

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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 (MDCH).

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

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

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

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

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

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

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

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

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

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

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

53 (l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

- 54 (m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following
55 services:
- 56 (i) constant nursing care and continuous cardiopulmonary and other support services for severely ill
57 infants;
 - 58 (ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;
 - 59 (iii) ventilatory support beyond that needed for immediate ventilatory stabilization;
 - 60 (iv) surgery and post-operative care during the neonatal period;
 - 61 (v) pharmacologic stabilization of heart rate and blood pressure; or
 - 62 (vi) total parenteral nutrition.
- 63 (n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of
64 a hospital which is both capable of providing neonatal intensive care services and is composed of licensed
65 hospital beds designated as NICU. This term does not include unlicensed SCN beds.
- 66 (o) "Neonatal transport system" means a specialized transfer program for neonates by means of an
67 ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.
- 68 (p) "Neonate" means an individual up to 28 days of age.
- 69 (q) "Perinatal care network," means the providers and facilities within a planning area that provide
70 basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.
- 71 (r) "Planning area" means the groups of counties shown in Appendix B.
- 72 (s) "Planning year" means the most recent continuous 12 month period for which birth data is
73 available from the Vital Records and Health Data Development Section.
- 74 (t) "Qualifying project" means each application in a comparative group which has been reviewed
75 individually and has been determined by the Department to have satisfied all of the requirements of
76 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
77 applicable requirements for approval in the Code and these standards.
- 78 (u) "Relocation of the designation of beds for NICU services" means a change within the same
79 planning area in the licensed site at which existing licensed hospital beds are designated for NICU
80 services.
- 81 (v) "Special care nursery services" or "SCN services" means provisions of the services identified in
82 subsections (i) through (v) for infants with problems that are expected to resolve rapidly and who would
83 not be anticipated to need subspecialty services on an urgent basis. Referral to a higher level of care
84 should occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants
85 receiving transitional care or being treated for developmental maturation may have formerly been treated
86 in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these
87 standards, SCN services are special newborn nursing services.
- 88 (i) Care for low birth weight infants weighing 1,500grams or more and/or greater than or equal to 32
89 weeks gestation;
 - 90 (ii) enteral tube feedings;
 - 91 (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
 - 92 (iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring
93 ventilatory support; or
 - 94 (v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration
95 (not to exceed 24 hours combined).
- 96
- 97 (2) The definitions in Part 222 shall apply to these standards.
- 98

99 **Section 3. Bed need methodology**

100

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

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

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

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

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

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

116
117 (2) The result of subsection (1) is the number of NICU beds needed in the planning area for the
118 planning year.

119 120 **Section 4. Requirements to initiate NICU services**

121
122 Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not
123 had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a
124 NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of
125 Section 6 shall not be considered as the initiation of NICU services/beds.

126
127 (1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall
128 demonstrate each of the following:

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

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

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

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

142 143 **Section 5. Requirements to REPLACE NICU services**

144
145 Sec. 5. Replacement of NICU beds means new physical plant space being developed through new
146 construction or newly acquired space (purchase, lease or donation), to house existing licensed and
147 designated NICU beds.

148
149 (1) An applicant proposing replacement beds shall not be required to be in compliance with the
150 needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the
151 following:

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

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

159 **Section 6. Requirements for approval to relocate NICU beds**
160

161 Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate
162 compliance with all of the following:
163

164 (1) The applicant is the licensed site to which the relocation of the designation of beds for NICU
165 services is proposed.
166

167 (2) The applicant shall provide a signed written agreement that provides for the proposed increase,
168 and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites
169 involved in the proposed relocation. A copy of the agreement shall be provided in the application.
170

171 (3) The existing licensed site from which the designation of beds for NICU services proposed to be
172 relocated is currently licensed and designated for NICU services.
173

174 (4) The proposed project does not result in an increase in the number of beds designated for NICU
175 services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.
176

177 (5) The proposed project does not result in an increase in the number of licensed hospital beds at the
178 applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital
179 Beds have also been met.
180

181 (6) The proposed project does not result in the operation of a NICU of less than 15 beds at the
182 existing licensed site from which the designation of beds for NICU services are proposed to be relocated.
183

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

- 186 (a) the proposed project involves the establishment of a NICU of at least 15 beds; and
187 (b) for each of the 3 most recent years for which birth data are available from the Vital Records and
188 Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the
189 licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the
190 licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles
191 from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If
192 the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the
193 applicant licensed site was established as the result of the consolidation and closure of 2 or more
194 obstetrical units, the combined number of live births from the obstetrical units that were closed and
195 relocated to the applicant licensed site may be used to evaluate compliance with this requirement for
196 those years when the applicant licensed site was not in operation.
197

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

- 200 (a) the proposed project involves the establishment of a NICU of at least 15 beds; and
201 (b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the
202 NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing
203 obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital
204 Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or
205 more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or
206 (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan
207 statistical area county and is located more than 100 miles from the nearest licensed site that operates or
208 has valid CON approval to operate NICU services.
209

210 (9) The project results in a decrease in the number of licensed hospital beds that are designated for
211 NICU services at the licensed site at which beds are currently designated for NICU services. The

212 decrease in the number of beds designated for NICU services shall be equal to or greater than the
213 number of beds designated for NICU services proposed to be increased at the applicant's licensed site
214 pursuant to the agreement required by this subsection. This subsection requires a decrease in the
215 number of licensed hospital beds that are designated for NICU services, but does not require a decrease
216 in the number of licensed hospital beds.

217
218 (10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the
219 proposed project involves the relocation of all beds designated for NICU services at the applicant's
220 licensed site.

221 222 **Section 7. Requirements for approval to expand NICU services**

223
224 Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating
225 additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase
226 will not result in a surplus of NICU beds based on the difference between the number of existing NICU
227 beds in the planning area and the number of beds needed for the planning year resulting from application
228 of the methodology set forth in Section 3.

229
230 (2) An applicant may apply and be approved for NICU beds in excess of the number determined as
231 needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides
232 NICU services to patients transferred from another licensed and designated NICU. The maximum
233 number of NICU beds that may be approved pursuant to this subsection shall be determined in
234 accordance with the following:

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

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

241 (c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC +$
242 $2.06 \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this subsection
243 up to 5 beds at each licensed site.

244 245 **Section 8. Requirements for approval to acquire a NICU service**

246
247 Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital
248 beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

249
250 (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the
251 needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU
252 subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are
253 met:

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

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

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

261
262

263 **Section 9. Requirements to initiate, acquire, or replace SCN services**
264

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

267 (1) All applicants shall demonstrate the following:

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

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

270 (i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to
271 24 hours;

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

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

274 (iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with
275 experience caring for premature infants.
276

277
278 (2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had
279 in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.

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

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

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

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

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

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

294 (A) mortality rates;

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

298 (C) infection rates.

299 (b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical
300 department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.
301

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

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

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

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

308 (iii) The proposed licensed site is in the same planning area as the existing licensed site.
309

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

312 (a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service
313 shall demonstrate all of the following:

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

315 (ii) The licensed site does not change as a result of the acquisition, unless the applicant meets
316 subsection 3.
317

318 **Section 10. Additional requirements for applications included in comparative reviews.**
319

320 Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being
321 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and
322 reviewed comparatively with other applications in accordance with the CON rules.
323

324 (2) Each application in a comparative review group shall be individually reviewed to determine
325 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
326 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the
327 Code and these standards. If the Department determines that one or more of the competing applications
328 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
329 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
330 defined in Section 22225(1), and which have the highest number of points when the results of subsection
331 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the
332 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
333 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an
334 application is submitted to the Department. If 2 or more qualifying projects are determined to have an
335 identical number of points and each operates a NICU at the time an application is submitted to the
336 Department, the Department shall approve those qualifying projects which, taken together, do not exceed
337 the need, as defined in Section 22225(1), in the order in which the applications were received by the
338 Department, based on the submission date and time, as determined by the Department when submitted.

339 (a) A qualifying project will have points awarded based on the geographic proximity to NICU services,
340 both operating and CON approved but not yet operational, in accordance with the following schedule:
341

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

352
353 (b) A qualifying project will have points awarded based on the number of very low birth weight infants
354 delivered at the applicant hospital or the number of very low birth weight infants admitted or refused
355 admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth
356 weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an
357 applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the
358 number of qualifying projects. The number of points to be awarded to each qualifying project shall be
359 calculated as follows:

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

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

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

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

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

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

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

379

380	Hospital	
381	Indigent	Points
382	<u>Volume</u>	<u>Awarded</u>
383		
384	0 - <6%	0.2
385	6 - <11%	0.4
386	11 - <16%	0.6
387	16 - <21%	0.8
388	21 - <26%	1.0
389	26 - <31%	1.2
390	31 - <36%	1.4
391	36 - <41%	1.6
392	41 - <46%	1.8
393	46% +	2.0

394

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

400

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

409

410 **Section 11. Requirements for Medicaid participation**

411

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

416

417 **Section 12. Project delivery requirements and terms of approval**

418

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

- 421 (1) Compliance with these standards.
422
423 (2) Compliance with the following applicable quality assurance standards for NICU services:
424 (a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal
425 and pediatric care in its planning area, and other planning areas in the case of highly specialized services.
426 (b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants
427 with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk
428 infants to ensure comprehensive and early intervention services.
429 (c) If an applicant operates a NICU that admits infants that are born at a hospital other than the
430 applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-
431 finding and social support which is integrated into perinatal care networks, as appropriate.
432 (d) If an applicant operates a NICU that admits infants that are born at a hospital other than the
433 applicant hospital, an applicant shall develop and maintain a neonatal transport system.
434 (e) An applicant shall coordinate and participate in professional education for perinatal and pediatric
435 providers in the planning area.
436 (f) An applicant shall develop and implement a system for discharge planning.
437 (g) A board certified neonatologist shall serve as the director of neonatal services.
438 (h) An applicant shall make provisions for on-site physician consultation services in at least the
439 following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.
440 (i) An applicant shall develop and maintain plans for the provision of highly specialized
441 neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology,
442 orthopedics, urology, otolaryngology and genetics.
443 (j) An applicant shall develop and maintain plans for the provision of transferring infants discharged
444 from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services
445 but unable to be discharged home.
446
447 (3) Compliance with the following applicable quality assurance standards for SCN services:
448 (a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal
449 and pediatric care in its planning area, and other planning areas in the case of highly specialized services.
450 (b) An applicant shall develop and implement a system for discharge planning.
451 (c) A board certified neonatologist shall serve as the SCN program director.
452 (d) The hospital continues to have the following capabilities and personnel continuously available and
453 on-site:
454 (i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to
455 24 hours;
456 (ii) portable x-ray equipment and blood gas analyzer;
457 (iii) pediatric physicians and/or neonatal nurse practitioners; and
458 (iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with
459 experience caring for premature infants.
460
461 (4) Compliance with the following access to care requirements:
462 (a) The NICU and SCN services shall participate in Medicaid at least 12 consecutive months within
463 the first two years of operation and continue to participate annually thereafter.
464 (b) The NICU and SCN services shall not deny NICU and SCN services to any individual based on
465 ability to pay or source of payment.
466 (c) The NICU and SCN services shall provide NICU and SCN services to any individual based on
467 clinical indications of need for the services.
468 (d) The NICU and SCN services shall maintain information by payor and non-paying sources to
469 indicate the volume of care from each source provided annually.
470 (e) Compliance with selective contracting requirements shall not be construed as a violation of this
471 term.
472
473 (5) Compliance with the following monitoring and reporting requirements:

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

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

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

489
490 (6) The agreements and assurances required by this section shall be in the form of a certification
491 agreed to by the applicant or its authorized agent.

492
493 **Section 13. Department inventory of beds**

494
495 Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning
496 area.

497
498 **Section 14. Effect on prior CON review standards; comparative reviews**

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500 Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for
501 Neonatal Intensive Care Services/Beds approved by the Commission on ~~June 10, 2010~~DECEMBER 12,
502 2013 and effective on ~~August 12, 2010~~MARCH 3, 2014.

503
504 (2) Projects reviewed under these standards shall be subject to comparative review except for:

505 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section
506 333.22229(3) of the Michigan Compiled Laws;

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

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

510 (d) SCN services requested under Section 9.

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CON REVIEW STANDARDS
FOR NEONATAL INTENSIVE CARE SERVICES/BEDS

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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