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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

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

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

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

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

(fe) "Department" means the Michigan Department of Community Health (MDCH).

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

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

(i) licensed hospital beds designated for NICU services;

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

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

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

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- 48 | (h) "Expansion of NICU services" means increasing the number of hospital beds designated for
49 | NICU services at a licensed site.
- 50 | (j) "Hospital" means a health facility licensed under Part 215 of the Code.
- 51 | (k) "Initiation of NICU services" means the establishment of a NICU at a licensed site that has not
52 | had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a
53 | NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements
54 | of Section 6 shall not be considered as the initiation of NICU services/beds.
- 55 | **(k) "INITIATION OF SCN SERVICES" MEANS**
- 56 | (k) "Infant" means an individual up to 1 year of age.
- 57 | (m) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by
58 | license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites,
59 | the location of each separate and distinct inpatient unit of the health facility as authorized by license and
60 | listed on that licensee's certificate of licensure.
- 61 | (am) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed
62 | pursuant to Section 333.2821(2) of the Michigan Compiled Laws.
- 63 | (on) "Maternal referral service" means having a consultative and patient referral service staffed by a
64 | physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in
65 | maternal/fetal medicine.
- 66 | (p) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
67 | and 1396r-8 to 1396v1396w-5.
- 68 | ~~— (q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as~~
69 | ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~
70 | ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~
71 | ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~
- 72 | ~~— (r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as~~
73 | ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~
74 | ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~
75 | ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~
- 76 | (sp) "Neonatal intensive care services" or "NICU services" means the provision of any of the following
77 | services:
78 | (i) constant nursing care and continuous cardiopulmonary and other support services for severely ill
79 | infants;
80 | (ii) care for neonates weighing less than 1,500 grams at birth, **AND/OR LESS THAN 32 WEEKS**
81 | **GESTATION;**
- 82 | (iii) ventilatory support beyond that needed for immediate ventilatory stabilization;
83 | (iv) surgery and post-operative care during the neonatal period;
84 | (v) pharmacologic stabilization of heart rate and blood pressure; or
85 | (vi) **TOTAL** parenteral nutrition.
- 86 | (t) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit
87 | of a hospital which is both capable of providing neonatal intensive care services and is composed of
88 | licensed hospital beds designated as NICU. This term does not include bassinets or special newborn
89 | care bassinets.
- 90 | (u) "Neonatal transport system" means a specialized transfer program for neonates by means of an
91 | ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.
- 92 | (vs) "Neonate" means an individual up to 28 days of age.
- 93 | (wt) "Perinatal care network," means the providers and facilities within a planning area that provide
94 | basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.
- 95 | (xu) "Planning area" means the groups of counties shown in **Section 12 APPENDIX B.**

Comment [A1]: Placeholder...

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- 96 | (~~yy~~) "Planning year" means the most recent continuous 12 month period for which birth data is
97 | available from the Vital Records and Health Data Development Section.
- 98 | (~~zw~~) "Qualifying project" means each application in a comparative group which has been reviewed
99 | individually and has been determined by the Department to have satisfied all of the requirements of
100 | Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
101 | applicable requirements for approval in the Code and these standards.
- 102 | (~~axx~~) "Relocation of the designation of beds for NICU services" means a change within the same
103 | planning area in the licensed site at which existing licensed hospital beds are designated for NICU
104 | services.
- 105 | (~~bbv~~) "Replacement of NICU beds" means new physical plant space being developed through new
106 | construction or newly acquired space (purchase, lease or donation), to house existing licensed and
107 | designated NICU beds.
- 108 | (~~eez~~) "Replacement zone" means a proposed licensed site which is in the same planning area as the
109 | existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of
110 | the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative
111 | review.
- 112 | (aa) "Special ~~newborn care~~ **NURSERY bassinetSERVICES" OR "SCN SERVICES"** means ~~an~~
113 | ~~unlicensed bassinet identified within the hospital obstetrical or newborn service which provides~~
114 | ~~PROVISIONS OF~~ the services identified in subsections (i) through (vi) for infants ~~WITH PROBLEMS~~
115 | ~~THAT ARE EXPECTED TO RESOLVE RAPIDLY AND~~ who ~~WOULD NOT BE ANTICIPATED TO NEED~~
116 | ~~SUBSPECIALTY SERVICES ON AN URGENT BASIS~~ require minimal care that goes beyond that of the
117 | ~~uncomplicated newborn, or transitional care or developmental maturation in preparation for discharge~~
118 | ~~home. REFERRAL TO A HIGHER LEVEL OF CARE SHOULD OCCUR FOR ALL INFANTS WHO~~
119 | ~~NEED PEDIATRIC SURGICAL OR MEDICAL SUBSPECIALTY INTERVENTION.~~ Infants receiving
120 | transitional care or being treated for developmental maturation may have formerly been treated in a
121 | neonatal intensive care unit in the same hospital or another hospital. ~~FOR PURPOSES OF THESE~~
122 | ~~STANDARDS, SCN SERVICES ARE SPECIAL NEWBORN NURSING SERVICES.~~
- 123 | (i) Care for low birth weight infants ~~between weighing 1,500 and 2,499 grams or more;~~ **AND/OR**
124 | **GREATER THAN OR EQUAL TO 32 WEEKS GESTATION;**
- 125 | (ii) enteral tube feedings;
126 | (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
127 | ~~(iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;~~
128 | (iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring
129 | ventilatory support; or
130 | ~~(vi) the administration of oxygen by hood or nasal canula~~ **PROVIDE MECHANICAL VENTILATION**
131 | **FOR BRIEF DURATION (LESS THAN 24 HOURS) OR CONTINUOUS POSITIVE AIRWAY PRESSURE**
132 | **OR BOTH;**
- 133 | ~~—(ee) "Rural county" means a county not located in a metropolitan statistical area or micropolitan~~
134 | ~~statistical areas as those terms are defined under the "standards for defining metropolitan and~~
135 | ~~micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of~~
136 | ~~the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as~~
137 | ~~shown in Appendix A.~~

138 |
139 | (2) The definitions in Part 222 shall apply to these standards.
140 |

141 | **Section 3. Bed need methodology**
142 |

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

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

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

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

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

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

158
159 (2) The result of subsection (1) is the number of NICU beds needed in the planning area for the
160 planning year.

161
162 **Section 4. Requirements for applicants proposing to initiate NICU services**

163
164 Sec. 4. An applicant proposing to initiate NICU services by designating hospital beds as NICU beds
165 shall demonstrate each of the following:

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

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

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

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

179
180
181 **Section 5. Requirements for applicants proposing to expand-REPLACE NICU services**

182
183 Sec. 5. (1) An applicant proposing replacement beds shall not be required to be in compliance with
184 the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the
185 following:

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

189 (b) the proposed licensed site is in the replacement zone.
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Section 6. Requirements for approval to relocate NICU beds

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

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

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

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

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

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

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

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

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

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

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

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

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

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239 (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan
240 statistical area county and is located more than 100 miles from the nearest licensed site that operates or
241 has valid CON approval to operate NICU services.
242

243 (9) The project results in a decrease in the number of licensed hospital beds that are designated for
244 NICU services at the licensed site at which beds are currently designated for NICU services. The
245 decrease in the number of beds designated for NICU services shall be equal to or greater than the
246 number of beds designated for NICU services proposed to be increased at the applicant's licensed site
247 pursuant to the agreement required by this subsection. This subsection requires a decrease in the
248 number of licensed hospital beds that are designated for NICU services, but does not require a decrease
249 in the number of licensed hospital beds.
250

251 (10) Beds approved pursuant to Section 57(2) shall not be relocated pursuant to this section, unless
252 the proposed project involves the relocation of all beds designated for NICU services at the applicant's
253 licensed site.
254

255 ~~—Sec. 5. (1) An applicant proposing to expand NICU services by designating additional hospital beds~~
256 ~~as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus~~
257 ~~of NICU beds based on the difference between the number of existing NICU beds in the planning area~~
258 ~~and the number of beds needed for the planning year resulting from application of the methodology set~~
259 ~~forth in Section 3.~~
260

261 ~~—(2) An applicant may apply and be approved for NICU beds in excess of the number determined as~~
262 ~~needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides~~
263 ~~NICU services to patients transferred from another licensed and designated NICU. The maximum~~
264 ~~number of NICU beds that may be approved pursuant to this subsection shall be determined in~~
265 ~~accordance with the following:~~
266

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

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

273 ~~—(c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC \div$~~
274 ~~$2.06 = \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this~~
275 ~~subsection up to 5 beds at each licensed site.~~
276

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

278
279 ~~—Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate~~
280 ~~compliance with all of the following:~~

281
282 ~~—(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU~~
283 ~~services is proposed.~~
284

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- 285 ~~—(2) The applicant shall provide a signed written agreement that provides for the proposed increase,~~
286 ~~and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites~~
287 ~~involved in the proposed relocation. A copy of the agreement shall be provided in the application.~~
- 288
- 289 ~~—(3) The existing licensed site from which the designation of beds for NICU services proposed to be~~
290 ~~relocated is currently licensed and designated for NICU services.~~
- 291
- 292 ~~—(4) The proposed project does not result in an increase in the number of beds designated for NICU~~
293 ~~services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.~~
- 294
- 295 ~~—(5) The proposed project does not result in an increase in the number of licensed hospital beds at~~
296 ~~the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital~~
297 ~~Beds have also been met.~~
- 298
- 299 ~~—(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the~~
300 ~~existing licensed site from which the designation of beds for NICU services are proposed to be relocated.~~
- 301
- 302 ~~—(7) If the applicant licensed site does not currently provide NICU services, an applicant shall~~
303 ~~demonstrate both of the following:~~
- 304 ~~—(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~
- 305 ~~—(b) for each of the 3 most recent years for which birth data are available from the Vital Records and~~
306 ~~Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if~~
307 ~~the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the~~
308 ~~licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles~~
309 ~~from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If~~
310 ~~the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the~~
311 ~~applicant licensed site was established as the result of the consolidation and closure of 2 or more~~
312 ~~obstetrical units, the combined number of live births from the obstetrical units that were closed and~~
313 ~~relocated to the applicant licensed site may be used to evaluate compliance with this requirement for~~
314 ~~those years when the applicant licensed site was not in operation.~~
- 315
- 316 ~~—(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an~~
317 ~~applicant shall demonstrate both of the following:~~
- 318 ~~—(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~
- 319 ~~—(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the~~
320 ~~NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing~~
321 ~~obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital~~
322 ~~Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or~~
323 ~~more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or~~
324 ~~(ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan~~
325 ~~statistical area county and is located more than 100 miles from the nearest licensed site that operates or~~
326 ~~has valid CON approval to operate NICU services.~~
- 327
- 328 ~~—(9) The project results in a decrease in the number of licensed hospital beds that are designated for~~
329 ~~NICU services at the licensed site at which beds are currently designated for NICU services. The~~
330 ~~decrease in the number of beds designated for NICU services shall be equal to or greater than the~~
331 ~~number of beds designated for NICU services proposed to be increased at the applicant's licensed site~~
332 ~~pursuant to the agreement required by this subsection. This subsection requires a decrease in the~~

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333 ~~number of licensed hospital beds that are designated for NICU services, but does not require a decrease~~
334 ~~in the number of licensed hospital beds.~~

335
336 ~~—(10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless~~
337 ~~the proposed project involves the relocation of all beds designated for NICU services at the applicant's~~
338 ~~licensed site.~~

340
341 **Section 7. Requirements for approval for replacement of NICU beds** **REQUIREMENTS FOR**
342 **APPROVAL TO EXPAND NICU SERVICES**

343
344
345 Sec. 7. (1) An applicant proposing to expand NICU services by designating additional hospital beds
346 as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus
347 of NICU beds based on the difference between the number of existing NICU beds in the planning area
348 and the number of beds needed for the planning year resulting from application of the methodology set
349 forth in Section 3.

350
351 (2) An applicant may apply and be approved for NICU beds in excess of the number determined as
352 needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides
353 NICU services to patients transferred from another licensed and designated NICU. The maximum
354 number of NICU beds that may be approved pursuant to this subsection shall be determined in
355 accordance with the following:

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

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

362 (c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC +$
363 $2.06 \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this
364 subsection up to 5 beds at each licensed site.

365
366 ~~Sec. 7. (1) An applicant proposing replacement beds shall not be required to be in compliance~~
367 ~~with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates~~
368 ~~all of the following:~~

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

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

373
374 **Section 8. Requirements for approval to acquire a NICU service**

375
376 Sec. 8. "Acquisition of a NICU" means obtaining possession and control of existing licensed hospital
377 beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

378
379 (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the
380 needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU

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381 subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are
382 met:

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

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

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

390 **SECTION 9. REQUIREMENTS TO INITIATE, ACQUIRE, OR REPLACE, SNGSCN SERVICES**

391 **SEC. 9. AN APPLICANT PROPOSING TO INITIATE SNGSCN SERVICES SHALL DEMONSTRATE**
392 **EACH OF THE FOLLOWING, AS APPLICABLE, BY VERIFIABLE DOCUMENTATION:**

393 **(1) ALL APPLICANTS SHALL DEMONSTRATE THE FOLLOWING AS APPLICABLE:**

394 **(a) THE HOSPITAL HAS THE FOLLOWING CAPABILITIES AND PERSONNEL CONTINUOUSLY**
395 **AVAILABLE AND ON-SITE:**

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

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

399 **(iii) NEONATOLOGIST SERVING AS THE PROGRAM DIRECTOR**

400 **(iv) PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE PRACTITIONERS; AND**

401 **(v) SPECIALIZED NURSES, RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, AND**
402 **LABORATORY TECHNICIANS WITH EXPERIENCE CARING FOR PREMATURE INFANTS.**

403 **(b) AN SCN SERVICES SHALL HAVE A WRITTEN CONSULTING AGREEMENT WITH A HOSPITAL**
404 **WHICH HAS AN EXISTING ACTIVE NICU ADMITTING A MINIMUM OF XXX PATIENTS PER YEAR**
405 **FOR THE THREE MOST RECENT CONSECUTIVE YEARS. THE AGREEMENT MUST SPECIFY**
406 **THAT THE EXISTING SERVICE SHALL, FOR THE FIRST TWO YEARS OF OPERATION OF THE NEW**
407 **SERVICE, PROVIDE THE FOLLOWING SERVICES TO THE APPLICANT HOSPITAL:**

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

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

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

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

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

419 **(A) MORTALITY RATES**

420 **(B) COMPLICATION RATES**

421 **(C) SUCCESS RATES, AND**

422 **(D) INFECTION RATES**

423 **(c) SCN SERVICES SHALL BE PROVIDED IN UNLICENSED BASSINETS LOCATED WITHIN THE**
424 **HOSPITAL OBSTETRICAL DEPARTMENT OR NICU SERVICE.**

Comment [A2]: Needs to be determined by workgroup.

KEY:

RED TEXT AND CAPS = technical changes by MDCH
Grey Highlight = Insertion from 4/22 NICU Workgroup
Aqua Highlight = Changes by MDCH re: SCNs
Yellow Highlight = Changes from 5/22 NICU Workgroup

429 (2) AN APPLICANT PROPOSING TO INITIATE AN SCN SERVICE SHALL **SUBMIT A REPORT**
430 **FOR EACH OF THE 3 MOST RECENT YEARS FOR WHICH BIRTH DATA ARE AVAILABLE FROM**
431 **THE VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION WITHIN THE DEPARTMENT.**
432 **THE LICENSED SITE AT WHICH THE **SNCSCN** SERVICE IS PROPOSED HAD EITHER:**

433 (I) 1,000 OR MORE LIVE BIRTHS IF THE LICENSED SITE IS LOCATED IN A METROPOLITAN
434 STATISTICAL AREA COUNTY; OR
435 (II) 300 OR MORE LIVE BIRTHS IF THE LICENSED SITE IS LOCATED IN A RURAL OR
436 MICROPOLITAN STATISTICAL AREA COUNTY AND IS LOCATED MORE THAN 100 MILES
437 (SURFACE TRAVEL) FROM THE NEAREST LICENSED SITE THAT OPERATES OR HAS A VALID
438 CON APPROVAL TO OPERATE NICU SERVICES;

439 (3) AN APPLICANT PROPOSING A REPLACEMENT SCN SERVICE SHALL DEMONSTRATE ALL
440 OF THE FOLLOWING:

441 (a) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO REPLACE THE ENTIRE
442 HOSPITAL.

443 (b) THE APPLICANT CURRENTLY OPERATES THE SCN SERVICE AT THE CURRENT
444 LICENSED SITE.

445 (c) THE PROPOSED LICENSED SITE IS IN THE SAME PLANNING AREA AS THE EXISTING
446 LICENSED SITE.

447 (4) AN APPLICANT PROPOSING TO ACQUIRE AN SCN SERVICE SHALL DEMONSTRATE ALL
448 OF THE FOLLOWING:

449 (a) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO ACQUIRE THE ENTIRE
450 HOSPITAL.

451 (b) THE LICENSED SITE DOES NOT CHANGE AS A RESULT OF THE ACQUISITION, UNLESS
452 THE APPLICANT MEETS SUBSECTION 3.

453 **Section 910. Additional requirements for applications included in comparative reviews.**

454 Sec. 109. (1) Any application subject to comparative review under Section 22229 of the Code, being
455 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and
456 reviewed comparatively with other applications in accordance with the CON rules.

457 (2) Each application in a comparative review group shall be individually reviewed to determine
458 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
459 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the
460 Code and these standards. If the Department determines that one or more of the competing applications
461 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
462 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
463 defined in Section 22225(1), and which have the highest number of points when the results of subsection
464 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the
465 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
466 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an
467 application is submitted to the Department. If 2 or more qualifying projects are determined to have an
468 identical number of points and each operates a NICU at the time an application is submitted to the
469 Department, the Department shall approve those qualifying projects which, taken together, do not exceed
470 the need, as defined in Section 22225(1), in the order in which the applications were received by the
471 Department, based on the submission date and time, as determined by the Department when submitted.

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477 (a) A qualifying project will have points awarded based on the geographic proximity to NICU
478 services, both operating and CON approved but not yet operational, in accordance with the following
479 schedule:
480

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	<u>Proximity</u>	<u>Points Awarded</u>
481		
482		
483		
484		
485	Less than 50 Miles	0
486	to NICU service	
487	Between 50-99 miles	1
488	to NICU service	
489		
490	100+ Miles	2
491	to NICU service	
492		

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

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

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

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

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

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

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

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

	<u>Hospital Indigent Volume</u>	<u>Points Awarded</u>
519		
520		
521		
522		
523		
524	0 - <6%	0.2
525	6 - <11%	0.4
526	11 - <16%	0.6
527	16 - <21%	0.8
528	21 - <26%	1.0

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529	26 - <31%	1.2
530	31 - <36%	1.4
531	36 - <41%	1.6
532	41 - <46%	1.8
533	46% +	2.0

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

539
540 (3) Submission of conflicting information in this section may result in a lower point reward. If an
541 application contains conflicting information which could result in a different point value being awarded in
542 this section, the Department will award points based on the lower point value that could be awarded from
543 conflicting information. For example, if submitted information would result in 6 points being awarded, but
544 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the
545 conflicting information does not affect the point value, the Department will award points accordingly. For
546 example, if submitted information would result in 12 points being awarded and other conflicting
547 information would also result in 12 points being awarded, then 12 points will be awarded.

548
549 **Section 4011. Requirements for ~~approval for all applicants~~ MEDICAID PARTICIPATION**

550
551 Sec. ~~4011~~. An applicant ~~for NICU SERVICES AND SNGSCN SERVICES~~ shall provide verification of
552 Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify
553 that proof of Medicaid participation will be provided to the Department within six (6) months from the
554 offering of services if a CON is approved.

555
556 **Section 4412. Project delivery requirements --~~AND~~ terms of approval ~~for all applicants~~**

557
558 Sec. ~~4412~~. (4) An applicant shall agree that, if approved, the ~~project~~ ~~NICU AND SNGSCN~~
559 ~~SERVICES~~ shall be delivered in compliance with the following terms of ~~CON~~ approval:

560 (a1) Compliance with these standards.

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

562 (e2) Compliance with the following applicable quality assurance standards **FOR NICU SERVICES:**

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

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

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

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

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

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

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- 577 (G) A board certified neonatologist shall serve as the director of neonatal services.
578 (H) An applicant shall make provisions for on-site physician consultation services in at least the
579 following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.
580 (I) An applicant shall develop and maintain plans for the provision of highly specialized
581 neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology,
582 orthopedics, urology, otolaryngology and genetics.
583 (J) An applicant shall develop and maintain plans for the provision of transferring infants discharged
584 from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU
585 services but unable to be discharged home.

586 **(3) COMPLIANCE WITH THE FOLLOWING APPLICABLE QUALITY ASSURANCE FOR SNGSCN**
587 **SERVICES:**

Comment [A3]: NICU Workgroup will need to develop SCN Project Delivery Requirements

- 589 (i4) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
590 An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
591 (Aa) THE NICU AND SNGSCN SERVICES shall participate in Medicaid at least 12 consecutive
592 months within the first two years of operation and continue to participate annually thereafter.
593 (Bb) THE NICU AND SNGSCN SERVICES SHALL not deny NICU and SNGSCN services to any
594 individual based on ability to pay or source of payment;
595 (Bc) THE NICU AND SNGSCN SERVICES SHALL provide NICU and SNGSCN services to any
596 individual based on clinical indications of need for the services;
597 (Cd) THE NICU AND SNGSCN SERVICES SHALL maintain information by payor and non-paying
598 sources to indicate the volume of care from each source provided annually.
599 (Ee) Compliance with selective contracting requirements shall not be construed as a violation of this
600 term.
601 (ii) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal
602 and pediatric care in its planning area, and other planning areas in the case of highly specialized
603 services.
604 (iii) An applicant shall develop and maintain a follow-up program for NICU graduates and other
605 infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for
606 high-risk infants to ensure comprehensive and early intervention services.
607 (iv) If an applicant operates a NICU that admits infants that are born at a hospital other than the
608 applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-
609 finding and social support which is integrated into perinatal care networks, as appropriate.
610 (v) If an applicant operates a NICU that admits infants that are born at a hospital other than the
611 applicant hospital, an applicant shall develop and maintain a neonatal transport system.
612 (vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric
613 providers in the planning area.
614 (vii) An applicant shall develop and implement a system for discharge planning.
615 (viii) A board certified neonatologist shall serve as the director of neonatal services.
616 (ix) An applicant shall make provisions for on-site physician consultation services in at least the
617 following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.
618 (x) An applicant shall develop and maintain plans for the provision of highly specialized
619 neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology,
620 orthopedics, urology, otolaryngology and genetics.
621 (xi) An applicant shall develop and maintain plans for the provision of transferring infants discharged
622 from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU
623 services but unable to be discharged home.
624

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- 625 (5) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:
626 (xiiA) The applicant NICU AND SNC SCN SERVICES shall participate in a data collection network
627 established and administered by the Department or its designee. The data may include, but is not limited
628 to, annual budget and cost information, operating schedules, THROUGH-PUT SCHEDULES, and
629 demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to
630 patients from all payor sources. The applicant shall provide the required data on a separate basis for
631 each licensed site; in a format established by the Department; and in a mutually agreed upon media. The
632 Department may elect to verify the data through on-site review of appropriate records.
633 (xiiiB) The applicant NICU AND SNC SCN SERVICES shall provide the Department with a TIMELY
634 notice ~~stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in~~
635 ~~operation and such notice shall be submitted to the Department OF THE PROPOSED PROJECT~~
636 IMPLEMENTATION consistent with applicable statute and promulgated rules.
637 ~~(xivC) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years~~
638 ~~of operation and continue to participate annually thereafter.~~
639
640
641 (6) The agreements and assurances required by this section shall be in the form of a certification
642 agreed to by the applicant or its authorized agent.

643
644 **Section 12. Planning areas**

645
646 ~~Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic boundaries~~
647 ~~of the group of counties as follows:~~

648
649 **Planning**

650 ~~Areas~~ Counties

651 ~~1~~ Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne

652
653 ~~2~~ Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee

654
655 ~~3~~ Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren

656
657 ~~4~~ Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa

658
659 ~~5~~ Genesee, Lapeer, Shiawassee

660
661 ~~6~~ Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw,
662 Osceola, Oscoda, Saginaw, Sanilac, Tuscola

663
664 ~~7~~ Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand
665 Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle,
666 Roscommon, Wexford

667
668 ~~8~~ Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce,
669 Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

670
671 **Section 13. Department inventory of beds**

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673 Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each
674 planning area.
675

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

677

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

Comment [A4]: Technical edit.

681

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

683 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section
684 333.22229(3) of the Michigan Compiled Laws;

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

687 (c) Beds requested under Section ~~57~~(2).

688 (d) SCN SERVICES REQUESTED UNDER SECTION 9.

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APPENDIX A

CON REVIEW STANDARDS
FOR NEONATAL INTENSIVE CARE SERVICES/BEDS

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs

CON Review Standards for NICU Services
Draft for Workgroup MAY 22, 2013

CON-204

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737 United States Office of Management and Budget
738

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APPENDIX B

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

Planning

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

NICU CON Standards Workgroup Notes

DATE: May 22, 2013 1:00-3:30 pm

LOCATION: Rooms B/C, 1st Floor Capitol View Building, 201 Townsend Street, Lansing

PURPOSE OF THE MEETING

This was the third meeting of the NICU Standards Workgroup. This meeting was intended to further discuss the proposed CON process and CON standards language to regulate special care nurseries as a new service within the existing NICU CON standards. CON Commissioner Gay Landstrom led the workgroup.

MDCH REVIEW OF LANGUAGE AND LEGAL RECOMMENDATIONS

Beth Nagel, MDCH, presented the proposed structure and process by which special care nurseries would be regulated within the existing NICU CON Standards. Currently, the NICU CON standards do not address special care nursery services. The CON Section proposes to begin regulation of special care nurseries as a service, not as a bed-defined program. To initiate a CON-approved service, any hospital would need to file a CON once new Standards became effective. The group discussed at length how long applicants would be given from the time the Standards were likely to take effect before they must apply and be approved. The general consensus of the group was that applicants and/or the Department would need as many as 21 months to complete the application, review and approval processes. With an assumed effective date of around March 2014, several workgroup members expressed support that applicants would be given until around January 1, 2016, to meet the special care nursery requirements and receive CON approval.

It was clarified that as a service, special care nurseries would not be restricted to a bed-need calculation like NICU services. Additionally, because special care nurseries are not currently defined, they can be considered a new service. It is the CON Section's discretion whether existing facilities that provide similar care should be grandfathered and it is the MDCH's position that grandfathering would not be recognized for special care nurseries.

OUTCOMES AND CAPACITY ISSUES IF SPECIAL CARE NURSERIES ARE REGULATED

Sue Grady, MSU Department of Geography, provided additional detail regarding the number of babies that might need to be transferred to NICUs once a special care nursery CON requirement was established. Ms. Grady reviewed the number of LBW babies who were retained at self-designated "special care nurseries." These data showed the potential for a relatively small number of babies (195) who would have met the requirements for transfer under the proposed definition of a special care nursery. It was determined that this small number could likely be accommodated by existing NICU programs.

The group discussed whether the AAP guidelines defined whether a Level I nursery must transfer neonates to NICUs, or if they could transfer them to special care nurseries. It was determined that the AAP guidelines would allow a Level I nursery to transfer to a special care nursery, but the workgroup members generally agreed that this was unlikely to occur because most special care nurseries do not have transport teams.

PAYOR PERSPECTIVE ON NURSERY LEVELS

Umbrin Ateequi, BCBS, added to her past comments in explaining payment practices for transferred neonates. BCBS currently pays the transferring (delivering) facility a prorated per diem DRG payment based on the number of days an neonate received treatment at its facility. The receiving NICU receives the full DRG payment. Ms. Ateequi was unsure the payment rate for neonates who are transferred back to a community hospital for stepdown care after NICU care.

REVIEW OF PROPOSED LANGUAGE

The group reviewed the proposed language (available on the MDCH website) for the NICU CON standards to include the special care nursery service. It was first determined that the appropriate term should be "Special Care Nursery/SCN" and not a Special Newborn Care Service. "Special Care Nursery" is the term used by the AAP. The proposed language needs to reflect this correct term throughout.

Changes to the proposed language included:

- Line 14: Section 1 needs to include the newly-proposed SCNs
- Line 44: The sentence "The term includes those beds designated by the Department as special newborn nursery units (SNNU) beds, should be removed, as this designation is obsolete.
- Line 77: Should include "or less than 32 weeks"
- Line 81: Parenteral nutrition is vague, and may not be in alignment with the AAP guidelines.
- Line 122: Should be deleted, as many neonates are given prophylactic antibiotics
- Line 246: The reference to Section 5(2) should be corrected to match the new section renumbering
- Line 389: The term "credible" should be replaced with "verifiable."
- Line 411: Should be rewritten to say, "A hospital proposing to initiate a Special care Nursery service shall have a.....
- Line 406: The group agreed that the language should specify that a SCN must have a Neonatologist as its program director.
- Line 406: The group decided the term "24-hour availability" should be replaced with "continually available on-site"
- Line 406: The group suggested lines 406 and 408 be combined.
- No Line: Provisions to acquire and relocate a SCN must be added to the proposed language (Section 9)

The group discussed at length the requirement of a consulting agreement with an existing NICU. It was clarified that this consulting agreement was not commensurate with a transport agreement; SCNs may still transfer neonates to the NICU of their choice. The group discussed what services the consulting agreement must include and whether the consulting NICU would be responsible for overseeing training of staff or the quality of care at the SCN. In particular, the group expressed concerns with the breadth of Line 421, which requires the consulting NICU to assist in the development of the SCNs' care protocols. The group discussed what documentation would be required to demonstrate that an applicant has a consulting agreement in place with a NICU. It was agreed that the proposed language should be specific so that the CON Section can accurately review applications.

The group discussed the birth volume requirements for a SCN. The 1000 births (urban) /300 (rural) in the language were simply one-half the volumes required for a NICU, and not based on any scientific evidence. Brenda Rogers reminded the group that it must have a clear rationale for any volume requirements, as the CON Commission will inquire about the development of these. Some members expressed concern that a certain number of neonates is necessary to annually ensure the staff receive adequate training and experience. Several members expressed concern that the proposed language allows for different volumes for rural/micropolitan facilities, effectively acknowledging that a lower level of experience (and by inference, quality) is acceptable. Other members of the group felt such volume differences were permitted in other CON-covered services. Some members expressed concerns that volume thresholds would prohibit willing facilities from developing SCN programs, and expressed concern that this was contrary to the spirit of the intent of creating SCN language.

NEXT STEPS

Commissioner Landstrom asked all workgroup participants to send other recommendations or changes to the proposed language to her before June 5, 2013. Submissions should be sent to: landstrg@trinity-health.org

AGENDA FOR NEXT MEETING

The group identified the following needs for additional information for discussion at the next workgroup meetings:

- Continued discussion of volume requirements for SCNs, if any
- Outcomes metrics to be added to any proposed CON language
- Other project delivery requirements

NEXT MEETING

The next meeting will be held on:

June 27 @ 9am Capital View Building, Conf. Rms B/C, Lansing

Persons interested in joining the workgroup discussion via phone should contact Brenda Rogers at rogersb1@michigan.gov for call-in information. Please also check the CON Meetings website page for meeting materials.