

## Agenda

Michigan CON NICU Standards Workgroup

May 22, 2013

### Agenda

1. Welcome and review of agenda – Commissioner Landstrom
2. Introductions - All
3. Presentation of MDCH recommended language and review of legal recommendations (ppt) – Beth Nagel
4. Outcomes and capacity issues if Level II regulated – Sue Grady
5. Outcome metrics to be added to proposed CON language - All
6. Other options to using CON language for improving Level II care – All
7. Next steps
8. Adjourn

## NICU CON Standards Workgroup Notes

**DATE:** April 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 second meeting of the NICU Standards Workgroup. At that first meeting, the group identified several additional pieces of information that were needed to further the discussion about if and how perinatal services might be addressed by the CON standards and what recommendations for specific changes might be made if changes are deemed appropriate.

CON Commission Gay Landstrom who was leading the workgroup again encouraged participants to invite others to future workgroups.

### CURRENT STATE IN MICHIGAN

Joette Laseur, CON Section, reviewed the current CON NICU Standards. Ms. Laseur clarified that the current standards do not include bassinets or special care nurseries and are limited only to NICUs. NICUs are a special designation for a portion of a hospital's existing, licensed beds. The relocation of NICU beds only relocates the designation of the beds. The current CON standards address staffing and resource requirements but do not specifically mention "levels" of care.

Tulika Bhattacharya, CON Section Manager, discussed past CON compliance actions including visits to hospitals that do not have NICU-designated beds. Ms. Bhattacharya noted that the current annual hospital survey collects information on the number of beds and patient days, but does not collect information regarding the resource requirements specified in the project delivery requirements of the CON standards because the standards do not provide specific, measureable metrics. Ms. Bhattacharya indicated the CON Section would be willing to collect more detailed data in its compliance monitoring if specific, measureable outcomes are identified by the group.

Sue Grady, MSU Department of Geography, shared a map of self-designated Level II hospitals in Michigan and births summarized at those hospitals. During the discussion an updated list of Level II hospitals was provided by Trudy Esch, MDCH. Dr. Grady agreed to present an updated summary of births at Level II hospitals using this updated hospital list at the next meeting.

### RECENT CHANGES IN NATIONAL STANDARDS

The American Academy of Pediatrics has issued new definitions for the levels of care for newborns. It was clarified that the AAP does not change these definitions frequently, and has not changed its definition since 1997.

The group briefly discussed a 2011 article that found that states with CON regulation of NICUs had more efficient delivery of neonatal care. This article reference is: *SA Lorch, P Maheshwari, and Even-Shoshan. "The impact of certificate of need programs on neonatal intensive care units" The Journal of Perinatology April 2011: 39-44*

The group supported the concept that Level II nurseries should be required to have a formal relationship with a regional NICU for purposes of education and monitoring. It was clarified that such a relationship would not dictate referral patterns. Other CON standards require similar inter-hospital requirements.

The group discussed whether it should also put forth recommendations for Level I nurseries. After some discussion it was agreed that the focus would be on Level II nurseries, although there certainly is the desire that Level I nurseries establish relationships with higher level neonatal providers.

It was suggested that recommendations, such as delivery requirements or staffing, made for Level II nurseries also be applied to existing NICUs as appropriate.

The group concurred that any changes to the CON standards should be aligned with the AAP definitions, with a focus on quality and safety. Much discussion occurred regarding the specifics within the AAP definitions, including whether the requirements for staffing for Level II nurseries (neonatologist, neonatal nurse practitioner and pediatric hospitals) implied these staff must be onsite 24/7 or available for consultation within a specific time period, and if all three types of staff would be required or some combination thereof. There was discussion regarding how strict staffing requirements could cause some nurseries to accept Level I status, and the group discussed the possible impact of more babies being transferred to already-busy NICUs if this resulted. The participants with NICUs were asked to consider whether they had sufficient capacity to care for additional babies if such transfers increased.

### **PAYOR PERSPECTIVE ON NURSERY LEVELS**

Umbrin Ateequi, BCBS, noted that BCBS does not distinguish between levels of care in its payments and does not desire to get into the business of evaluating neonates. She could not speak for other payors and their practices. The group discussed insurance-related barriers to appropriate transfers. Several people asked for more information on how payments are split between providers when transfers occur.

### **REVIEW OF OPTIONS**

Several options were put forth. Providence Park indicated that it had used education to ensure obstetricians were not delivering babies less than 32 weeks at its facility. Others suggested increased monitoring through data sharing; however it was agreed that not all facilities participate in the most common database by Vermont Oxford Network, and that the costs of participation might be prohibitive for some facilities. Others again recommended a mechanism which would increase collaboration between Level II programs and existing NICUs.

Ms. Bhattacharya offered that if special care nurseries were to be regulated under CON, it would be regulated as a new service, and not based on bed designation as NICU beds are currently regulated. This would eliminate the need to determine bed need for special care nurseries.

Bob Meeker, Spectrum Health, walked through some potential-proposed CON standards language that could be applied to Level II nursery services. He noted that this proposal was modeled on the existing CON standards for NICU beds and included provisions for a consulting agreement with a NICU service and also included some of the requirements of the AAP. The group again discussed the intent of the AAP's definitions and requirements for staffing and whether Michigan should use AAP as its baseline, with the possibility of having an even higher standard. Several expressed interest in including outcomes metrics in the project delivery requirements and as part of the consulting relationship Level II nurseries would have with NICUs. There was also discussion regarding C-pap services, and whether it would be appropriate to for CON standards to include a time limit for C-pap care in a Level II nursery.

### **AGENDA FOR NEXT MEETING**

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

- Capacity at existing NICUs if more babies were transferred to them as a consequence of new Level II CON requirements
- Outcomes metrics to be added to any proposed CON language
- A revised version of the proposed language presented by Mr. Meeker which includes other technical changes the CON Section might make to the existing NICU CON Standards
- A discussion of the process by which services currently providing this level of care could/should/must become CON approved

### **NEXT MEETING**

The next meeting date has been changed and now will be held on:

May 22 @ 1pm Capital View Building, Conf. Rms B/C, Lansing

Additional workgroup meetings will be scheduled if needed. Persons interested in joining the workgroup discussion via phone should contact Brenda Rogers at [rogersb1@michigan.gov](mailto:rogersb1@michigan.gov) for call-in information. Please also check the CON Meetings website page for meeting materials.

## MDCH Proposed Process for Approving CONs for Special Newborn Care Services (SNC)

### Assumptions

- SNC services are considered a Level II NICU service
- SNCs are not currently regulated by CON
- No one in Michigan holds a CON for an SNC
- SNC services are a new service within CON
- All providers of SNC services will need to obtain a CON

## Proposed Process

- All SNCs will have to apply for a CON to continue operations within ## months of the effective date of the standards
  - SNCs will be allowed to continue service within the ## month window of time until the application is processed
- All SNCs will need to meet the initiation criteria and the project delivery requirements that are specific to SNCs within the NICU standards (as opposed to the entire NICU standard as noted in the standard)
- After the ## month window, all SNCs will be subject to CON standards, compliance

## Proposed Process



## Points of Clarification

- All programs believed to be an SNC will need to apply for a CON
- CON approved NICU programs will not need to apply for a CON for any SNC programs within the same physical location as the NICU program.
- MDCH will provide a window of time for all proposed SNCs to meet the standards
- Proposed SNCs will not be required to discontinue service while applications are being processed
- SNCs will be considered a service and bassinets will not count against the number of licensed beds within a facility

**KEY:**

Red text = technical changes by MDCH

Grey Highlight = Insertion from 4/22 NICU Workgroup

Aqua Highlight = Changes by MDCH re: SNCs

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

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

(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. Pursuant to Part 222 of the Code, neonatal intensive care services/beds ~~is~~ ARE a covered clinical service. 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.

(h) "Expansion of NICU services" means increasing the number of hospital beds designated for NICU services at a licensed site.

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

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

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

54 | ~~(ml)~~ "Licensed site" means in the case of a single site hospital, the location of the facility authorized by  
55 | license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites,  
56 | the location of each separate and distinct inpatient unit of the health facility as authorized by license and  
57 | listed on that licensee's certificate of licensure.

58 | ~~(am)~~ "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed  
59 | pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

60 | ~~(en)~~ "Maternal referral service" means having a consultative and patient referral service staffed by a  
61 | physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in  
62 | maternal/fetal medicine.

63 | ~~(po)~~ "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396f-6 and 1396f-  
64 | 8 to 1396v1396w-5.

65 | ~~(q)~~ "Metropolitan statistical area county" means a county located in a metropolitan statistical area as  
66 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
67 | the statistical policy office of the office of information and regulatory affairs of the United States office of  
68 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

69 | ~~(r)~~ "Micropolitan statistical area county" means a county located in a micropolitan statistical area as  
70 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
71 | the statistical policy office of the office of information and regulatory affairs of the United States office of  
72 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

73 | ~~(sp)~~ "Neonatal intensive care services" or "NICU services" means the provision of any of the following  
74 | services:  
75 | (i) constant nursing care and continuous cardiopulmonary and other support services for severely ill  
76 | infants;  
77 | (ii) care for neonates weighing less than 1,500 grams at birth;  
78 | (iii) ventilatory support beyond that needed for immediate ventilatory stabilization;  
79 | (iv) surgery and post-operative care during the neonatal period;  
80 | (v) pharmacologic stabilization of heart rate and blood pressure; or  
81 | (vi) parenteral nutrition.

82 | ~~(tq)~~ "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of  
83 | a hospital which is both capable of providing neonatal intensive care services and is composed of licensed  
84 | hospital beds designated as NICU. This term does not include bassinets or special newborn care  
85 | bassinets.

86 | ~~(ur)~~ "Neonatal transport system" means a specialized transfer program for neonates by means of an  
87 | ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

88 | ~~(vs)~~ "Neonate" means an individual up to 28 days of age.

89 | ~~(wt)~~ "Perinatal care network," means the providers and facilities within a planning area that provide  
90 | basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

91 | ~~(xu)~~ "Planning area" means the groups of counties shown in Section 12.

92 | ~~(yv)~~ "Planning year" means the most recent continuous 12 month period for which birth data is  
93 | available from the Vital Records and Health Data Development Section.

94 | ~~(zw)~~ "Qualifying project" means each application in a comparative group which has been reviewed  
95 | individually and has been determined by the Department to have satisfied all of the requirements of  
96 | Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other  
97 | applicable requirements for approval in the Code and these standards.

98 | ~~(aax)~~ "Relocation of the designation of beds for NICU services" means a change within the same  
99 | planning area in the licensed site at which existing licensed hospital beds are designated for NICU  
100 | services.

101 | ~~(bby)~~ "Replacement of NICU beds" means new physical plant space being developed through new  
102 | construction or newly acquired space (purchase, lease or donation), to house existing licensed and  
103 | designated NICU beds.

104 | ~~(eez)~~ "Replacement zone" means a proposed licensed site which is in the same planning area as the  
105 | existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of

106 the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative  
107 review.  
108 (dda) "Special newborn care ~~bassinets~~"SERVICES" OR "SNC" means ~~an unlicensed bassinets identified~~  
109 ~~within the hospital obstetrical or newborn service which provides~~ PROVISIONS OF the services identified  
110 in subsections (i) through (vi) for infants WITH PROBLEMS THAT ARE EXPECTED TO RESOLVE  
111 RAPIDLY AND who WOULD NOT BE ANTICIPATED TO NEED SUBSPECIALTY SERVICES ON AN  
112 URGENT BASIS ~~require minimal care that goes beyond that of the uncomplicated newborn, or transitional~~  
113 ~~care or developmental maturation in preparation for discharge home. REFERRAL TO A HIGHER LEVEL~~  
114 ~~OF CARE SHOULD OCCUR FOR ALL INFANTS WHO NEED PEDIATRIC SURGICAL OR MEDICAL~~  
115 ~~SUBSPECIALTY INTERVENTION.~~ Infants receiving transitional care or being treated for developmental  
116 maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or  
117 another hospital.

- 118 (i) Care for low birth weight infants ~~between weighing 1,500 and 2,499 grams or more;~~ AND/OR  
119 ~~GREATER THAN OR EQUAL TO 32 WEEKS GESTATION;~~
- 120 (ii) enteral tube feedings;
- 121 (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
- 122 (iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;
- 123 (v) extended care following an admission to a neonatal intensive care unit for an infant not requiring  
124 ventilatory support; or
- 125 (vi) ~~the administration of oxygen by hood or nasal canula~~ PROVIDE MECHANICAL VENTILATION  
126 ~~FOR BRIEF DURATION (LESS THAN 24 HOURS) OR CONTINUOUS POSITIVE AIRWAY PRESSURE~~  
127 ~~OR BOTH;~~

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

133  
134 (2) The definitions in Part 222 shall apply to these standards.

### 135 136 Section 3. Bed need methodology

137  
138 Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following  
139 formula:

- 140 (a) Determine, using data obtained from the Vital Records and Health Data Development Section, the  
141 total number of live births which occurred in the planning year at all hospitals geographically located within  
142 the planning area.
- 143 (b) Determine, using data obtained from the Vital Records and Health Data Development Section, the  
144 percent of live births in each planning area and the state that were less than 1,500 grams. The result is  
145 the very low birth weight rate for each planning area and the state, respectively.
- 146 (c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight  
147 rate. The result is the very low birth weight rate adjustment factor for each planning area.
- 148 (d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The  
149 result is the bed need formula for each planning area adjusted for the very low birth weight rate.
- 150 (e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for  
151 the applicable planning area adjusted for the very low birth weight adjustment factor as determined in  
152 subsection (1)(d).

153  
154 (2) The result of subsection (1) is the number of NICU beds needed in the planning area for the  
155 planning year.

### 156 157 Section 4. Requirements ~~for applicants proposing to initiate NICU services~~

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Comment [A1]: Aqua Highlight changes were made to make language in definition of SNC consistent with the AAP Policy Statement on Levels of Neonatal Care

159 Sec. 4. An applicant proposing to initiate NICU services by designating hospital beds as NICU beds  
160 shall demonstrate each of the following:  
161 (1) There is an unmet bed need of at least 15 NICU beds based on the difference between the  
162 number of existing NICU beds in the planning area and the number of beds needed for the planning year  
163 as a result of application of the methodology set forth in Section 3.  
164 (2) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area  
165 based on the difference between the number of existing NICU beds in the planning area and the number  
166 of beds needed for the planning year resulting from application of the methodology set forth in Section 3.  
167 (3) A unit of at least 15 beds will be developed and operated.  
168 (4) For each of the 3 most recent years for which birth data are available from the Vital Records and  
169 Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or  
170 more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more  
171 live births, if the licensed site is located in a rural or micropolitan statistical area county and is located  
172 more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON  
173 approval to operate NICU services.

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**Section 5. Requirements ~~for applicants proposing to expand~~ REPLACE NICU services**

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

- (a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and
- (b) the proposed licensed site is in the replacement zone.

**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.

212 (7) If the applicant licensed site does not currently provide NICU services, an applicant shall  
213 demonstrate both of the following:  
214 (a) the proposed project involves the establishment of a NICU of at least 15 beds; and  
215 (b) for each of the 3 most recent years for which birth data are available from the Vital Records and  
216 Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the  
217 licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the  
218 licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles  
219 from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If  
220 the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the  
221 applicant licensed site was established as the result of the consolidation and closure of 2 or more  
222 obstetrical units, the combined number of live births from the obstetrical units that were closed and  
223 relocated to the applicant licensed site may be used to evaluate compliance with this requirement for  
224 those years when the applicant licensed site was not in operation.  
225  
226 (8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an  
227 applicant shall demonstrate both of the following:  
228 (a) the proposed project involves the establishment of a NICU of at least 15 beds; and  
229 (b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the  
230 NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing  
231 obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital  
232 Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or  
233 more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or  
234 (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan  
235 statistical area county and is located more than 100 miles from the nearest licensed site that operates or  
236 has valid CON approval to operate NICU services.  
237  
238 (9) The project results in a decrease in the number of licensed hospital beds that are designated for  
239 NICU services at the licensed site at which beds are currently designated for NICU services. The  
240 decrease in the number of beds designated for NICU services shall be equal to or greater than the  
241 number of beds designated for NICU services proposed to be increased at the applicant's licensed site  
242 pursuant to the agreement required by this subsection. This subsection requires a decrease in the  
243 number of licensed hospital beds that are designated for NICU services, but does not require a decrease  
244 in the number of licensed hospital beds.  
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246 (10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless the  
247 proposed project involves the relocation of all beds designated for NICU services at the applicant's  
248 licensed site.  
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250  
251 ~~—Sec. 5. (1) An applicant proposing to expand NICU services by designating additional hospital beds as~~  
252 ~~NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of~~  
253 ~~NICU beds based on the difference between the number of existing NICU beds in the planning area and~~  
254 ~~the number of beds needed for the planning year resulting from application of the methodology set forth in~~  
255 ~~Section 3.~~  
256  
257 ~~—(2) An applicant may apply and be approved for NICU beds in excess of the number determined as~~  
258 ~~needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides~~  
259 ~~NICU services to patients transferred from another licensed and designated NICU. The maximum~~  
260 ~~number of NICU beds that may be approved pursuant to this subsection shall be determined in~~  
261 ~~accordance with the following:~~  
262 ~~—(a) An applicant shall document the average annual number of patient days provided to neonates or~~  
263 ~~infants transferred from another licensed and designated NICU, for the 2 most recent years for which~~  
264 ~~verifiable data are available to the Department.~~

265 ~~—(b) The average annual number of patient days determined in accordance with subsection (a) shall~~  
266 ~~be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services~~  
267 ~~provided to patients transferred from another licensed and designated NICU.~~  
268 ~~—(c) Apply the ADC determined in accordance with subsection (b) in the following formula:  $ADC \div$~~   
269 ~~2.06  $\div$  ADC. The result is the maximum number of beds that may be approved pursuant to this subsection~~  
270 ~~up to 5 beds at each licensed site.~~

271  
272 **Section 6. Requirements for approval to relocate NICU beds**

273  
274 ~~—Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate~~  
275 ~~compliance with all of the following:~~

276  
277 ~~—(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU~~  
278 ~~services is proposed.~~

279  
280 ~~—(2) The applicant shall provide a signed written agreement that provides for the proposed increase,~~  
281 ~~and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites~~  
282 ~~involved in the proposed relocation. A copy of the agreement shall be provided in the application.~~

283  
284 ~~—(3) The existing licensed site from which the designation of beds for NICU services proposed to be~~  
285 ~~relocated is currently licensed and designated for NICU services.~~

286  
287 ~~—(4) The proposed project does not result in an increase in the number of beds designated for NICU~~  
288 ~~services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.~~

289  
290 ~~—(5) The proposed project does not result in an increase in the number of licensed hospital beds at the~~  
291 ~~applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital~~  
292 ~~Beds have also been met.~~

293  
294 ~~—(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the~~  
295 ~~existing licensed site from which the designation of beds for NICU services are proposed to be relocated.~~

296  
297 ~~—(7) If the applicant licensed site does not currently provide NICU services, an applicant shall~~  
298 ~~demonstrate both of the following:~~

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

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

310  
311 ~~—(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an~~  
312 ~~applicant shall demonstrate both of the following:~~

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

314 ~~—(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the~~  
315 ~~NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing~~  
316 ~~obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital~~  
317 ~~Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or~~

318 ~~more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or~~  
319 ~~(ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan~~  
320 ~~statistical area county and is located more than 100 miles from the nearest licensed site that operates or~~  
321 ~~has valid CON approval to operate NICU services.~~

322  
323 ~~— (9) The project results in a decrease in the number of licensed hospital beds that are designated for~~  
324 ~~NICU services at the licensed site at which beds are currently designated for NICU services. The~~  
325 ~~decrease in the number of beds designated for NICU services shall be equal to or greater than the~~  
326 ~~number of beds designated for NICU services proposed to be increased at the applicant's licensed site~~  
327 ~~pursuant to the agreement required by this subsection. This subsection requires a decrease in the~~  
328 ~~number of licensed hospital beds that are designated for NICU services, but does not require a decrease~~  
329 ~~in the number of licensed hospital beds.~~

330  
331 ~~— (10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless the~~  
332 ~~proposed project involves the relocation of all beds designated for NICU services at the applicant's~~  
333 ~~licensed site.~~

334  
335

336 **Section 7. Requirements for approval for replacement of NICU beds REQUIREMENTS FOR**  
337 **APPROVAL TO EXPAND NICU SERVICES**

338  
339  
340 Sec. 7. (1) An applicant proposing to expand NICU services by designating additional hospital beds as  
341 NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of  
342 NICU beds based on the difference between the number of existing NICU beds in the planning area and  
343 the number of beds needed for the planning year resulting from application of the methodology set forth in  
344 Section 3.

345  
346 (2) An applicant may apply and be approved for NICU beds in excess of the number determined as  
347 needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides  
348 NICU services to patients transferred from another licensed and designated NICU. The maximum  
349 number of NICU beds that may be approved pursuant to this subsection shall be determined in  
350 accordance with the following:

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

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

357 (c) Apply the ADC determined in accordance with subsection (b) in the following formula:  $ADC +$   
358  $2.06 \sqrt{ADC}$ . The result is the maximum number of beds that may be approved pursuant to this subsection  
359 up to 5 beds at each licensed site.

360

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

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

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

368

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

370

371 Sec. 8. "Acquisition of a NICU" means obtaining possession and control of existing licensed hospital  
372 beds designated for NICU services by contract, ownership, lease or other comparable arrangement.  
373

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

- 378 (a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds  
379 designated for NICU services, at the licensed site to be acquired;
- 380 (b) the licensed site does not change as a result of the acquisition, unless the applicant meets  
381 Section 6; and,
- 382 (c) the project does not involve the initiation, expansion or replacement of a covered clinical service,  
383 a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the  
384 applicant facility, unless the applicant meets other applicable sections.

385  
386 **SECTION 9. REQUIREMENTS TO INITIATE SNC SERVICES**  
387

388 **SEC. 9. AN APPLICANT PROPOSING TO INITIATE SNC SERVICES SHALL DEMONSTRATE**  
389 **EACH OF THE FOLLOWING BY CREDIBLE DOCUMENTATION:**

390  
391 (1) **SUBMIT A REPORT FOR EACH OF THE 3 MOST RECENT YEARS FOR WHICH BIRTH DATA**  
392 **ARE AVAILABLE FROM THE VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION**  
393 **WITHIN THE DEPARTMENT, THE LICENSED SITE AT WHICH THE SNC SERVICE IS PROPOSED**  
394 **HAD EITHER:**

- 395 (I) **1,000 OR MORE LIVE BIRTHS IF THE LICENSED SITE IS LOCATED IN A METROPOLITAN**  
396 **STATISTICAL AREA COUNTY; OR**
- 397 (II) **300 OR MORE LIVE BIRTHS IF THE LICENSED SITE IS LOCATED IN A RURAL OR**  
398 **MICROPOLITAN STATISTICAL AREA COUNTY AND IS LOCATED MORE THAN 100 MILES**  
399 **(SURFACE TRAVEL) FROM THE NEAREST LICENSED SITE THAT OPERATES OR HAS A VALID**  
400 **CON APPROVAL TO OPERATE NICU SERVICES.**

401  
402 (2) **THE HOSPITAL HAS THE FOLLOWING CAPABILITIES AND PERSONNEL:**

- 403 (A) **THE ABILITY TO PROVIDE MECHANICAL VENTILATION AND/OR CONTINUOUS POSITIVE**  
404 **AIRWAY PRESSURE FOR UP TO 24 HOURS;**
- 405 (B) **AVAILABILITY OF PORTABLE X-RAY EQUIPMENT AND BLOOD GAS ANALYZER;**
- 406 (C) **24-HOUR AVAILABILITY OF PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE**  
407 **PRACTITIONERS; AND**
- 408 (D) **SPECIALIZED NURSES, RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, AND**  
409 **LABORATORY TECHNICIANS WITH EXPERIENCE CARING FOR PREMATURE INFANTS.**

410  
411 (3) **A HOSPITAL PROPOSING TO INITIATE SNC SERVICES AS A NEW SERVICE SHALL HAVE A**  
412 **WRITTEN CONSULTING AGREEMENT WITH A HOSPITAL WHICH HAS AN EXISTING ACTIVE NICU**  
413 **ADMITTING A MINIMUM OF XXX PATIENTS PER YEAR FOR THE THREE MOST RECENT**  
414 **CONSECUTIVE YEARS. THE AGREEMENT MUST SPECIFY THAT THE EXISTING SERVICE SHALL,**  
415 **FOR THE FIRST TWO YEARS OF OPERATION OF THE NEW SERVICE, PROVIDE THE FOLLOWING**  
416 **SERVICES TO THE APPLICANT HOSPITAL:**

- 417 (A) **RECEIVE AND MAKE RECOMMENDATIONS ON THE PROPOSED DESIGN OF SNC AND**  
418 **SUPPORT AREAS THAT MAY BE REQUIRED;**
- 419 (B) **PROVIDE STAFF TRAINING RECOMMENDATIONS FOR ALL PERSONNEL ASSOCIATED**  
420 **WITH THE NEW PROPOSED SERVICE;**
- 421 (C) **ASSIST IN DEVELOPING APPROPRIATE PROTOCOLS FOR THE CARE AND TRANSFER, IF**  
422 **NECESSARY, OF PREMATURE INFANTS;**

**Comment [A2]:** Aqua Highlight changes were made to make language in definition of SNC consistent with the AAP Policy Statement on Levels of Neonatal Care

423 (D) PROVIDE RECOMMENDATIONS ON STAFFING NEEDS FOR THE PROPOSED SERVICE;  
424 AND  
425 (E) WORK WITH THE MEDICAL STAFF AND GOVERNING BODY TO DESIGN AND IMPLEMENT  
426 A PROCESS THAT WILL ANNUALLY MEASURE, EVALUATE, AND REPORT TO THE MEDICAL  
427 STAFF AND GOVERNING BODY THE CLINICAL OUTCOMES OF THE NEW SERVICE, INCLUDING:  
428 (i) MORTALITY RATES  
429 (ii) COMPLICATION RATES  
430 (iii) SUCCESS RATES, AND  
431 (iv) INFECTION RATES  
432  
433 (4) SNC SERVICES SHALL BE PROVIDED IN UNLICENSED BASSINETS IDENTIFIED LOCATED  
434 WITHIN THE HOSPITAL OBSTETRICAL DEPARTMENT OR NEWBORNNICU SERVICE.  
435  
436

437 **Section 910. Additional requirements for applications included in comparative reviews.**  
438

439 Sec. 109. (1) Any application subject to comparative review under Section 22229 of the Code, being  
440 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and  
441 reviewed comparatively with other applications in accordance with the CON rules.  
442

443 (2) Each application in a comparative review group shall be individually reviewed to determine  
444 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section  
445 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the  
446 Code and these standards. If the Department determines that one or more of the competing applications  
447 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The  
448 Department shall approve those qualifying projects which, taken together, do not exceed the need, as  
449 defined in Section 22225(1), and which have the highest number of points when the results of subsection  
450 (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the  
451 Department shall approve those qualifying projects which, taken together, do not exceed the need, as  
452 defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an  
453 application is submitted to the Department. If 2 or more qualifying projects are determined to have an  
454 identical number of points and each operates a NICU at the time an application is submitted to the  
455 Department, the Department shall approve those qualifying projects which, taken together, do not exceed  
456 the need, as defined in Section 22225(1), in the order in which the applications were received by the  
457 Department, based on the submission date and time, as determined by the Department when submitted.

458 (a) A qualifying project will have points awarded based on the geographic proximity to NICU services,  
459 both operating and CON approved but not yet operational, in accordance with the following schedule:  
460

461		
462		Points
463	<u>Proximity</u>	<u>Awarded</u>
464		
465	Less than 50 Miles	0
466	to NICU service	
467	Between 50-99 miles	1
468	to NICU service	
469		
470	100+ Miles	2
471	to NICU service	
472		

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

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

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

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

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

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

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

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

499		
500	Hospital	
501	Indigent	Points
502	<u>Volume</u>	<u>Awarded</u>
503		
504	0 - <6%	0.2
505	6 - <11%	0.4
506	11 - <16%	0.6
507	16 - <21%	0.8
508	21 - <26%	1.0
509	26 - <31%	1.2
510	31 - <36%	1.4
511	36 - <41%	1.6
512	41 - <46%	1.8
513	46% +	2.0

514 For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its  
515 total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement  
516 Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for  
517 rates in effect at the time the application is deemed submitted will be used by the Department in  
518 determining the number of points awarded to each qualifying project.  
519

520 (3) Submission of conflicting information in this section may result in a lower point reward. If an  
521 application contains conflicting information which could result in a different point value being awarded in  
522 this section, the Department will award points based on the lower point value that could be awarded from  
523 conflicting information. For example, if submitted information would result in 6 points being awarded, but  
524 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the  
525 conflicting information does not affect the point value, the Department will award points accordingly. For  
526 example, if submitted information would result in 12 points being awarded and other conflicting information  
527 would also result in 12 points being awarded, then 12 points will be awarded.  
528

529 | **Section 4011. Requirements for approval for all applicants MEDICAID PARTICIPATION**

531 | Sec. 4011. An applicant for NICU SERVICES AND SNC SERVICES shall provide verification of  
532 Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify  
533 that proof of Medicaid participation will be provided to the Department within six (6) months from the  
534 offering of services if a CON is approved.  
535

536 | **Section 4412. Project delivery requirements --AND terms of approval for all applicants**

538 Sec. 4412. (4) An applicant shall agree that, if approved, the project NICU AND SNC SERVICES shall  
539 be delivered in compliance with the following terms of CON approval:

540 (a1) Compliance with these standards.

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

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

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

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

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

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

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

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

556 (G) A board certified neonatologist shall serve as the director of neonatal services.

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

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

562 (J) An applicant shall develop and maintain plans for the provision of transferring infants discharged  
563 from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services  
564 but unable to be discharged home.  
565

566 (3) COMPLIANCE WITH THE FOLLOWING APPLICABLE QUALITY ASSUARANCE FOR SNC  
567 SERVICES:

569 (i4) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

570 ~~An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~

571 (Aa) THE NICU AND SNC SERVICES shall participate in Medicaid at least 12 consecutive months  
572 within the first two years of operation and continue to participate annually thereafter.

573 (Bb) THE NICU AND SNC SERVICES SHALL not deny NICU and SNC services to any individual  
574 based on ability to pay or source of payment.

575 (Bc) THE NICU AND SNC SERVICES SHALL provide NICU and SNC services to any individual based  
576 on clinical indications of need for the services.

577 (Cd) THE NICU AND SNC SERVICES SHALL maintain information by payor and non-paying sources  
578 to indicate the volume of care from each source provided annually.

579 (Ee) Compliance with selective contracting requirements shall not be construed as a violation of this  
580 term.

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

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

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

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

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

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

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

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

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

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

603 (5) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

604 (xiiiA) The applicant NICU AND SNC SERVICES shall participate in a data collection network  
605 established and administered by the Department or its designee. The data may include, but is not limited to,  
606 annual budget and cost information, operating schedules, THROUGH-PUT SCHEDULES, and  
607 demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to  
608 patients from all payor sources. The applicant shall provide the required data on a separate basis for  
609 each licensed site; in a format established by the Department; and in a mutually agreed upon media. The  
610 Department may elect to verify the data through on-site review of appropriate records.

611 (xiiiB) The applicant NICU AND SNC SERVICES shall provide the Department with a TIMELY notice  
612 stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in  
613 operation and such notice shall be submitted to the Department OF THE PROPOSED PROJECT  
614 IMPLEMENTATION consistent with applicable statute and promulgated rules.

615 ~~(xivC) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years  
616 of operation and continue to participate annually thereafter.~~

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

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

621 | **Section 12. Planning areas**

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

624 | **Planning**

625 | ~~Areas~~ ~~Counties~~

626 | ~~1 Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne~~

627 | ~~2 Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee~~

628 | ~~3 Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren~~

629 | ~~4 Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa~~

630 | ~~5 Genesee, Lapeer, Shiawassee~~

631 | ~~6 Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw,~~  
632 | ~~Osceola, Oscoda, Saginaw, Sanilac, Tuscola~~

633 | ~~7 Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand~~  
634 | ~~Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle,~~  
635 | ~~Roscommon, Wexford~~

636 | ~~8 Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce,~~  
637 | ~~Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft~~

638 | **Section 13. Department inventory of beds**

639 | Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning  
640 | area.

641 |

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

655

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

659

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

661 (a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section

662 333.22229(3) of the Michigan Compiled Laws;

663 (b) The designation of beds for NICU services being relocated pursuant to Section 6 of these

664 standards; or

665 (c) Beds requested under Section 5(2).

**APPENDIX A**

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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

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**APPENDIX B**

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

**Planning**

<b><u>Areas</u></b>	<b><u>Counties</u></b>
<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>