight infants

365 delivered at the applicant hospital or the number of very low birth weight infants admitted or refused

366 admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth

367 weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an

368 applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the

369 number of qualifying projects. The number of points to be awarded to each qualifying project shall be

370 calculated as follows:

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

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

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

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

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

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

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

391	Hospital	
392	Indigent	Points
393	<u>Volume</u>	<u>Awarded</u>
394		
395	0 - <6%	0.2
396	6 - <11%	0.4
397	11 - <16%	0.6
398	16 - <21%	0.8
399	21 - <26%	1.0
400	26 - <31%	1.2
401	31 - <36%	1.4
402	36 - <41%	1.6
403	41 - <46%	1.8
404	46% +	2.0
405		

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

411
 412 (3) Submission of conflicting information in this section may result in a lower point reward. If an
 413 application contains conflicting information which could result in a different point value being awarded in
 414 this section, the Department will award points based on the lower point value that could be awarded from
 415 conflicting information. For example, if submitted information would result in 6 points being awarded, but
 416 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the
 417 conflicting information does not affect the point value, the Department will award points accordingly. For
 418 example, if submitted information would result in 12 points being awarded and other conflicting
 419 information would also result in 12 points being awarded, then 12 points will be awarded.

420
 421 **Section 11. Requirements for Medicaid participation**
 422

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

427
428 **Section 12. Project delivery requirements and terms of approval**
429

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

432 (1) Compliance with these standards.

433
434 (2) Compliance with the following applicable quality assurance standards for NICU services:

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

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

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

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

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

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

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

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

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

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

458
459 (3) Compliance with the following applicable quality assurance standards for SCN services:

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

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

464 (c) A ~~board-certified~~board-certified neonatologist shall serve as the SCN program director.

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

467 (i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to
468 24 hours;

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

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

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

473
474 (4) Compliance with the following access to care requirements:

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

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

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

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

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

485

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

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

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

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

502

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

505

506 **Section 13. Department inventory of beds**

507

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

510

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

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513 Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for
514 Neonatal Intensive Care Services/Beds approved by the Commission on September 2521, 2014-2016
515 and effective on December 229, 2014-2016.

516

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

518 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section
519 333.22229(3) of the Michigan Compiled Laws;

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

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

523 (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:

<u>Planning Areas</u>	<u>Counties</u>
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