

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~~ARE:

85 (i) ~~Care care~~ for infants born greater than or equal to 32 weeks gestation and/or weighing greater
86 than or equal to 1,500 grams;

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 **AND HIGH FLOW NASAL**
92 **CANNULA (HFNC); AND**

93 (vi) ~~mechanical ventilation or both~~ for a brief duration (~~not to exceed~~UP TO 24 hours~~combined~~).

94 **FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL**
95 **REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION.** Referral to

96 a higher level of care should **ALSO** occur for all infants who need pediatric surgical or medical

97 subspecialty intervention. Infants receiving transitional care or being treated for developmental

98 maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or

99 another hospital. For purposes of these standards, SCN services are special newborn nursing services.

100 (w) **"TELEMEDICINE" MEANS THE USE OF AN ELECTRONIC MEDIA TO LINK PATIENTS WITH**
101 **HEALTH CARE PROFESSIONALS IN DIFFERENT LOCATIONS. TO BE CONSIDERED**
102 **TELEMEDICINE UNDER THIS SECTION, THE HEALTH CARE PROFESSIONAL MUST BE ABLE TO**
103 **EXAMINE THE PATIENT VIA A HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF**
104 **1996, PUBLIC LAW 104-191 COMPLIANT, SECURE INTERACTIVE AUDIO, VIDEO, OR BOTH,**
105 **TELECOMMUNICATIONS SYSTEM, OR THROUGH THE USE OF STORE AND FORWARD ONLINE**
106 **MESSAGING.**

107 (x) "Well newborn nursery services" means providing the following services and does not require a
108 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 who remain physiologically
112 stable; and
- 113 (iv) stabilize newborn infants who are ill and those born less than 35 weeks of gestation until they can
114 be transferred to a higher level of care facility.

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

117 118 **Section 3. Bed need methodology**

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

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

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

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

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

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

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

138 139 **Section 4. Requirements to initiate NICU services**

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

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

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

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

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

155 (d) For each of the 3 most recent years for which birth data are available from the Vital Records and
156 Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or
157 more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more
158 live births, if the licensed site is located in a rural or micropolitan statistical area county and is located

159 more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON
160 approval to operate NICU services.

161
162 **Section 5. Requirements to replace NICU services**
163

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

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

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

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

177
178 **Section 6. Requirements for approval to relocate NICU beds**
179

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

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

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

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

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

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

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

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

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

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

212 applicant licensed site was established as the result of the consolidation and closure of 2 or more
213 obstetrical units, the combined number of live births from the obstetrical units that were closed and
214 relocated to the applicant licensed site may be used to evaluate compliance with this requirement for
215 those years when the applicant licensed site was not in operation.

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

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

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

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

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

241 Section 7. Requirements for approval to expand NICU services

242
243 Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating
244 additional hospital beds as NICU beds in a planning area, EXCEPT AN APPLICANT MEETING THE
245 REQUIREMENTS OF SUBSECTION (2), shall demonstrate that the proposed increase will not result in a
246 surplus of NICU beds based on the difference between the number of existing NICU beds in the planning
247 area and the number of beds needed for the planning year resulting from application of the methodology
248 set forth in Section 3.

249
250 (2) An applicant may apply and be approved TO EXPAND NICU SERVICES AT A LICENSED SITE
251 BY DESIGNATING ADDITIONAL HOSPITAL BEDS for AS NICU beds in excess of the number
252 determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate
253 ALL OF THE FOLLOWING SUBSECTIONS ARE MET that it provides NICU services to patients
254 transferred from another licensed and designated NICU. The maximum number of NICU beds that may
255 be approved pursuant to this subsection shall be determined in accordance with the following:

256 (a) An applicant shall document the average annual number of patient days provided to neonates or
257 infants transferred from another licensed and designated NICU, for the 2 most recent years for which
258 verifiable data are available to the Department THE PROPOSED NICU BEDS ARE BEING ADDED AT
259 THE EXISTING LICENSED SITE.

260 (b) The EXISTING NICU BEDS HAVE OPERATED AT AN OCCUPANCY RATE OF 80 PERCENT
261 OR ABOVE FOR THE PREVIOUS, CONSECUTIVE 24 MONTHS BASED ON THE EXISTING SITE'S
262 LICENSED AND APPROVED NICU BED CAPACITY. THE OCCUPANCY RATE SHALL BE
263 CALCULATED AS FOLLOWS:

264 (i) average annual CALCULATE THE number of patient days determined in accordance with
265 subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census
266 (ADC) for NICU services provided to patients transferred from another licensed and designated NICU
267 -PROVIDED TO NEONATES IN THE APPLICANT'S EXISTING NICU BEDS FOR THE MOST RECENT,
268 CONSECUTIVE 24 MONTHS FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE
269 DEPARTMENT.

270 (ii) CALCULATE THE TOTAL POSSIBLE PATIENT DAYS BY MULTIPLYING THE EXISTING
271 LICENSED AND APPROVED NICU BEDS BY 730 (OR 731 IF INCLUDING A LEAP YEAR).

272 (iii) CALCULATE THE OCCUPANCY RATE BY DIVIDING THE NUMBER CALCULATED IN (i) BY
273 THE NUMBER CALCULATED IN (ii).

274 (c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC +$
275 $2.06 \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this
276 subsection. THE NUMBER OF NICU BEDS THAT MAY BE APPROVED PURSUANT TO THIS
277 SUBSECTION SHALL BE THE NUMBER OF NICU BEDS NECESSARY TO REDUCE THE
278 OCCUPANCY RATE FOR THE NICU TO 70 PERCENT. THE NUMBER OF NICU BEDS TO BE ADDED
279 SHALL BE CALCULATED AS FOLLOWS:

280 (i) DIVIDE THE NUMBER OF PATIENT DAYS CALCULATED IN SUBSECTION (b)(i) BY .70 TO
281 DETERMINE LICENSED NICU BED DAYS AT 70 PERCENT OCCUPANCY.

282 (ii) DIVIDE THE RESULT OF STEP (c)(i) BY 730 (OR 731 IF INCLUDING A LEAP YEAR) AND
283 ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER.

284 (iii) SUBTRACT THE NUMBER OF EXISTING NICU BED DESIGNATIONS AS DOCUMENTED ON
285 THE "DEPARTMENT INVENTORY OF NICU BEDS" FROM THE RESULT OF STEP (c)(ii) AND ROUND
286 THE RESULT UP TO THE NEXT WHOLE NUMBER TO DETERMINE THE MAXIMUM NUMBER OF
287 BEDS THAT MAY BE APPROVED PURSUANT TO THIS SUBSECTION. IF THE RESULT IS LESS
288 THAN 5 BEDS, THE APPLICANT MAY BE APPROVED FOR UP TO 5 BEDS.

289 (d) A NICU THAT HAS RELOCATED NICU BEDS, AFTER THE EFFECTIVE DATE OF THESE
290 STANDARDS, SHALL NOT BE APPROVED FOR NICU BEDS UNDER THIS SUBSECTION FOR FIVE
291 YEARS FROM THE EFFECTIVE DATE OF THE RELOCATION OF BEDS.

292 (e) APPLICANTS PROPOSING TO ADD NICU BEDS UNDER THIS SUBSECTION SHALL NOT BE
293 SUBJECT TO COMPARATIVE REVIEW.

294 (f) AN APPLICANT PROPOSING TO ADD NICU BEDS SHALL NOT BE REQUIRED TO BE IN
295 COMPLIANCE WITH THE BED NEED METHODOLOGY IF THE APPLICATION MEETS ALL OTHER
296 APPLICABLE CON REVIEW STANDARDS, AND THE APPLICANT AGREES AND ASSURES TO
297 COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

299 Section 8. Requirements for approval to acquire a NICU service

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

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

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

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

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

316 **Section 9. Requirements to initiate, acquire, or replace SCN services**
317

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

320
321 (1) All applicants shall demonstrate the following:

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

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

324 (i) ~~the ability to provide~~mechanical ventilation **FOR A BRIEF DURATION (UP TO 24 HOURS).**
325 **FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL**
326 **REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION;**

327 (ii) ~~and/or~~continuous positive airway pressure **AND HFNC for up to 24 hours;**

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

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

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

332
333 (2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had
334 in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.

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

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

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

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

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

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

349 (A) mortality rates;

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

353 (C) infection rates.

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

356
357 (3) Replacement of SCN services means new physical plant space being developed through new
358 construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.

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

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

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

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

364
365 (4) Acquisition of an SCN service means obtaining possession and control of an existing SCN
366 service by contract, ownership, lease or other comparable arrangement.

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

- 369 (i) The proposed project is part of an application to acquire the entire hospital.
- 370 (ii) The licensed site does not change as a result of the acquisition, unless the applicant meets
- 371 subsection 3.
- 372

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

374
 375 Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being
 376 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and
 377 reviewed comparatively with other applications in accordance with the CON rules.

378
 379 (2) Each application in a comparative review group shall be individually reviewed to determine
 380 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
 381 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the
 382 Code and these standards. If the Department determines that one or more of the competing applications
 383 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
 384 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
 385 defined in Section 22225(1), and which have the highest number of points when the results of subsection
 386 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the
 387 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
 388 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an
 389 application is submitted to the Department. If 2 or more qualifying projects are determined to have an
 390 identical number of points and each operates a NICU at the time an application is submitted to the
 391 Department, the Department shall approve those qualifying projects which, taken together, do not exceed
 392 the need, as defined in Section 22225(1), in the order in which the applications were received by the
 393 Department, based on the submission date and time, as determined by the Department when submitted.

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

<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

397
 398
 399
 400
 401
 402
 403
 404
 405
 406
 407
 408
 409 (b) A qualifying project will have points awarded based on the number of very low birth weight infants
 410 delivered at the applicant hospital or the number of very low birth weight infants admitted or refused
 411 admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth
 412 weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an
 413 applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the
 414 number of qualifying projects. The number of points to be awarded to each qualifying project shall be
 415 calculated as follows:

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

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

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

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

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

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

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

435	Hospital	
436	Indigent	Points
437	<u>Volume</u>	<u>Awarded</u>
438		
439		
440	0 - <6%	0.2
441	6 - <11%	0.4
442	11 - <16%	0.6
443	16 - <21%	0.8
444	21 - <26%	1.0
445	26 - <31%	1.2
446	31 - <36%	1.4
447	36 - <41%	1.6
448	41 - <46%	1.8
449	46% +	2.0
450		

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

456
457 (3) Submission of conflicting information in this section may result in a lower point reward. If an
458 application contains conflicting information which could result in a different point value being awarded in
459 this section, the Department will award points based on the lower point value that could be awarded from
460 conflicting information. For example, if submitted information would result in 6 points being awarded, but
461 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the
462 conflicting information does not affect the point value, the Department will award points accordingly. For
463 example, if submitted information would result in 12 points being awarded and other conflicting
464 information would also result in 12 points being awarded, then 12 points will be awarded.

465 466 **Section 11. Requirements for Medicaid participation**

467
468 Sec. 11. An applicant for NICU services and SCN services shall provide verification of Medicaid
469 participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof
470 of Medicaid participation will be provided to the Department within six (6) months from the offering of
471 services if a CON is approved.

472 473 **Section 12. Project delivery requirements and terms of approval**

474

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

477 (1) Compliance with these standards.

478
479 (2) Compliance with the following applicable quality assurance standards for NICU services:

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

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

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

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

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

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

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

495 (h) An applicant shall make provisions for ~~on-site~~ physician consultation services EITHER ON-SITE
496 OR BY PREARRANGED CONSULTATIVE AGREEMENTS in at least the following neonatal/pediatric
497 specialties: cardiology, ophthalmology, surgery and neurosurgery. PREARRANGED CONSULTATIVE
498 AGREEMENTS CAN BE PERFORMED BY USING TELEMEDICINE TECHNOLOGY.

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

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

505
506 (3) Compliance with the following applicable quality assurance standards for SCN services:

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

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

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

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

514 (i) ~~The ability to provide~~ mechanical ventilation FOR A BRIEF DURATION (UP TO 24 HOURS),
515 FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL
516 REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION-;

517 (ii) ~~and/or~~ continuous positive airway pressure AND HFNC for up to 24 hours;

518 (iii) portable x-ray equipment and blood gas analyzer;

519 (iiii) pediatric physicians and/or neonatal nurse practitioners; and

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

522
523 (4) Compliance with the following access to care requirements:

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

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

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

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

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

534

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

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

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

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

551

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

554

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

556

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

559

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

561

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

565

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

567 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section
568 333.22229(3) of the Michigan Compiled Laws;

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

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

572 (d) SCN services requested under Section 9.

573
574
575
576
577
578
579
580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619

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

620
621
622 The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group
623 of counties as follows:

624	625 Planning	
626	<u>Areas</u>	<u>Counties</u>
627		
628	1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
629		
630	2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
631		
632	3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
633		
634	4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
635		
636	5	Genesee, Lapeer, Shiawassee
637		
638	6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw,
639		Osceola, Oscoda, Saginaw, Sanilac, Tuscola
640		
641	7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand
642		Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle,
643		Roscommon, Wexford
644		
645	8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce,
646		Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft
647		
648		