

1 | MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2
3 | CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR
4 | NEONATAL INTENSIVE CARE SERVICES/BEDS

5
6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)
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10 | **Section 1. Applicability**

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12 | ~~Sec. 1. (1) These standards are requirements for the approval OF THE INITIATION, EXPANSION,~~
13 | ~~RELOCATION, OR REPLACEMENT OF NEONATAL INTENSIVE CARE SERVICES/BEDS and THE~~
14 | ~~delivery of NEONATAL INTENSIVE CARE services/BEDS for all projects approved and Certificates of~~
15 | ~~Need issued under Part 222 of the Code which involve neonatal intensive care services/beds.~~
16 | ~~PURSUANT TO PART 222 OF THE CODE, NEONATAL INTENSIVE CARE SERVICES/BEDS~~

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18 | ~~(2) The initiation, expansion, relocation, or replacement of neonatal intensive care services/beds is a~~
19 | ~~covered clinical service for purposes of Part 222 of the Code.~~

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21 | ~~(3) The Department shall use sections 3, 4, 5, 6, 7, and 8, as applicable, these standards in applying~~
22 | ~~Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

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24 | ~~(4) The Department shall use Section 11, as applicable, in applying and Section 22225(2)(c) of the~~
25 | ~~Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

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27 | ~~(5) The Department shall use Section 10, as applicable, in applying Section 22215(1)(b) of the Code,~~
28 | ~~being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

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30 | **Section 2. Definitions**

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

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

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

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

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

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

45 | (f) "Department" means the Michigan Department of Community Health (MDCH).

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

49 | (h) "Existing NICU beds" means the total number of all of the following:

50 | (i) licensed hospital beds designated for NICU services;

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

52 | (iii) NICU beds under appeal from a final decision of the Department; and

- 53 (iv) proposed NICU beds that are part of an application for which a proposed decision has been
54 issued, but is pending final Department decision. The term includes those beds designated by the
55 Department as special newborn nursery unit (SNNU) beds.
- 56 (i) "Expansion of NICU services" means increasing the number of hospital beds designated for
57 NICU services at a licensed site.
- 58 (j) "Hospital" means a health facility licensed under Part 215 of the Code.
- 59 (k) "Initiation of NICU services" means the establishment of a NICU at a licensed site that has not
60 had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a
61 NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements
62 of Section 6 shall not be considered as the initiation of NICU services/beds.
- 63 (l) "Infant" means an individual up to 1 year of age.
- 64 (m) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by
65 license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites,
66 the location of each separate and distinct inpatient unit of the health facility as authorized by license and
67 listed on that licensee's certificate of licensure.
- 68 (n) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed
69 pursuant to Section 333.2821(2) of the Michigan Compiled Laws.
- 70 (o) "Maternal referral service" means having a consultative and patient referral service staffed by a
71 physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in
72 maternal/fetal medicine.
- 73 (p) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
74 and 1396r-8 to 1396v.
- 75 (q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as
76 that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
77 the statistical policy office of the office of information and regulatory affairs of the United States office of
78 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 79 (r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as
80 that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
81 the statistical policy office of the office of information and regulatory affairs of the United States office of
82 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 83 (s) "Neonatal intensive care services" or "NICU services" means the provision of any of the following
84 services:
- 85 (i) constant nursing care and continuous cardiopulmonary and other support services for severely ill
86 infants;
- 87 (ii) care for neonates weighing less than 1,500 grams at birth;
- 88 (iii) ventilatory support beyond that needed for immediate ventilatory stabilization;
- 89 (iv) surgery and post-operative care during the neonatal period;
- 90 (v) pharmacologic stabilization of heart rate and blood pressure; or
- 91 (vi) parenteral nutrition.
- 92 (t) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit
93 of a hospital which is both capable of providing neonatal intensive care services and is composed of
94 licensed hospital beds designated as NICU. This term does not include bassinets or special newborn
95 care bassinets.
- 96 (u) "Neonatal transport system" means a specialized transfer program for neonates by means of an
97 ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.
- 98 (v) "Neonate" means an individual up to 28 days of age.
- 99 (w) "Perinatal care network," means the providers and facilities within a planning area that provide
100 basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.
- 101 (x) "Planning area" means the groups of counties shown in Section 12.
- 102 (y) "Planning year" means the most recent continuous 12 month period for which birth data is
103 available from the Vital Records and Health Data Development Section.
- 104 (z) "Qualifying project" means each application in a comparative group which has been reviewed
105 individually and has been determined by the Department to have satisfied all of the requirements of

106 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
107 applicable requirements for approval in the Code and these standards.

108 (aa) "Relocation of the designation of beds for NICU services" means a change within the same
109 planning area in the licensed site at which existing licensed hospital beds are designated for NICU
110 services.

111 (bb) "Replacement of NICU beds" means new physical plant space being developed through new
112 construction or newly acquired space (purchase, lease or donation), to house existing licensed and
113 designated NICU beds.

114 (cc) "Replacement zone" means a proposed licensed site which is in the same planning area as the
115 existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of
116 the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative
117 review.

118 (dd) "Special newborn care bassinets" means an unlicensed bassinet identified within the hospital
119 obstetrical or newborn service which provides the services identified in subsections (i) through (vi) for
120 infants who require minimal care that goes beyond that of the uncomplicated newborn, or transitional care
121 or developmental maturation in preparation for discharge home. Infants receiving transitional care or
122 being treated for developmental maturation may have formerly been treated in a neonatal intensive care
123 unit in the same hospital or another hospital.

124 (i) Care for low birth weight infants between 1,500 and 2,499 grams;

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 (v) 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.

131 (ee) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
132 statistical areas as those terms are defined under the "standards for defining metropolitan and
133 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
134 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
135 shown in Appendix A.

136

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

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139 **Section 3. Bed need methodology**

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

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

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

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

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

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

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

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Section 4. Requirements for applicants proposing to initiate NICU services

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

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

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

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

(4) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed 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 micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements for applicants proposing to expand NICU services

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

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

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

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

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

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.

212
213 (3) The existing licensed site from which the designation of beds for NICU services proposed to be
214 relocated is currently licensed and designated for NICU services.

215
216 (4) The proposed project does not result in an increase in the number of beds designated for NICU
217 services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

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

222
223 (6) The proposed project does not result in the operation of a NICU of less than 15 beds at the
224 existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

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

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

239
240 (8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an
241 applicant shall demonstrate both of the following:

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

251
252 (9) The project results in a decrease in the number of licensed hospital beds that are designated for
253 NICU services at the licensed site at which beds are currently designated for NICU services. The
254 decrease in the number of beds designated for NICU services shall be equal to or greater than the
255 number of beds designated for NICU services proposed to be increased at the applicant's licensed site
256 pursuant to the agreement required by this subsection. This subsection requires a decrease in the
257 number of licensed hospital beds that are designated for NICU services, but does not require a decrease
258 in the number of licensed hospital beds.

259
260 (10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless
261 the proposed project involves the relocation of all beds designated for NICU services at the applicant's
262 licensed site.

265 **Section 7. Requirements for approval for replacement of NICU beds**

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

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

273 (b) the proposed licensed site is in the replacement zone.
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275 **Section 8. Requirements for approval to acquire a NICU service**

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277 Sec. 8. (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with
278 the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU
279 subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are
280 met:

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

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

285 (c) the project does not involve the initiation, expansion or replacement of a covered clinical service,
286 a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the
287 applicant facility, unless the applicant meets other applicable sections.
288

289 **Section 9. Additional requirements for applications included in comparative reviews.**

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291 Sec. 9. (1) Any application subject to comparative review under Section 22229 of the Code, **BEING**
292 **SECTION 333.22229 OF THE MICHIGAN COMPILED LAWS,** or **UNDER** these standards, shall be
293 grouped and reviewed **COMPARATIVELY** with other applications in accordance with the CON rules
294 **applicable to comparative reviews.**
295

296 (2) Each application in a comparative review group shall be individually reviewed to determine
297 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
298 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the
299 Code and these standards. If the Department determines that one or more of the competing applications
300 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
301 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
302 defined in Section 22225(1), and which have the highest number of points when the results of subsection
303 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the
304 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
305 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an
306 application is submitted to the Department. If 2 or more qualifying projects are determined to have an
307 identical number of points and each operates a NICU at the time an application is submitted to the
308 Department, the Department shall approve those qualifying projects which, taken together, do not exceed
309 the need, as defined in Section 22225(1), in the order in which the applications were received by the
310 Department, based on the submission date and time, as determined by the Department when submitted.

311 (a) A qualifying project will have points awarded based on the geographic proximity to NICU
312 services, both operating and CON approved but not yet operational, in accordance with the following
313 schedule:
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	Points
<u>Proximity</u>	<u>Awarded</u>

318	Less than 50 Miles	0
319	to NICU service	
320	Between 50-99 miles	1
321	to NICU service	
322		
323	100+ Miles	2
324	to NICU service	
325		

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

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

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

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

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

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

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

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

352	Hospital	
353	Indigent	Points
354	<u>Volume</u>	<u>Awarded</u>
355		
356	0 - <6%	0.2
357	6 - <11%	0.4
358	11 - <16%	0.6
359	16 - <21%	0.8
360	21 - <26%	1.0
361	26 - <31%	1.2
362	31 - <36%	1.4
363	36 - <41%	1.6
364	41 - <46%	1.8
365	46% +	2.0
366		
367		

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for

371 rates in effect at the time the application is deemed submitted will be used by the Department in
372 determining the number of points awarded to each qualifying project.

373 (3) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A
374 LOWER POINT REWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH
375 COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE
376 DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE
377 AWARDED FROM CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION
378 WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION
379 WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE
380 CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL
381 AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT
382 IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO
383 RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED. The minimum
384 number of points will be awarded to an applicant under the individual subsections of this Section for
385 conflicting information presented in this section and related information provided in other sections of the
386 CON application.

387

388 **Section 10. Requirements for approval for all applicants**

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390 Sec. 10. An applicant shall provide verification of Medicaid participation. An applicant that is a new
391 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
392 to the Department within six (6) months from the offering of services if a CON is approved.

393

394 **Section 11. Project delivery requirements -- terms of approval for all applicants**

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396 Sec. 11. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance
397 with the following terms of CON approval:

398 (a) Compliance with these standards.

399 (b) Compliance with applicable operating standards.

400 (c) Compliance with the following applicable quality assurance standards:

401 (i) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

402 (A) not deny NICU services to any individual based on ability to pay or source of payment;

403 (B) provide NICU services to any individual based on clinical indications of need for the services;

404 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
405 source provided annually.

406 Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

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

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

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

418 (vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric
419 providers in the planning area.

420 (vii) An applicant shall develop and implement a system for discharge planning.

421 (viii) A board certified neonatologist shall serve as the director of neonatal services.

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

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

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

430 (xii) The applicant shall participate in a data collection network established and administered by the
431 Department or its designee. The data may include, but is not limited to, annual budget and cost
432 information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as
433 well as the volume of care provided to patients from all payor sources. The applicant shall provide the
434 required data on a separate basis for each licensed site; in a format established by the Department; and
435 in a mutually agreed upon media. The Department may elect to verify the data through on-site review of
436 appropriate records.

437 (xiii) The applicant shall provide the Department with a notice stating the date the initiation, expansion,
438 replacement or relocation of the NICU service is placed in operation and such notice shall be submitted to
439 the Department consistent with applicable statute and promulgated rules.

440 (xiv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
441 of operation and continue to participate annually thereafter.

442
443 (2) The agreements and assurances required by this section shall be in the form of a certification
444 agreed to by the applicant or its authorized agent.

445
446 **Section 12. Planning areas**

447
448 Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic boundaries
449 of the group of counties as follows:

450

451 <u>Planning</u>	
452 <u>Areas</u>	452 <u>Counties</u>
453 1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
454	
455 2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
456	
457 3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
458	
459 4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
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461 5	Genesee, Lapeer, Shiawassee
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463 6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, 464 Osceola, Oscoda, Saginaw, Sanilac, Tuscola
465	
466 7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand 467 Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, 468 Roscommon, Wexford
469	
470 8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, 471 Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft
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473 **Section 13. Department inventory of beds**

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

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

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care and Special Newborn Nursery Services/Beds approved by the Commission on ~~March 9, 2004~~ **SEPTEMBER 18, 2007** and effective on ~~June 4, 2004~~ **NOVEMBER 13, 2007**.

- (2) Projects reviewed under these standards shall be subject to comparative review except for:
- (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;
 - (b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or
 - (c) Beds requested under Section 5(2).

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**CON REVIEW STANDARDS
FOR NEONATAL INTENSIVE CARE SERVICES/BEDS**

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
United States Office of Management and Budget