NICU Workgroup Meeting

June 4, 2020

Meeting Summary

**Attendees:**

Ascension Michigan

Beaumont Health

Trinity Health

Spectrum Health

Munson Health

University of Michigan Health System

McLaren

Henry Ford Health System

Michigan Department of Health and Human Services

**I. Call to Order**

**II. Charge 1 – High Flow Nasal Cannula Treatment as Accepted Services for Special Care Nurseries – Review of Survey Results**

The survey related to the use of high flow nasal cannula treatment was sent to all Special Care Nurseries in March, but unfortunately only 3 responses had been received as of June 3, 2020. The chair ran through the responses received thus far but the group agreed it would be best to wait for more responses before discussing the results and coming to any conclusions. The chair will be working with workgroup participants to confirm email addresses and encourage more participation. It was reiterated that the survey results will only be used to inform and guide the workgroup discussion on this topic and will not be used punitively. Dr. Oca plans to send out survey results prior to the July meeting.

**III. Charge 4 – Occupancy Requirements and High Occupancy Provisions for NICU – Subcommittee Update**

The workgroup reviewed language provided by the subgroup formed to review this charge. The subgroup recommended allowing a NICU operating at 80% occupancy or higher for at least 24 months to add NICU beds. The applicant would be allowed to add enough NICU beds to bring their occupancy down to 70% or 5 beds, whichever is higher.

The workgroup discussed whether this would replace the current provision or be added so that applicants would have both options. After some discussion and the realization that the formulas result in a very similar number of beds allowed, the workgroup agreed that this provision would replace the existing high occupancy provision.

**IV. Charge 5 – Minimum NICU Size Exception for Rural or Micropolitan Counties – Review of Draft Language**

The workgroup reviewed language provided by the Department that would decrease the minimum size for facilities located in rural and micropolitan counties from 15 beds to 10. The language also included a

provision that would allow any applicant to request a waiver of the minimum bed size if appropriate or necessary to assure access to healthcare services.

The group discussed the possibility of limiting the waiver language to just rural/micropolitan counties, but some members raised concern that there could be an access concern in a metropolitan area. The Department expressed their concerns with flexibility, such as this, in CON standards generally but indicated that if the workgroup felt it was the best solution to provide the State with discretion they would not oppose. The workgroup discussed the possibility of including specific criteria for the waiver option that the State could use in reviewing a waiver request.

Members of the workgroup urged the group to keep quality of care at the highest level of consideration in making recommendations on this charge. Studies have shown that volume is closely linked to quality in NICU services.

The workgroup agreed to have a subgroup review this charge and bring back a recommendation at the July meeting.

**V. Charge 6 – Definition of NICU Services in Section 2 - Discussion**

The workgroup reviewed language brought forward by the Department which makes it clear that the 24-hour limitation applies to mechanical ventilation only, and not to CPAP. There was a fair amount of discussion, and even some disagreement about whether not the AAP guidelines limit the use of CPAP to 24-hours.

That led to discussion on what kind of limitations could or should be added to the use of CPAP and HFNC at SCNs. The group agreed to continue those discussions once we have the results from the HFNC survey at the July meeting.

Representatives of Henry Ford Health System also proposed that the 24-hour limit be clarified to require that a request for transfer be made within 24 hours, rather than transfer completed within 24 hours. The Department agreed to include that clarification in the draft language for the July meeting.

**VI. Review of Assignments & Next Steps**

The Workgroup agreed to the following assignments/next steps:

- Melissa Reitz will lead a subgroup to discuss Charge 5 regarding minimum NICU size.
- The Department will incorporate the new high occupancy provision and 24-hour transfer request language.
- Dr. Oca will work with participants to ensure HFNC survey is getting to proper contacts at SCNs and will send out survey results before July meeting.

The workgroup will meet again July 9th and August 12th. All will be held at 9:30am virtually (format to be posted on the CON meetings page).

**VII. Adjourn**

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

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

## Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222 of the Code, neonatal intensive care services/beds and special newborn nursing services are covered clinical services. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

## Section 2. Definitions

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

(a) "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.

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

(c) "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.

(d) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(e) "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.

(f) "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~~issued but is pending final Department decision.

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

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

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

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

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

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

(m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) total parenteral nutrition.

(n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include unlicensed SCN beds.

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

(p) "Neonate" means an individual up to 28 days of age.

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

(r) "Planning area" means the groups of counties shown in Appendix B.

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

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

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

(v) "Special care nursery services" or “SCN services” means provisions of services for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. These services include:

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

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v) provide mechanical ventilation FOR A BRIEF DURATION (UP TO 24 HOURS) ~~or~~AND continuous positive airway pressure ~~or both, for a brief duration (not to exceed 24 hours combined).~~ FOR BABIES REQUIRING MECHANICAL VENTILATION EXEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION.

Referral to a higher level of care should occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these standards, SCN services are special newborn nursing services.

(w) “TELEMEDICINE” MEANS THE USE OF AN ELECTRONIC MEDIA TO LINK PATIENTS WITH HEALTH CARE PROFESSIONALS IN DIFFERENT LOCATIONS. TO BE CONSIDERED TELEMEDICINE UNDER THIS SECTION, THE HEALTH CARE PROFESSIONAL MUST BE ABLE TO

EXAMINE THE PATIENT VIA A HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191 COMPLIANT, SECURE INTERACTIVE AUDIO OR VIDEO, OR BOTH, TELECOMMUNICATIONS SYSTEM, OR THROUGH THE USE OF STORE AND FORWARD ONLINE MESSAGING.

(x) "Well newborn nursery services" means providing the following services and does not require a certificate of need:

(i) the capability to perform neonatal resuscitation at every delivery;

(ii) evaluate and provide postnatal care for stable term newborn infants;

(iii) stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable; and

(iv) stabilize newborn infants who are ill and those born less than 35 weeks of gestation until they can be transferred to a higher level of care facility.

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

**Section 3. Bed need methodology**

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

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

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

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

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

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

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

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

Sec. 4. 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.

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

(a) 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.

(b) 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.

(c) A unit of at least 15 beds IN A METROPOLITAN STATISTICAL AREA COUNTY OR 10 BEDS IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY will be developed and operated. THIS SUBSECTION MAY BE WAIVED BY THE DEPARTMENT IF THE DEPARTMENT DETERMINES, IN ITS SOLE DISCRETION, THAT A SMALLER UNIT IS NECESSARY OR APPROPRIATE TO ASSURE ACCESS TO HEALTHCARE SERVICES.

(d) 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 to replace NICU services**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating additional hospital beds as NICU beds in a planning area, EXCEPT AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (2), 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 TO EXPAND NICU SERVICES AT A LICENSED SITE BY DESIGNATING ADDITIONAL HOSPITAL BEDS ~~for~~ AS NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate

ALL OF THE FOLLOWING SUBSECTIONS ARE METthat 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: FURTHER, AN APPLICANT PROPOSING TO ADD NICU BEDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE BED NEED METHODOLOGY IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(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 DepartmentTHE PROPOSED NICU BEDS ARE BEING ADDED AT THE EXISTING LICENSED SITE.

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

(i) average annualCALCULATE THE 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 PROVIDED TO NEONATES IN THE APPLICANT'S EXISTING NICU BEDS FOR THE MOST RECENT, CONSECUTIVE 24 MONTHS FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

(ii) DIVIDE THE NUMBER CALCULATED IN (i) ABOVE BY THE TOTAL POSSIBLE PATIENT DAYS [EXISTING LICENSED AND APPROVED NICU BEDS MULTIPLIED BY 730 (OR 731 IF INCLUDING A LEAP YEAR)]. THIS IS THE OCCUPANCY RATE.

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

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

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

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

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

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

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

Sec. 8. 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.

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

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

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

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

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

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

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

(1) All applicants shall demonstrate the following:

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

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

(i) the ability to provide mechanical ventilation FOR A BRIEF DURATION (UP TO 24 HOURS) and~~/or~~ continuous positive airway pressure ~~for up to 24 hours.~~ FOR BABIES REQUIRING MECHANICAL VENTILATION EXEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION.~~-~~

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

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

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

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

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

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

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

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

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

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

(A) mortality rates;

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

(C) infection rates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

| Proximity | Points Awarded |
|---|---|
| Less than 50 Miles to NICU service | 0 |
| Between 50-99 miles to NICU service | 1 |
| 100+ Miles to NICU service | 2 |

(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.

| Hospital Indigent Volume | Points Awarded |
|---|---|
| 0 - <6% | 0.2 |
| 6 - <11% | 0.4 |
| 11 - <16% | 0.6 |
| 16 - <21% | 0.8 |
| 21 - <26% | 1.0 |
| 26 - <31% | 1.2 |
| 31 - <36% | 1.4 |
| 36 - <41% | 1.6 |
| 41 - <46% | 1.8 |
| 46% + | 2.0 |

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

(3) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from conflicting information. For example, if submitted information would result in 6 points being awarded, but

other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

**Section 11. Requirements for Medicaid participation**

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

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

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

(1) Compliance with these standards.

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

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

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

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

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

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

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

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

(h) An applicant shall make provisions for on-site OR BY PREARRANGED CONSULTATIVE AGREEMENTS physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery. PREARRANGED CONSULTATIVE AGREEMENTS CAN BE PERFORMED BY USING TELEMEDICINE TECHNOLOGY AND/OR TELEPHONE CONSULTATION FROM A DISTANT LOCATION.

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

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

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

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

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

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

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

(i) The ability to provide mechanical ventilation FOR A BRIEF DURATION (UP TO 24 HOURS) and/~~or~~ continuous positive airway pressure ~~for up to 24 hours~~. FOR BABIES REQUIRING MECHANICAL VENTILATION EXEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION.~~:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Section 13. Department inventory of beds**

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

**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 Services/Beds approved by the Commission on September ~~25~~21, ~~2014~~ 2016 and effective on December ~~22~~9, ~~2014~~2016.

(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 7(2).

(d) SCN services requested under Section 9.

**APPENDIX A**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

**APPENDIX B**

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

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

NICU Workgroup 2019-2020

Charge 5 Subgroup Recommendation

**Charge 5 – Minimum NICU Size Exception for Rural or Micropolitan Counties**

The subgroup was tasked with digging deeper into Charge 5 to determine if the current minimum size for NICU units of 15 beds should be modified and if a provision should be added to allow for the Department to waive the minimum size. The group considered the following threshold points in making their determination:

1. Is access a concern across Michigan, and especially in the more rural areas of Michigan?
2. How would a reduction in the minimum size of NICU units impact cost and quality?
3. Could a waiver option be developed without ultimately creating no true minimum size for a NICU?

**The subgroup recommends no change to the current CON standards relative to the minimum size of NICU units and recommends the minimum size continue to be 15 beds. The subgroup also recommends no waiver provision be added.**

The subgroup recommendation is based on the following key factors:

1. Studies have consistently found a strong correlation between volume and quality in NICU services. A January 16, 2020 article published in the Journal of Perinatology (attached) highlights the need for a return to regionalization of NICU services and strongly urges against the proliferation of smaller NICUs as an attempt to improve access.
2. No evidence was found to support any concerns with access currently in Michigan.
3. By reducing the minimum size of NICU units we would be opening the door to more and smaller units. This would result in lower volume both at the new units and at existing units that are currently providing NICU services to the area. All evidence confirms this would be detrimental to quality of NICU services.
4. Establishing new NICU services requires significant financial investment. Although no specific studies were found that speak directly to the minimum size of an NICU from a financial sustainability perspective, based on the experience of subgroup members, 15 seemed to be an appropriate number for ensuring financial sustainability. Smaller NICUs that are succeeding today in Michigan are doing so based on a larger capacity thanks to their in-house Special Care Nurseries, which allow them to flex to a larger capacity when needed.
5. Establishing new NICU services requires a significant investment and dedication to staff training. This often requires sending future NICU nurses to quaternary care centers for a week of training, which is an extraordinary expense when considering the number of nurses required to start a new NICU service. This is an expense that should not be duplicated unless necessary to meet a true access concern.
6. Developing a true waiver option with Department discretion, could result in no true minimum size of a NICU unit, as any denial by the Department could be, and perhaps likely would be, challenged in court. The group considered the possibility of instead developing standard under which an applicant could propose a smaller unit, but felt any attempts to define what would justify a smaller unit were outweighed by the quality risks and higher costs, especially since access has not been raised as a concern.

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Lynette - FYI.

COMMENT

Please return to me.

# Why so little progress in regionalization of perinatal care when transport of high-risk neonates remains a substantial risk?

Mitch

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The concept of transferring sick neonates to tertiary care centers originated in the 1930s after the establishment of the first Premature Infant Station by Dr Julius Hess at Sarah Morris Hospital in Chicago. Formalized policies recommending such transfers began in the late 1960s, led by Dr Joseph Butterfield. Working as a member of the Committee on Maternal and Child Care of the American Medical Association, Butterfield and a handful of leading pediatricians of the day wrote a one-page policy statement on regional perinatal care in October 1969 [1, 2]. These efforts evolved into the widely circulated policy statement by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists in the 1976 March of Dimes report "Toward Improving the Outcome of Pregnancy." [3]

Regionalization was soon widely adopted in the United States, in part due to regulatory efforts spearheaded by state certificate of need programs [4], and subsequent improvements in the morbidity and mortality of preterm infants were observed [5]. In recent decades, increases in patient volume and practicing neonatologists, advances in obstetric and neonatal care, and the desire of hospital systems to extend services have all contributed to the growth of smaller volume neonatal intensive care units (NICUs) caring for more complex infants, de-regionalizing perinatal care in many areas.

In 2012, the American Academy of Pediatrics Committee on Fetus and Newborn updated their 2004 policy statement on levels of neonatal care [6]. The policy emphasized the need for continued efforts to return to a regionalized approach to perinatal care to ensure that each newborn is delivered and cared for in an institution equipped to achieve optimal outcomes [6]. This recommendation was supported by data which demonstrated a higher odds of pre-discharge mortality in very low birth weight (VLBW) infants born in hospitals without a level III/IV NICU and with lower rates of VLBW admissions [7, 8], reported state-to-state variability in defining and regulating levels of neonatal care [9], and concerns regarding the potential adverse outcomes associated with a lack of regulatory oversight [10].

In this issue of the *Journal of Perinatology*, Kroelinger et al. [11] provide a current overview of state regulatory and monitoring policies and practices related to the designation of neonatal levels of care. A review of publicly available data from all 50 states and the District of Columbia collected from January to June of 2019 uncovered a continued lack of state-to-state uniformity in defining and enforcing levels of neonatal care, similar to that reported over a decade ago [9]. In 20 states (39%), defined levels of care were reported to be either nonexistent or to be contained in policies without a clear designating authority. Thirty-one states (61%) reported having a designating authority responsible for supervising level of care designation (most commonly the state department of public health), but direct oversight (i.e., a site visit) and ongoing monitoring of adherence was not uniform [11]. The authors concluded that limited direct oversight and regulation may hinder compliance with levels of care which may in turn negatively impact the management of a highly complex and vulnerable patient population. The findings suggest that we continue to fall short of the primary goals outlined in 2012 by the Committee on Fetus and Newborn [6].

While regionalization of care remains an important factor in improving neonatal outcomes, unanticipated deliveries of VLBW infants in institutions with nonlevel III/IV NICUs will inevitably occur, even in states where designation and oversight of neonatal care has been optimized. Also in this issue, Brasher et al. from Texas Children's Hospital and Pai et al. from California report increased morbidity and/or mortality in neonates requiring transport to centers with higher levels of care [12, 13]. Both Texas and California are states that have designating authorities responsible for supervising level of care designation and provide ongoing direct oversight [11]. In

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Texas, hospital are required to obtain formal NICU level designation to receive Medicaid reimbursement [14].

Brasher et al. retrospectively compared outcomes of inborn and outborn low birth weight infants admitted to Texas Children's Hospital over a 4-year period. Outborn infants had less prenatal care, maternal hypertension, multiple gestation, antenatal steroids, and Cesarean sections, but more intubations during initial resuscitation and more infants with a temperature below 36 °C in the first hour of admission. Outborn infants had significantly increased mortality at 28 days of life (28% vs 16%) and higher incidences of severe intraventricular hemorrhage (36% vs 13%), bronchopulmonary dysplasia (98% vs 88%), and late onset sepsis (28% vs 8%). The authors suggested several possible contributing factors to the differences in outcome between inborn and outborn infants, including lower antenatal steroid exposure, suboptimal resuscitation and initial care, and the transport process itself [12].

Pai et al. utilized data from the California Perinatal Quality Care Collaborative, a population-based database, to assess outcomes of infants of any gestational age transported in the first week of life over a 10-year period. Clinical deterioration during transport, defined as increased Ca-TRIPS scores after transport, was associated with prematurity, low birth weight, request for delivery room attendance, need for delivery room resuscitation, severe birth defects, emergency transports, especially by helicopter, and time from initial assessment to NICU admission [13].

Not all infants who require transport will be born in regional perinatal centers as delivery of infants born precipitously, who require emergent delivery, or with unexpected risk factors cannot be predicted. Thus birth hospitals need to be prepared to initiate care for high-risk mothers (e.g., administer antenatal steroids and other interventions as indicated). They also need to be equipped for delivery, resuscitation, stabilization, and preparation for transport of a high-risk infant, with attention to endotracheal tube placement, maintenance of thermal stability, and attention to infection prevention.

With improved outcomes of infants born in tertiary care centers and the high risk of neonatal transport, even in states like Texas and California noted above, why have all states not adopted regulatory guidelines? Barriers to regionalization include cost of program implementation and maintenance, lack of policies for maternal transport, and poorly developed reimbursement strategies for maternal and neonatal transport, particularly true for transports with a Medicaid component and for neonatal return transports [15]. Lack of regulatory oversight, a steady increase in the number of practicing neonatologists, and desires of hospital systems to extend patient services have contributed to de-regionalization. Data from these manuscripts [11–13] are a wake-up call for practitioners, politicians, and administrators to review their own policies and practices and to begin to develop, implement, and enforce strategies to protect our smallest and most vulnerable patients.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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ARTICLE

# Designation of neonatal levels of care: a review of state regulatory and monitoring policies

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## Abstract

**Objective** Summarize policies on levels of neonatal care designation among 50 states and District of Columbia (DC).

**Study design** Systematic review of publicly available, web-based information on levels of neonatal care designation policies for each state/DC. Information on designating authorities, designation oversight, licensure requirement, and ongoing monitoring for designated levels of care abstracted from 2019 published rules, statutes, and regulations.

**Result** Thirty-one (61%) of 50 states/DC had designated authority policies for neonatal levels of care. Fourteen (27%) incorporated oversight of neonatal levels of care into the licensure process. Among jurisdictions with designated authority, 25 (81%) used a state agency and 15 (48%) had direct oversight. Twenty-two (71%) of 31 states with a designating authority required ongoing monitoring, 14 (64%) used both hospital reporting and site visits for monitoring with only ten requiring site visits.

**Conclusions** Limited direct oversight influences regulation of regionalized systems, potentially impacting facility service monitoring and consequent management of vulnerable infants.

## Introduction

The advent of neonatology as a subspecialty, and the availability of neonatal intensive care units (NICUs) during the late 1960s to 1970s, resulted in decreased infant mortality and improved outcomes for premature infants [1–5]. To further impact outcomes and enhance efficient care for all high-risk infants and mothers, the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG), in collaboration with March of Dimes, published recommendations for a regionalized system of NICUs in 1976 called *Toward Improving the Outcome of Pregnancy* (TIOP) [6]. These recommendations included the referral of high-risk mothers and infants to a hospital with a regional NICU [6].

In the following decade, most states widely implemented these regional systems of perinatal care coordination. Neonatal mortality rates decreased as the number of pregnant women who were at risk for a preterm delivery were antenatally transferred to hospital NICUs with the highest capabilities and staffing to provide risk-appropriate obstetrical and neonatal care [6–9]. In addition, hospitals with no or intermediate NICUs were expected to refer all infants weighing 2000 g or less to a regional NICU, [2] with referring facilities benefiting from the integrated health care, professional education, and transport services offered by the regional centers [10]. Regulation of the regionalized process was in part maintained by certificate of need (CON) laws [11]. State-developed CON laws, enacted in the 1960s and early 1970s, allowed state regulatory review of health-related capital expenditures [11]. By the 1970s, states adopted federally funded Section 1122 programs, an early form of state CON programs, which supported state agency approval of Medicare and Medicaid reimbursements [11]. The passage of the National Health Planning and Resources Development Act (NHPRDA) of 1974 required all states to designate an agency to regulate the expansion or

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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modernization of hospitals, and often, the provision of new hospital services [11–14]. Therefore, state CON programs were critical in this early phase, to establish and monitor perinatal costs, quality, and accessibility of services including NICUs, within a regionalized system [11].

However, during the late 1980s and 1990s a "deregionalization" of care occurred [15–18]. Managed care systems developed and began to direct care in many communities [16, 17], changing state reimbursement systems. At the same time, the number of trained and available neonatologists increased, and concurrently, hospital capabilities increased, stemming from changes in technology (e.g., use of surfactant, advanced isolettes, etc.), resulting in increased staffing and advanced capabilities for lower to midlevel NICUs [3, 17, 19]. This shift increased the rate of high-risk infants born in nontertiary hospitals [19, 20]. In addition, it produced competition between level II and level III centers, generating disincentives for patient referrals [3, 15, 21]. Several studies showed that deregionalization of perinatal care adversely affected outcomes, particularly for low birthweight deliveries [20–25]. For instance, Menard et al. (1998) found that very low birthweight (VLBW) infants were more likely to survive if born in level III hospitals than in level I or II facilities, with or without neonatologists [23]. Kastenberg et al. (2015) demonstrated that the deregionalization continued in California from 2005 to 2011 and that risk-adjusted mortality was still higher for VLBW infants born in lower-level, lower-volume centers—an observation consistent with findings from previous decades [19].

Parallel to deregionalization, Congress repealed the NHPRDA in 1986 giving states the option to continue or disband CON programs [14]. Although a substantial number of states currently maintain CON programs, they are often less restrictive compared with preceding programs [14, 26]. An independent survey, utilizing a web based search strategy similar to this study, performed by the Section on Perinatal Pediatrics of the AAP in 2002, found that not all 50 states had published definitions of levels of care, and among states with defined levels of care, the process for designating NICU levels and enforcing NICU-related regulations varied [27]. Further, a study by Blackmon, Barfield, and Stark (2009) examined regulatory language in levels of care policies, and noted variability in mechanisms identified for enforcement, ranging from CON programs and hospital licensure to state health departments or other affiliated programs [28]. Building on earlier work with similar methodology, the objective of this study is to review the more recent process of designating levels of care among the 50 states and the District of Columbia (DC) by (1) identifying the current designating authority and the initial process for designating levels of neonatal care in each state, and (2) describing the ongoing monitoring process for these designations.

## Materials and methods

### Study design and data collection process

A systematic review of web-based, publicly available information on levels of neonatal care designation including CON laws was conducted in all 50 states and DC between January and June of 2019. All policies and legislation published by state agencies or state governments on levels of care were examined for inclusion. Available state-level CON requirements, policies, mandates, rules, codes, licensure regulations, health planning documents, and affiliated nongovernmental state perinatal health entities' publications were identified for data extraction using search engines such as Google and Bing. Both electronic copies of documents and/or the website link to the information source were catalogued. In addition, CON laws for each state were identified through the National Conference of State Legislatures website [26], and were included in analysis if specific to designation of neonatal levels of care, rather than general NICU requirements (e.g., number of beds). A standardized search strategy was applied based on multiple search terms to include a broad grouping of policies (Table 1). Search terms were amended as information was located for review, and expanded based on language identified in policies and/or legislation.

Study authors divided the United States into the ten Health Resources and Services Administration regions to facilitate an organized review and abstraction process. Information was captured by four abstractors using a standardized template developed by the authors. State policies in a region were searched separately by two abstractors. Each abstractor then independently cross-referenced the search findings of the other following double data entry. Study authors (DAG and CDK) further validated all abstracted information by reviewing and comparing it with source information. Discrepancies were reconciled during in-person meetings among researchers (EMO and CDK) and data abstractors to ensure consistency in search strategy and abstraction. Information abstracted included (1) state policies specifying designating authorities for hospital levels and/or hospital level capabilities; (2) documented processes for conducting designation oversight; (3) policies requiring hospital licensure in the designation process for providing neonatal services; and (4) mechanisms to perform ongoing monitoring for designated levels of care.

**Table 1** Summary of search terms used for data collection and abstraction

| Individual search terms ("State" was included in subsequent searches and variations of search phrases were subsequently searched) |
|---|
| [State] Perinatal regionalization |
| [State] Level I policy (ies) |
| [State] Level II policy (ies) |
| [State] Level III policy (ies) |
| [State] Perinatal program |
| [State] Perinatal designation policy |
| [State] Perinatal policy |
| [State] Level I perinatal policy (ies) |
| [State] Level II perinatal policy (ies) |
| [State] Level III perinatal policy (ies) |
| [State] Perinatal licensure |
| [State] Neonatal levels of care |
| [State] Neonatal program |
| [State] Neonatal designation policy |
| [State] Neonatal policy |
| [State] Level I neonatal policy (ies) |
| [State] Level II neonatal policy (ies) |
| [State] Level III neonatal policy (ies) |
| [State] Neonatal licensure |
| [State] Designation neonatal intensive care unit (NICU) |
| [State] NICU policy [ies] |
| [State] Health plans |
| [State] Certificate of need |
| [State] Neonatal certificate of need |
| [State] Perinatal certificate of need |

### Data summary process and definitions

The primary abstractors (DAG and SML) reviewed and created an initial summary of all abstracted data. The secondary abstractors (EMO and CDK) validated abstracted data by reviewing summaries, verifying all summary information in the data, and classifying the policy language. A designating authority or 'designee' was classified as a 'state agency' if the designee was part of the health department or a state agency. If the designee was a nonprofit in partnership with the state, then the grouping was noted as a 'public/private partnership'. States with policies that did not clearly identify a designee were categorized as 'not specified' and no further categorizations (i.e., oversight or licensure) were reported. The oversight process by the designating authority was grouped as 'direct' or 'indirect'. We defined direct oversight as a process, in which a state policy *required* a site visit as part of its designation process. Required site visits may confirm the designating authority's designation or self-designation by hospitals. Conversely, an indirect oversight process was noted when a state policy permitted a hospital to self-designate neonatal levels of care with no required site visit from the designating authority for review. Among the subset of states with policy language specifying designating authorities, we classified ongoing monitoring in two ways. First, we grouped ongoing monitoring as 'yes' or 'no' depending on notation in policy language. Second, we grouped the mechanism, noted in the policies, for conducting ongoing monitoring as 'hospital reporting', 'site visit', or 'not specified', Among states with policies for site visits as part of the ongoing monitoring process, we further categorized visits into 'required' site visits or 'permitted' site visits to highlight differences in monitoring.

### Statistical methods

Descriptive statistics were used to summarize the abstracted information. Counts of states with identified policies for initiating and monitoring graduated neonatal levels of care are reported and variations described. This study was determined to not need Institutional Review Board review at the Centers for Disease Control and Prevention because it did not include human subjects.

## Results

### Designating levels of care

Thirty-one (61%) of the 50 states and DC had a designating authority to oversee levels of care (Table 2). Maryland, Oklahoma, and Rhode Island had slight variations in oversight under the designating authority. While Maryland and Rhode Island had designating authority oversight only for Level III facilities or tertiary care NICU facilities, Oklahoma had oversight for emergency obstetric (OB) services only.

Among the group of jurisdictions with a designating authority, 25 (81%) used a state agency to determine designation, while the remaining 19% used a public/private partnership (Table 2). Fifteen (48%) of the states with a designating authority had direct oversight. Only 14 (27%) of the 50 states and DC incorporated oversight of neonatal levels of care into the licensure process. Of states with oversight incorporated into licensure, 10 (71%) required direct oversight by the designating authority.

### Ongoing monitoring of levels of care

Among the 31 states with an authority identified for designating levels of care, 22 (71%) required ongoing monitoring (Table 3). Of these, six had specific language

**Table 2** Summary of levels of neonatal care policies specifying designating authority, oversight, and licensure by States and District of Columbia[a]

| States/District of Columbia | Designee | Designating authority oversight process | Licensure included in designation |
|---|---|---|---|
| Alabama | State agency | Indirect | No |
| Alaska | – | – | – |
| Arizona | Public/private partnership | Direct | No |
| Arkansas | Public/private partnership | Indirect | No |
| California | State agency | Direct | Yes |
| Colorado | Public/private partnership | Indirect | No |
| Connecticut | – | – | – |
| Delaware[b] | +++ | +++ | +++ |
| District of Columbia | – | – | – |
| Florida | – | – | – |
| Georgia | State agency | Direct | Yes |
| Hawaii | – | – | – |
| Idaho | – | – | – |
| Illinois | State agency | Direct | Yes |
| Indiana | State agency | Direct | No |
| Iowa | State agency | Direct | No |
| Kansas | – | – | – |
| Kentucky | State agency | Indirect | No |
| Louisiana | State agency | Indirect | Yes |
| Maine | – | – | – |
| Maryland[c] | State agency | Direct | No |
| Massachusetts | State agency | Indirect | Yes |
| Michigan | – | – | – |
| Minnesota | – | – | – |
| Mississippi | State agency | Indirect | No |
| Missouri | State agency | Indirect | No |
| Montana | – | – | – |
| Nebraska | – | – | – |
| Nevada | State agency | Direct | Yes |
| New Hampshire | – | – | – |
| New Jersey | State agency | Direct | Yes |
| New Mexico | – | – | – |
| New York | State agency | Indirect | No |
| North Carolina | State agency | Indirect | No |
| North Dakota | – | – | – |
| Ohio | State agency | Direct | Yes |
| Oklahoma[d] | State Agency | Direct | Yes |
| Oregon | – | – | – |
| Pennsylvania | State agency | Direct | Yes |
| Rhode Island[e] | State agency | Indirect | Yes |
| South Carolina | State agency | Direct | Yes |
| South Dakota | – | – | – |
| Tennessee | Public/private partnership | Indirect | No |
| Texas | State agency | Direct | No |
| Utah | State agency | Indirect | Yes |
| Vermont | – | – | – |
| Virginia | State agency | Direct | Yes |
| Washington | State agency | Indirect | No |
| West Virginia | Public/private partnership | Indirect | No |
| Wisconsin | Public/private partnership | Indirect | No |
| Wyoming | – | – | – |

[a]The dashes in columns represent policies without an authority for designating levels of care, or where the authority is unclear, not specified, or not applicable

[b]The crosses in this row represent a state without levels of care

[c]The oversight occurs for Level III facilities only

[d]The oversight occurs for emergency obstetric level care facilities only

[e]The oversight occurs for tertiary care service neonatal intensive care units only

regarding what was covered by ongoing monitoring that included monitoring if participating in a public/private partnership (Arizona), monitoring for specific levels of care (Maryland, Nevada, and Rhode Island), monitoring for regional care centers (Georgia), monitoring for OB facilities (Oklahoma), or as part of general licensure (Utah; Table 3). Nineteen (86%) of the 22 states with ongoing monitoring for levels of neonatal care used either hospital reporting or site visits to monitor designations, while 14 (64%) had both. Among the 17 states (77%) reporting site visits as part of their monitoring process, only 10 (59%) required a site visit.

## Discussion

In the 40 years since TIOP was published encouraging regionalized care for the perinatal population, changes in technology, emergence of managed care, and changes in federal legislation, have affected state policies and the implementation of risk-appropriate neonatal care. In the last decade, federally funded initiatives, including the Collaborative Improvement and Innovation Networks and expert panels like the Secretary's Advisory Committee on Infant Mortality, have highlighted state-led improvements in infant health and renewed interest in perinatal regionalization

**Table 3** Summary of ongoing monitoring for levels of neonatal care policies by states with an identified designating authority[a]

| States | Ongoing monitoring | Process for monitoring | | |
|---|---|---|---|---|
| | | Hospital report | Site visit | Requirement for site visit |
| Alabama | No | No | No | No |
| Arizona[b] | Yes | Yes | Yes | Permitted |
| Arkansas | No | No | No | No |
| California | Yes | Yes | Yes | Permitted |
| Colorado | – | – | – | – |
| Georgia[c] | Yes | – | – | – |
| Illinois | Yes | Yes | Yes | Required |
| Indiana | No | No | No | No |
| Iowa | Yes | Yes | Yes | Required |
| Kentucky | Yes | – | – | – |
| Louisiana | Yes | Yes | Yes | Permitted |
| Maryland[d] | Yes | No | Yes | Required |
| Massachusetts | Yes | Yes | Yes | Permitted |
| Mississippi | Yes | – | – | – |
| Missouri | – | – | – | – |
| Nevada[e] | Yes | Yes | Yes | Required |
| New Jersey | Yes | Yes | Yes | Required |
| New York | Yes | Yes | Yes | Permitted |
| North Carolina | No | No | No | No |
| Ohio | Yes | Yes | Yes | Required |
| Oklahoma[f] | Yes | No | Yes | Required |
| Pennsylvania | Yes | Yes | Yes | Required |
| Rhode Island[g] | Yes | Yes | No | – |
| South Carolina | Yes | Yes | Yes | Required |
| Tennessee | Yes | Yes | Yes | Permitted |
| Texas | Yes | Yes | No | No |
| Utah[h] | Yes | Yes | Yes | Permitted |
| Virginia | Yes | No | Yes | Required |
| Washington | No | No | No | No |
| West Virginia | No | No | No | No |
| Wisconsin | – | – | – | – |

[a]The dashes in the columns represent a monitoring policy that was unclear, not specified, or not applicable

[b]The monitoring occurs only for facilities participating in the public/private partnership

[c]The monitoring occurs only for regional perinatal centers

[d]The monitoring occurs only for Level III facilities

[e]The monitoring occurs only for Level II and Level III facilities

[f]The monitoring occurs for obstetric level care facilities

[g]The monitoring occurs for tertiary care service neonatal intensive care units only

[h]The monitoring occurs as part of general licensure not specific to levels of neonatal care

[29, 30]. We provide the first comprehensive assessment, among 50 states and DC, of approaches to regulation of perinatal regionalization, or risk-appropriate levels of care. We found that almost two-thirds of states designate an entity for monitoring neonatal levels of care, and state health departments were the major designating authority used; however, more than half of the states with a designating authority allow facility designation or self-designation with no direct oversight. Direct oversight can serve as a mechanism to ensure that criteria are uniformly met or maintained and risk-appropriate services are improved [31]. Lack of direct oversight can influence regulation of regionalized systems that may impact neonatal survival, particularly for very low and extremely low birthweight infants, transport between facilities, and development of perinatal telemedicine programs for remote or

rural facilities, though minimal research exists to examine the direct influence of these policies [32–35]. Although national standardized definitions have been developed for designating levels of neonatal care [36], lack of oversight, together with inconsistency in state-level policy language or level-specific measurement has impacted consistency in implementation.

Almost half of states with a designated authority included licensure as a part of the oversight process. State licensing and certification include authority to conduct compliance reviews of health care practitioners, health care entities, or providers for registration renewal, verification, or update of regulated professions [37]. The direct link from designation oversight to licensure allows states to query standards for health care entities or facilities, and take action to resolve noncompliance through reporting to federal entities including the National Practitioner Data Bank and consultation with nonfederal entities like the Joint Commission [37, 38]. Professional clinical membership organizations like the AAP have piloted 'NICU verification' programs consisting of surveys to further assess adherence to the standards for neonatal levels of care among neonatologists, neonatal nurses, and pediatric surgeons [39]. State policies may include such facility surveys or questionnaires filled by clinicians at facilities, for use by the designating authority to determine levels of care. Likewise, other federal agencies have partnered directly with state health departments to assess level of care designations, and determine comparability with the 2012 AAP guidelines [40] among those states where risk-appropriate care policies exist [41]. The Levels of Care Assessment Tool, developed by the Centers for Disease Control and Prevention, is based on the most recent AAP and American College of Obstetricians and Gynecologists (ACOG)/Society for Maternal-Fetal Medicine (SMFM) guidelines, and is a web-based tool supporting state self-assessment of levels of care through collection of nonsurvey based information on facility capabilities, staffing, and infant outcomes [40]. While licensure and standard of care surveys or assessments provide one mechanism to inform regulation of levels of care, how states implement consistent monitoring varies.

Although the majority of states with a designated authority noted ongoing monitoring, the processes varied. Among states requiring site visits as the mechanism for monitoring, language on whether the visit is required or permitted also varied. Site visits provide designated authorities the opportunity to observe the actual structure and functioning of the NICU at the time of designation. Language requiring site visits and defining site visit frequency could provide the designated authority opportunity to collect independently verifiable data for continuous monitoring and oversight. Zimring offers a 'Guide to Conducting Healthcare Facility Visits' with a detailed toolkit for public use [42]. Other instruments exist to measure compliance and quality management of facilities [39, 43], and resources for assessing quality improvement are plentiful [44–46]; however, facility site assessment resources are limited, impacting enforcement of regulations and consequences for facility violations.

State variation in the monitoring process could reflect changes in CON laws and programs, with many states changing enforcement for a portion or all of oversight authority for hospital planning standards [41]. Existing CON programs, typically targeting outpatient or long-term care, may be used for state oversight and enactment of state CON laws [26]. However, evidence suggests CON laws and programs may negatively affect facility competition, reimbursement, and expenditures [14, 47]. Review of CON laws' impact on health care indicates that the laws may be less effective for cost control and more effective as a mechanism to redirect obligation and expenditure of funds [14]. For example, while a CON program may restrict the number of beds in a facility, it may not restrict the facility from purchasing electronic equipment. For neonatal risk-appropriate care, CON programs are associated with fewer functioning NICUs, including decreased bed supply in Level III NICUs, though no differences in infant mortality are reported [48]. By contrast, Rosko and Mutter (2014) concluded that in acute care settings, for example, CON programs could increase hospital efficiency and decrease costs [49], improving health outcomes. Differences in study findings may reflect the distinct capabilities or staffing required for emergency departments compared with labor and delivery departments, as the impact of CON programs on hospital quality of care and health outcomes is complex. Further research on the impact of CON programs, designation authority, and monitoring on neonatal outcomes is warranted [35].

Several limitations exist in interpreting our findings. First, we did not contact all states to verify policies related to monitoring and regulation of neonatal levels of care. Second, we included publicly available policies only, potentially missing any new, non-publically available or unpublished policies. Third, since the data collection timeframe, some state policies may have been reviewed or amended, potentially affecting our categorization of state results. Regardless of these potential limitations, our analysis identifying the frequency of state-specific designated authorities with required site visits can inform states that aim to regulate and continuously monitor neonatal levels of care, potentially impacting the quality and availability of services to infants born in delivery facilities.

Designating an authority for monitoring and oversight can increase facility and hospital network accountability, efficiency, and ability to transfer neonatal patients to the most appropriate facility for care. Such oversight may result

in the comprehensive access to risk-appropriate care necessary to increase survival of high-risk neonates. Inclusion of neonatal levels of care regulation language, whether through CON laws and programs or licensure and certification, enables systematic regulation of facility compliance and care quality that can improve equity in neonatal risk-appropriate care and outcomes.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.



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