

**Fletcher Hospital, Incorporated d/b/a AdventHealth Hendersonville**  
**Certificate of Need Application to Develop a Unit for Five Neonatal Care Beds**  
**Project ID B-012488-24**  
**Comments in Opposition on Behalf of MH Mission Hospital, LLLP**

**Introduction:**

AdventHealth Hendersonville (“AdventHealth”), has submitted an application (Project I.D. No. B-012488-24) to the Department to renovate existing space within its existing hospital to develop a five-bed neonatal care unit to care for Level II and III infants at a cost of \$2,849,526.

First and foremost, Mission supports and welcomes increased access to neonatal care and high-risk OB services to the citizens of western North Carolina. Mission as the regional perinatal provider of western North Carolina offers an extensive range of neonatal, pediatric, and OB services as well as employees OB clinical experts and subspecialty trained physicians, who support the most acuity complex infants and mothers across Western North Carolina. As an existing provider of these services, Mission understands and appreciates the clinical expertise required to support a robust neonatal program. It is also because of this knowledge that Mission has concerns about the project proposed in AdventHealth’s application.

The 2024 SMFP Chapter 5 identifies the need for licensed acute care beds by county or multi-county service area, but it does not provide a separate method for determining a need for neonatal bassinets. As such, AdventHealth as an applicant applying to develop new neonatal beds does not rely on the SMFP for a quantitative bed need determination but rather must demonstrate the need for five “new beds” for which it has applied. The current disconnect between CON, which separates neonatal bassinets from licensed acute care beds, and Facility Licensure, which combines the two bed types in the total licensed acute care bed count, makes the examination of need for a bed addition related to neonatal care a murky process.<sup>1</sup>

As will be described, there are inconsistencies between the 2024 SMFP, the North Carolina CON Statute, and the recently adopted licensure rules 10A NCAC 14C .1401 to .1403 which relate to neonatal intensive care services. As will be shown, this regulatory conflict puts AdventHealth squarely in the position of applying for new licensed acute care beds for which there is no ability to review these beds pursuant to the 2024 SMFP other than under the general acute care bed capacity, which shows a need for no (0) additional licensed acute care beds in Henderson County. Because new acute care beds require a need determination and there is no such need determination in Henderson County AdventHealth’s application should be denied.

Leaving aside the general confusion outlined above, and assuming there were new acute care beds for AdventHealth to apply for, AdventHealth fails to demonstrate the need for the five new beds for which it has applied. AdventHealth’s application presumes that it will capture an unrealistic number of babies to be served in Level II or III neonatal care without any reliable quantitative basis based on actual utilization statistics. AdventHealth relies upon a faulty methodology that

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<sup>1</sup> A phone call with the Licensure Section confirmed that Level II, III, and IV beds are included in the total licensed acute care beds for each facility that operates such beds, and that the hospital license does not distinguish beds by type only indicating the total number of licensed beds.

produces an unrealistic volume of high-risk babies in relation to its existing well baby deliveries. In addition, an analysis of AdventHealth's actual deliveries by DRG shows that it currently serves many of the Level II babies in its existing nursery that it claims require transfer to other providers. While AdventHealth will not come close to serving the number of babies it projects, the proposed project will allow it to utilize a higher charge mechanism for some babies it already serves.

In addition, AdventHealth attempts to justify its need for additional beds by utilizing an unrealistic compounded annual growth rate ("CAGR") and an overstated methodology that captures babies it is already serving. Moreover, AdventHealth failed to consider more reasonable alternatives to its proposed project. A smaller unit utilizing existing underutilized beds makes more sense than the addition of acute care beds to support a unit that will not be fully utilized.

Further, AdventHealth in its application fails to include proper staffing to support a Level III NICU and the related Level III bassinets. This, paired with overstated utilization projections, leads to related issues with its financial projections and related pro forma financial reports.

Mission Hospital supports the expansion of access to neonatal care services to ensure access for patients throughout the region, but it does not support an incremental increase in licensed acute beds at AdventHealth for a level of utilization it cannot support for either Level II and III beds or general acute care beds. Additionally, new acute care beds require a need determination for the Agency to grant an applicant a CON. There is no such need determination in Henderson County and as such AdventHealth's application should be denied.

AdventHealth's proposed project would result in five additional licensed acute care beds for an already underutilized facility and in a market for which there is no published bed need. Ultimately, if AdventHealth is approved for this project it should convert existing underutilized acute care beds rather than be awarded five new beds.

### **Criterion (1): The 2024 SMFP Requires this Project to be Denied**

AdventHealth proposes to add 5 Level II/Level III neonatal beds. Due to the statutory and licensure implications outlined below, these beds will be considered new licensed acute care beds and would increase the licensed bed capacity of its hospital in Hendersonville to 67 acute care beds. A review of the North Carolina CON Statute, the CON Administrative Rules, and the 2024 SMFP, shows that the only way in which this project can be reviewed and approved under the 2024 SMFP is as an addition to AdventHealth's licensed bed capacity for which there is no need in Henderson County contained in the 2024 SMFP. As such, AdventHealth's application must be denied.

#### The CON Statute Does Not Recognize Level II/Level III Neonatal Beds

Under the NC CON Statute, Level II and Level III are not neonatal intensive care beds or "NICU" beds. Only Level IV neonatal beds are defined as NICU beds. The NC Statute § 131E-176. **Definitions** sets forth:

***(15b) Neonatal intensive care services. - Those services provided by a health service facility to high-risk newborn infants who require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care.***

This definition does not include neonatal Level II and III –newborns, who do not need continuous nursing care. In addition, the Statute at § 131E-176 (16) sets forth new institutional health services that require prior CON approval including:

- f. The development or offering of a health service as listed in this subdivision by or on behalf of any person:*
- 1. Bone marrow transplantation services.*
  - 2. Burn intensive care services.*
  - 2a. Cardiac catheterization services, except cardiac catheterization services provided on equipment furnished by a person authorized to operate the equipment in North Carolina pursuant to either a certificate of need issued for mobile cardiac catheterization equipment or a settlement agreement executed by the Department for provision of cardiac catheterization services.*
  - 3. Neonatal intensive care services.***
  - 4. Open-heart surgery services.*
  - 5. Solid organ transplantation services.*

AdventHealth’s project does not meet the definition of neonatal intensive care services and does not exceed the \$4 million definition of a new institutional health service. Thus, there is no statutory mechanism to approve the proposed beds other than a change in any licensed bed capacity under § 131E-176 (16)c. As noted previously, the Licensure Section only recognizes total licensed acute care beds and does not separately distinguish various uses of licensed beds.

The CON Rules Do Not Acknowledge Level II/Level III Neonatal Beds

Under the CON Rules 10A NCAC 14C, Level II and Level III beds are not NICU beds. As of January 1, 2024, the CON Administrative Rules further defines NICU beds to be only Level IV beds:

*10A NCAC 14C .1401 DEFINITIONS The following definitions shall apply to all rules in this Section:*

- (1) “Approved neonatal intensive care unit (NICU) beds” means acute care beds in a hospital that were issued a certificate of need to provide Level IV neonatal intensive care services but are not providing those services as of the application deadline for the review period.*
- (2) “Average daily census (ADC)” means the total number of existing, approved, and proposed NICU days of care provided during a full fiscal year of operation divided by 365 days.*

(3) “Existing NICU beds” means acute care beds in a hospital that are providing Level IV neonatal intensive care services as of the application deadline for the review period.

(4) “Level IV neonatal intensive care services” means services provided to high-risk medically unstable or critically ill neonates less than 32 weeks of gestational age, or infants requiring constant nursing care or supervision in NICU beds.

(5) “Occupancy rate” means the ADC divided by the total number of existing, approved, and proposed NICU beds expressed as a percentage.  
“Proposed NICU beds” means the acute care beds proposed to provide Level IV neonatal intensive care services in a hospital in the application under review.

The performance standards that follow at **10A NCAC 14C .1403** have also been revised as of January 1, 2024, to identify specific requirements for a hospital proposing to add Level IV NICU beds. Thus, neither the CON Statute, the CON Administrative Rules, nor the 2024 SMFP recognize Level II and Level III neonatal beds, yet these beds are counted as licensed acute care beds by Licensure.

#### The 2024 SMFP Does not Consider Level II/Level III Beds

There is no dispute that the 2024 SMFP subtracts Level II/Level III beds from the inventory and in the analysis of need for general acute care beds. In Chapter 5, the first step of the acute care bed need methodology states:

***Step 1:** Determine the number of acute care beds in the planning inventory by totaling:*  
*a. the number of licensed acute care beds at each hospital (Column D) exclusive of beds licensed or approved at academic medical center teaching hospitals (listed in Appendix F) pursuant to Policy AC-3, and exclusive of beds that provide **Level II, III** and IV NICU services; and...*

While this change, originally under the 2023 SMFP, there is nothing in the current SMFP that regulates Level II/Level III beds. It is also clear that there is a surplus of acute care beds in Henderson County, specifically at AdventHealth Hendersonville.

#### Reconciling This Information Leaves Only New Acute Care Beds for AdventHealth to Apply For

For these reasons, the only thing that requires AdventHealth to request CON approval for its proposed project is it that it seeks to increase its licensed bed capacity. This is the only way in which the Agency should accept and review this application. It appears that recent changes to the SMFP and CON Administrative Rules, when read in concert with the Statute, have likely unintentionally created a “loophole” in which Level II and Level III beds are completely ignored but can still be used to increase a hospital’s total licensed acute care bed count.

The Statute requires CON approval for an increase in licensed bed capacity (§ **131E-176. 16c**) but Level II and III neonatal beds are not recognized by Statute, Rule or the SMFP. With this

conundrum, the Department must examine AdventHealth's application carefully to avoid the unintentional and unpermitted addition of licensed general acute care bed capacity. Because a general acute care bed designation is the only way in which the project can be considered under the Statute, the SMFP shows a bed surplus for Henderson County, and licensed acute care beds are undesignated under licensure regulations, this project must be denied under the 2024 SMFP.

For these same reasons, it is critical that the Agency carefully consider this review as it is the first application filed proposing to develop new Level II/III beds following the SMFP changes to eliminate neonatal beds from the acute care bed methodology and the first under the recently adopted rules and performance standards that do not acknowledge Level II/III beds. It is critical that the disconnect between the Statute, rules, and SMFP not result in a situation where seeking Level II/III beds can serve as a loophole to obtain new acute care beds in the absence of a bed need determination.

### **Criterion (3) AdventHealth Fails to Adequately Document Need for the Project**

#### ***Population to be Served***

AdventHealth premises its project with a patient "story" immediately following the application cover page, which describes the "hardships" faced by a patient with a high-risk delivery/C-Section transferred to a local provider of high-risk OB services. The premature infant had a subsequent stay at the regional NICU provider. Undoubtedly this is Mission Hospital, given the descriptive proximity to Hendersonville and Mission's role as the only Level IV NICU provider in western North Carolina. What this story fails to recognize is that Mission's team of maternal/fetal medicine physicians and neonatologists successfully delivered this infant and cared for him post-delivery. The story also does not acknowledge the fact that the mother was transferred to Mission due to the inability of AdventHealth to care for the high-risk delivery. Neonatal services go hand in hand with high-risk OB programs, which AdventHealth does not have and does not propose to offer as part of this project. It is likewise unclear whether this neonate in AdventHealth's patient story needed Level IV NICU services that AdventHealth could not provide even if it were approved for this project.

Inconsistently, the distance AdventHealth describes as a "hardship" at 30 minutes, is relatively short compared to the fact that AdventHealth proposes to serve Level II/Level III patients from a 9-county service area including communities in Buncombe County, expecting such patients to travel a similar 30 minutes to their hospital. AdventHealth projects to serve patients from such places as:

- Rutherfordton (Rutherford County) located approximately 50 minutes from AdventHealth
- Hot Springs (Madison County) located approximately an hour from AdventHealth, and
- Clyde (Haywood County) is located approximately 35-40 minutes from AdventHealth and only 25 minutes to Harris Regional, with a Level II Neonatal Special Care Unit.

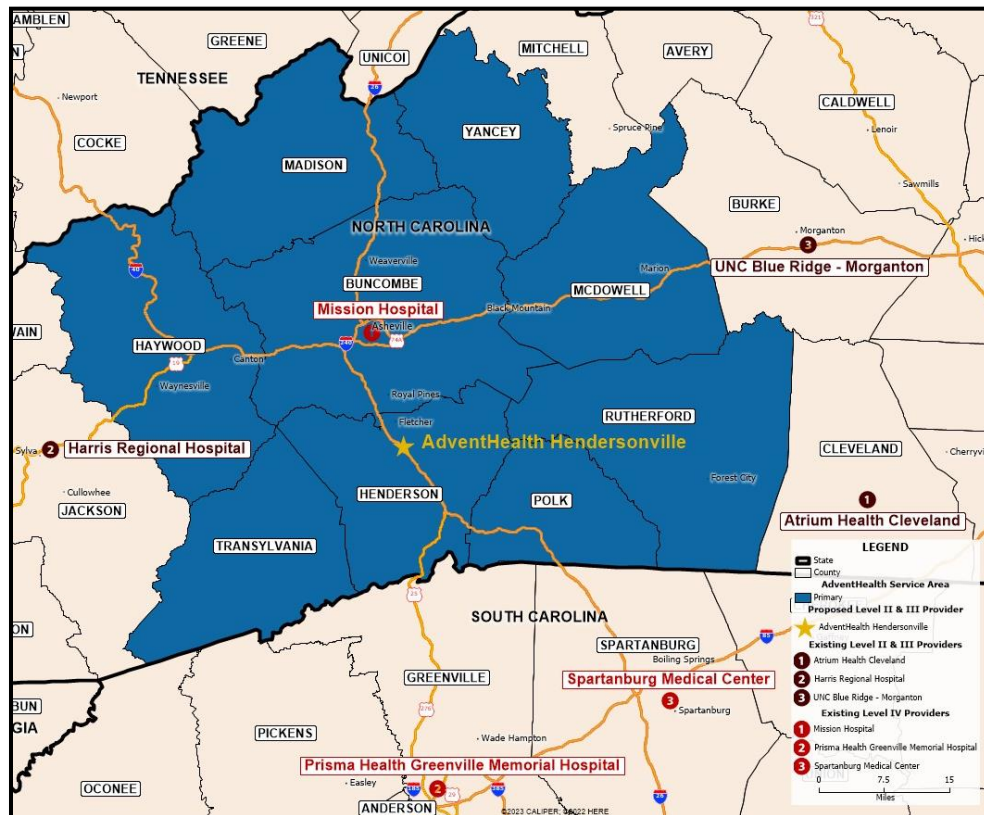
If AdventHealth’s “statistic/metric” example represents a hardship rather than a success story, then the patients AdventHealth projects to serve throughout its unreasonably broad service area will face similar hardships to receive care at AdventHealth.

AdventHealth proposes an unreasonably large, 9-county “catchment area” from which is projects to draw Level II/Level III patients. See application page 45. It is unclear the basis for this large area, as AdventHealth does not meaningfully draw patient volume from all of these 9 counties.

On page 45, AdventHealth also ignores several existing Level II/Level III providers who also serve this area including Atrium Health Cleveland, DLP Harris Regional Medical Center (“Harris Regional”), and UNC Blue Ridge Hospital -Morganton (“UNC Blue Ridge – Morganton”). AdventHealth also ignores large NICU providers in Greenville and Spartanburg Counties directly to the south of its catchment area. See **Exhibit 1**.

It should also be noted that on page 38 of its application, AdventHealth provides a footnote to document that Harris Regional was not included in its analysis because recent LRAs do not show any Level II days. This is incorrect. Harris Regional’s 2022 LRA shows 573 days of care for its Level II beds. While Harris omitted neonatal patient days on its 2023 LRA, it did include them in the year prior and should not be ignored. In fact, the very same market data used extensively by AdventHealth shows that Harris Regional served Level II/Level III DRGs in FY 2023.

### Exhibit 1 Existing Providers of Neonatal Care in or Near the Service Area



It is unclear how AdventHealth projects to draw significant Level II/III patient volume from all of these counties when they do not serve any meaningful number of OB patients from many of these counties. Most Level II/III neonates are born at the same hospital their mother receives care, and therefore, the mother chose to deliver at that hospital. AdventHealth’s application is devoid of any meaningful information on its current OB services, which hides the fact that AdventHealth does not have the patient base to support the proposed service and has not appropriately defined the population to be served.

As shown in **Exhibit 2**, AdventHealth’s FY 2023 OB patient origin reveals that it serves very few patients from many of its projected 9 catchment area counties. Madison, Yancey, and McDowell Counties each account for less than 2 percent of AdventHealth’s OB patients. Rutherford and Haywood account for only 2.6% and 2.2% of OB patients, respectively. Defining AdventHealth’s catchment area from which it received generously 90% of its OB patients would result in a 4-county catchment area including only Henderson, Buncombe, Transylvania, and Polk Counties. **Exhibit 2** also shows that projected patient origin percentages for Rutherford and Haywood are far overstated as well as “in-migration” from outside of the catchment area.

**Exhibit 2**  
**AdventHealth OB v. Level II/III Patient Origin**

<b>County</b>	<b>Advent FY 2023 Births</b>	<b>% of Total</b>	<b>Cumulative %</b>	<b>Projected Level II/III Patients</b>	<b>% of Total</b>
Henderson	307	56.6%	56.64%	89	41.6%
Buncombe	121	22.3%	78.97%	42	19.6%
Transylvania	33	6.1%	85.06%	13	6.1%
Polk	27	5.0%	90.04%	6	2.8%
Rutherford	14	<b>2.6%</b>	92.62%	20	<b>9.3%</b>
Haywood	12	<b>2.2%</b>	94.83%	24	<b>11.2%</b>
Madison	8	1.5%	96.31%	2	0.9%
Yancey	6	1.1%	97.42%	3	1.4%
McDowell	4	0.7%	98.15%	4	1.9%
All Others	10	<b>1.8%</b>	100.00%	11	<b>5.1%</b>
<b>Total</b>	<b>542</b>	<b>100%</b>		<b>214</b>	<b>100.0%</b>

*Source: Market Births - Application p101. Advent Births - HiDi market data*

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Level II/III providers do not receive a significant number of transfers from other providers. One instance in which a Level II/III provider may receive a transfer is a back transfer of a Level IV neonate who transfers back to their local provider as they step down to a lower level of care. As will be shown, AdventHealth’s transfers to Mission for Level IV services are insufficient to justify AdventHealth’s population to be served and the need for the project.

AdventHealth has not reasonably projected the population to be served and unreasonably identifies the needs of this population and should not be found conforming with Criterion (3).

## ***Projection Methodology***

AdventHealth's projection methodology is flawed and utilizes an illogical basis that plagues almost every step. To produce an adequate number of births, the methodology is rooted in theory and completely fails to consider the actual volumes of AdventHealth's births and transfers. A comparison of the projected utilization with the actual utilization of both AdventHealth Hendersonville and other nearby providers demonstrates that the utilization projections are entirely overstated and are not rooted in real volumes.

### Review of Issues with the Projection Methodology by Step

AdventHealth generates a theoretical methodology based on 2022 OB utilization for the proposed catchment area and applies arbitrary assumptions to these figures to generate the utilization it needs. AdventHealth does not use its own historical utilization as a basis for any step in its projection process. This leads to a flaw in AdventHealth's methodology and an unrealistic outcome. AdventHealth's projection methodology is explained step by step below.

Step 1 (Application p101) – AdventHealth first quantified the number of total births and total neonatal discharges (DRGs 789-793) in 2022 by catchment area county. AdventHealth then calculates a ratio of neonatal discharges to total births for each county and the catchment area. The overall ratio for the catchment area is calculated to be 22.5%. In other words, AdventHealth estimates that 22.5% of the births in the catchment area require a higher level of neonatal care.

It should be noted that Step 1 reflects the utilization for the residents of the service area as a whole, regardless of the county where the birth took place or where the neonatal care was provided. **The location a patient delivers is an excellent predictor of where they will get neonatal care. Conversely using where a patient lives is a less likely predictor of where a patient will receive care, especially given the number of rural counties in the service area that have no hospital at all or a hospital that does not offer OB services.** The entire process is predicated on overall DRG ratios or percentages, which are entirely overstated. Infants are routinely assigned to several of these DRGs who do not need Level II/III Care as AdventHealth's own utilization will show.

Step 2 (Application p102) – AdventHealth then drills the above data down further to reflect only discharges captured under DRG 792 and a portion of discharges captured under DRG 793 that AdventHealth believes it can safely accommodate. A historical utilization trend for these discharges from 2020-2022 is presented in Application Table 2. In 2022, AdventHealth's nine-county catchment area had a total of 748 discharges for 3,535 days for this cohort of patients.<sup>2</sup> Again, this is for the entire catchment area (regardless of where the infant was delivered or where the neonatal service was provided). Again, this data is not based on AdventHealth's historical deliveries or OB utilization.

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<sup>2</sup> It should be noted that these figures are slightly different than those presented in Exhibit C-4.2. In theory, they should correspond.



As will be shown, this theoretical Level II/III ratio ignores one very critical factor that overstates the potential demand for AdventHealth’s service: Patients in these DRGs are served in hospitals without Level II or Level III services including AdventHealth. In other words, **the DRGs defined to support AdventHealth’s projection do not all require Level II/III care.**

Step 3 (Application pp102-103) – In order to project the number of discharges adjusted for the scope of services AdventHealth intends to provide, it applies a CAGR to reflect expected population growth for women ages 15-44 to the 2022 figures referenced in Step 2 to determine projected discharges for the adjusted scope of services through 2028.

This step is flawed in numerous ways as the CAGR is unreasonable.

- First, AdventHealth fails to identify the source of or demonstrate the CAGR(s) used in this projection. It simply states, “Based on historical data, AdventHealth identified over 700 annual inpatient discharges from the catchment area that could be served by the proposed neonatal acute care beds at AdventHealth Hendersonville (p102).” AdventHealth does generate a CAGR by county on page 45 of its application. However, when it is applied to the 2022 days on Table 2, the projections do not tie exactly to the 2023-2028 projected days on Table 3. Moreover, AdventHealth fails to explain or demonstrate why population growth would be a reasonable measure of growth or decline for the proposed services.
- Table 2 in Step 2 (Below and Application p102) shows that discharges for this cohort of services and service area declined 2.1% from 2021 to 2022. If anything, the 2020-2022 volumes show that discharges are at best relatively consistent, but certainly do not show a trend of growth.
- Like AdventHealth’s historical OB utilization, OB services in general are not growing. In fact, Advent’s 2023 deliveries were at their lowest level in six years (Application, page 43).

**Table 2:**  
**AdventHealth Hendersonville Neonatal Acute Care Bed Catchment Area:**  
**Neonatal Acute Care Discharges, Adjusted Based on Scope of Services for Proposed Project**

County	2020		2021		2022	
	Discharges	Days	Discharges	Days	Discharges	Days
Buncombe	317	1,646	344	1,610	344	1,650
Haywood	66	343	61	449	75	407
Henderson	115	487	123	581	130	514
Madison	31	136	27	98	21	95
McDowell	46	185	67	336	38	164
Polk	15	73	13	79	11	101
Rutherford	93	436	71	315	66	377
Transylvania	21	171	34	156	32	113
Yancey	23	71	24	81	31	114
<b>Total</b>	<b>727</b>	<b>3,548</b>	<b>764</b>	<b>3,705</b>	<b>748</b>	<b>3,535</b>

\*Annualized based on Jan-June data.

Source: AdventHealth application page 102.

It is completely unreasonable for AdventHealth to use population growth rates when the trend for the actual service proposed is declining, birth rates are declining, and especially considering that AdventHealth’s own OB utilization is declining.

It is a well-known fact that American society at large is waiting until later in life to have children and having less children than ever before. In fact, more Americans are choosing not to have children than ever before. According to an article published by the Washington Post (“*Millennials aren’t having kids. Here’s why.*,” Andrew Van Dam), the US birthrate is at its lowest level in history and is not expected to change anytime soon. The Millennial generation is opting to not have children more frequently than any other before it. See **Attachment A**. As a result, any consistent growth in OB services related to small levels of population growth or other minor demographic factors does not make sense.

Step 4 (Application p103) – AdventHealth arbitrarily chooses market share percentages by county for the first three years of operation and applies these percentages to the volumes generated in Step 3. The market shares presented in the application are shown below.

**Table 4:**  
**AdventHealth Hendersonville Neonatal Acute Care Bed Catchment Area: Projected Market Share**

	2026	2027	2028
Buncombe	5.0%	10.0%	12.0%
Haywood	10.0%	20.0%	30.0%
Henderson	45.0%	55.0%	65.0%
Madison	2.5%	5.0%	10.0%
McDowell	2.5%	5.0%	10.0%
Polk	30.0%	40.0%	50.0%
Rutherford	10.0%	20.0%	30.0%
Transylvania	20.0%	30.0%	40.0%
Yancey	2.5%	5.0%	10.0%

AdventHealth applied the annual market share percentages to the projected catchment area discharges appropriate to be served at AdventHealth Hendersonville.  
*Source: AdventHealth application page 103.*

There is no explanation for the market share percentages chosen and no data or analysis to support their reasonableness. In fact, at first glance, they appear to be completely illogical. In 2028, Henderson County is projected to generate a 65% market share for neonatal services, while AdventHealth currently has a 35% market share for births originating from Henderson County. This would presume that Henderson County mothers who deliver at another facility will transfer babies to be treated at AdventHealth, which is unlikely. See **Exhibit 2** and discussion to follow for a comparison of all service area counties.

In addition, geographically, these percentages are illogical. Much of Haywood County, projected to result in a 30% market share for AdventHealth in Year 3, is closer to Buncombe County and Mission Hospital than to AdventHealth in Henderson County. In fact, most residents would have to travel through Buncombe County to reach AdventHealth Hendersonville. Rutherford County, also with a 30% market share in Year 3, has relatively similar geographic access to UNC Blue Ridge - Morganton, AdventHealth, and Mission. See Table 4 excerpt from AdventHealth application page 103.

Step 5 (Application p104) – The market share capture rates presented in Step 4 are then applied to the total projected discharges by county calculated in Step 3 to determine county-level projected utilization for years 2026-2028. For the reasons outlined in the steps above, this application results in highly overstated volumes.

Step 6 (Application p105) – A five percent in-migration factor is applied to the total above to determine total acute care discharges for the first three years of operation with no analysis or basis. As shown in **Exhibit 2**, AdventHealth only captured 1.8% of births from outside of the catchment area, which undermines the use of a 5% in-migration fact.

Step 7 (Application p 105) – The projected average length of stay (“ALOS”) was determined to be 4.8 days and was applied to total discharges to determine total days of care. Using AdventHealth’s own data from Step 2 (748 births; 3,535 inpatient days) results in an ALOS of 4.7. Therefore, AdventHealth inflates its ALOS to create higher utilization.

This step was also premature. Since AdventHealth breaks down the days by level, Level II and Level III babies will likely have differing ALOS as the acuity of Level III babies is higher than Level II.

Step 8 (Application p106) – AdventHealth works backwards to apply another set of arbitrary percentages (73% and 27%, respectively) to delineate Level II/III days from the total days of care. There is no source for these percentages that justifies this delineation of service. Moreover, AdventHealth ignores the fact that a neonate, who initially needs Level III care, will typically “step down” to Level II care resulting in potential Level II days for a neonate in a Level III DRG.

From beginning to end, AdventHealth’s methodology is arbitrary and inflated, resulting in an unrealistic level of utilization that will be discussed and analyzed below.

### ***AdventHealth’s Neonatal Care Projections vs Real Data***

Comparing AdventHealth’s projected utilization to its historical utilization and to other similar facilities within the service area further highlights its oversized project and overstated projections. AdventHealth’s OB service is not growing, which is likely why AdventHealth used theoretical projections, rather than its own historical utilization, to demonstrate the need for the project.

AdventHealth’s OB Utilization is Declining

AdventHealth seems to forget that you cannot have neonates without delivering mothers. Its application is devoid of information about the use of its OB program and how the patients served by it need Level II/III services.

As shown in **Exhibit 3**, there is no growth for births at AdventHealth Hendersonville. 2023 resulted in the lowest number of births in six years at AdventHealth Hendersonville. Even using a six-year trend, there is a decline from 2018 figures. These totals include ALL babies born at AdventHealth Hendersonville, whether they need higher level neonatal care or not. Given the figures below and current birth rate trends, there is no reason to assume any future growth in OB services. It is fair to assume that future levels may be higher than 2023, as it appears to be an anomaly. However, there is no reason to assume that total births will significantly exceed 600 per year in the foreseeable future.

**Exhibit 3**  
**Births at AdventHealth Hendersonville 2018-2023**

	2018	2019	2020	2021	2022	2023	2018-2023 Average	CAGR
Vaginal Births	433	426	421	399	422	380	414	-2.58%
C-Sections	168	156	159	209	216	167	179	-0.12%
Stillbirths	0	0	0	1	1	1	1	
<b>Total</b>	<b>601</b>	<b>582</b>	<b>580</b>	<b>609</b>	<b>639</b>	<b>548</b>	<b>593</b>	<b>-1.83%</b>

Source: Application p44

Using Actual Births AdventHealth Cannot Project Sufficient Demand for Level II/III Services

Starting with the catchment area ratios of Level II/III discharges to birth and taking into account the “adjusted” definition used based on expected capability then applying this to AdventHealth’s actual OB utilization is a more realistic projection methodology. Based on data in the AdventHealth application, **Exhibit 4** shows that the adjusted ratio of Level II/III discharges to births for the catchment area is 13.1% and these patients have an ALOS of 4.73 days based on data presented by AdventHealth.

**Exhibit 4**  
**Analysis of Catchment Area Level II/III Adjusted Utilization**

"Adjusted" Discharges	748
Births	5,691
Ratio of Adjusted Discharges to Births	13.1%
Adjusted Days	3,535
ALOS	4.73

Source: CON Tables 1-2, CON pages 102-103

Applying this actual information to the births at AdventHealth shows that the births at AdventHealth would generate about 78 potential Level II/III neonatal discharges and 368 days of care. See **Exhibit 5**. This equates to an ADC of 1 or 20% occupancy of the proposed 5 beds. This is based generously on the average births from 2018 to 2023 and not the lowest level of births in 2023.

**Exhibit 5**  
**AdventHealth Projected Level II/III Utilization**

Average 2018-2023 Births	593
Ratio of Adjusted Discharges to Births	13.1%
Projected Level II/III Neonates	78
ALOS	4.73
Projected Level II/III Days	368.35
Projected Level II/III ADC	1.01
Proposed Level II/III Beds	5
Percent Occupancy	20%

*Source: Ratio and ALOS based on AdventHealth application page 101-102*

AdventHealth’s Projected Market Share Ignores the Reality of its OB Market Share

AdventHealth’s market share for births in 2023 is presented in **Exhibit 6** below. Births originating from residents of Henderson County resulted in 30.76% market share for AdventHealth. AdventHealth’s Market share for Polk County births was 31.76%. All other market shares by county were significantly lower.

**Exhibit 6**  
**AdventHealth Market Share of Births by County of Origin FY**

County	Advent Births	Total Births	Market Share
Buncombe	121	2,293	5.28%
Haywood	12	515	2.33%
Henderson	307	998	30.76%
Madison	8	195	4.10%
McDowell	4	381	1.05%
Polk	27	85	31.76%
Rutherford	14	601	2.33%
Transylvania	33	215	15.35%
Yancey	6	145	4.14%
<b>Total</b>	<b>532</b>	<b>5,428</b>	<b>9.80%</b>

*Source: FY 2023 HiDi market data.*

A comparison of the actual market share by county shown in **Exhibit 6** above to -Projected Market Share for Neonatal Acute Care Beds (AdventHealth Table 4 shown previously), is striking. This comparison, **Exhibit 7**, shows market shares for neonatal care are projected to be at least twice the 2023 market share for births for Henderson County. Other counties show many multiples of market share capture without justification. There is absolutely no justification for AdventHealth to capture

market share increases as high as 18 to 34 percentage points for this service. There is no reasonable way to reconcile a current 2% market share of births and a projected 30% market share of Level II/III discharges, as AdventHealth projects for Haywood County. AdventHealth’s projected market shares are unreasonable, without justification, and unsupported by any reasonable conceptual basis.

**Exhibit 7**  
**AdventHealth Actual vs Projected Market Shares**

<b>County</b>	<b>FY 2023 OB/Birth Market Share</b>	<b>2028 Neonatal Market Share</b>	<b>% Increase in Neonatal Market Share</b>
Buncombe	5%	12%	7%
Haywood	2%	30%	28%
Henderson	31%	65%	34%
Madison	4%	10%	6%
McDowell	1%	10%	9%
Polk	32%	50%	18%
Rutherford	2%	30%	28%
Transylvania	15%	40%	25%
Yancey	4%	10%	6%

*Source: FY 2023 HiDi market data.*

There is no explanation by AdventHealth to justify these unrealistic increases. AdventHealth makes no mention of nor quantifies potential transfers from other hospitals where a neonate is delivered to AdventHealth for Level II/III care. As further evidence of this omission, AdventHealth offers no discussion of the provision of neonatal transport services, which is a highly specialized and resource-intensive service required for the safe transport of neonates. Without a discussion of the potential transfers, all volumes are assumed to be generated from AdventHealth Hendersonville births. As a result, it is not possible for AdventHealth to generate the volumes of patients it projects.

Comparisons to Existing Level II/III Programs Show AdventHealth’s Projection Flaws

Another way in which to test the reasonability of AdventHealth’s projections is to compare Level II/III days to total births across facilities, including Advent’s projections. As most Level II/III programs generate their patient volume from births that occur at their own hospital and the fact that AdventHealth does not project any transfers from other hospital OB programs, the ratio of Level II/III days to births for existing programs in the region provides a good benchmark for the Level II/III days that AdventHealth will experience. Moreover, AdventHealth recognizes the relationship between births and neonatal services in Table 1, page 101 of its application.

Using data from the hospital LRAs shows that the ratio of Level II/III days per birth ratio for all of the Level II/III providers in the state (Level IV providers excluded) as demonstrated in **Exhibit 8**. The average across hospitals offering just Level II/III care is 0.73 days per birth. For smaller programs with 10 or less beds, like that proposed by AdventHealth, the ratio is even lower at 0.59 days per birth. There are only two hospitals in the state that have higher Level II/III days per birth than projected by AdventHealth: Catawba Valley Medical Center and Duke Regional Hospital,

which have much larger neonatal programs with 20 and 18 beds, respectively. Each also provides for thousands of births each year compared to the 593-birth average for AdventHealth.

### Exhibit 8

FY2022 Statewide Level II and III Provider Utilization Ratios

HL #:	Facility	Total Acute Care Beds	Neonatal Beds	Neonatal Days	Total Births	Neonatal Days to Birth Ratio
H0223	Catawba Valley Medical Center	200	20	4,357	2,067	2.11
H0233	Duke Regional Hospital	316	18	5,453	2,828	1.93
H0048	Onslow Memorial Hospital	162	18	909	1,316	0.69
H0105	CaroMont Regional Medical Center	372	16	1,725	1,731	1.00
H0100	FirstHealth Moore Regional Hospital	337	13	3,236	2,468	1.31
H0272	Alamance Regional Medical Center	182	12	1,984	1,159	1.71
H0228	Nash General Hospital^	262	12	1,339	945	1.42
H0042	Atrium Health Pineville	278	10	3,022	2,479	1.22
H0258	Vidant Edgecombe Hospital	101	10	230	407	0.57
H0255	Atrium Health University City	104	9	1,961	1,645	1.19
H0276	WakeMed Cary Hospital	208	8	2,368	2,976	0.80
H0270	Novant Health Matthews Medical Center	154	8	2,006	2,587	0.78
H0024	<b>Atrium Health Cleveland*</b>	<b>241</b>	<b>8</b>	<b>398</b>	<b>1,355</b>	<b>0.29</b>
H0259	Lake Norman Regional Medical Center	123	8	17	774	0.02
H0064	Southeastern Regional Medical Center	292	7	1,227	1,225	1.00
H0053	Frye Regional Medical Center	209	6	137	323	0.42
H0052	High Point Regional Health	307	6	449	1,320	0.34
H0199	WakeMed North Hospital	61	6	1,340	5,933	0.23
	<b>AdventHealth Projection</b>	<b>62</b>	<b>5</b>	<b>1,020</b>	<b>593</b>	<b>1.72</b>
H0107	Scotland Memorial Hospital	97	5	1,102	842	1.31
H0224	Cape Fear Valley Betsy Johnson Hospital	87	5	220	451	0.49
H0040	Novant Health Rowan Medical Center	203	5	114	775	0.15
H0050	Atrium Health Union	142	4	1,242	946	1.31
H0087	<b>Harris Regional Hospital^*</b>	<b>86</b>	<b>4</b>	<b>573</b>	<b>556</b>	<b>1.03</b>
H0062	<b>UNC Health Blue Ridge - Morganton*</b>	<b>162</b>	<b>4</b>	<b>943</b>	<b>985</b>	<b>0.96</b>
H0282	Novant Health Huntersville Medical Center	139	4	1,717	2,131	0.81
H0077	Watauga Medical Center	117	4	68	575	0.12
H0257	Wayne UNC Health Care	255	4	106	1,224	0.09
H0225	Atrium Health Lincoln	101	4	20	472	0.04
H0210	Wilson Medical Center	270	3	170	669	0.25
H0222	Carteret General Hospital	135	3	241	1,032	0.23
H0151	UNC Health Johnston -Smithfield	129	3	160	1,924	0.08
H0267-A	Maria Parham Health	91	3	16	413	0.04
H0243	Central Carolina Hospital	127	1	12	354	0.03
H0273	The Outer Banks Hospital	21	1	3	290	0.01
	<b>Statewide Average</b>	<b>175</b>	<b>7</b>	<b>1,140</b>	<b>1,365</b>	<b>0.73</b>
	<b>Avg for Providers with 10 or Less Beds</b>	<b>154</b>	<b>5</b>	<b>746</b>	<b>1,259</b>	<b>0.59</b>

Source: 2023 LRAs,

^2022 LRA used for Harris Regional, Lake Norman Regional, and Nash General due to anomalies in reporting.

\*Provider serves the AdventHealth 9-county catchment area.

If the Statewide Average or Average for Providers with 10 or less beds ratio was applied to AdventHealth’s 593 births (average for 2018-2023), it would predict 351 to 435 days of care depending on which ratio was used. By contrast, AdventHealth unrealistically projects 1,020 days of care. **Exhibit 9** shows the degree of overstatement included in AdventHealth’s projections. This analysis shows that AdventHealth’s theoretical projections and unsupported market shares far overstate its projected Level II/III utilization in relation to its OB program.

**Exhibit 9**  
**AdventHealth’s Realistic Utilization Based the Ratio of Level II/III Days per Birth for Level II/III Programs FY2022**

	<b>AdventHealth Projections</b>	<b>High End Ratio</b>	<b>Low End Ratio</b>
Ratio of Level II/II Days to Births	1.72	0.73	0.59
Historical Average Births (2018-2023)	593	593	593
Projected Level II/III Days of Care	1,020	435	351
ADC	2.79	1.19	0.96
Occupancy of 5 Beds	55.9%	23.8%	19.2%
ALOS	4.8	4.7	4.7
Projected Level II/III Discharges	212	93	75

*AdventHealth is Already Caring for Babies with the DRGs Identified for this Project*

AdventHealth implies that this project will give it the ability to serve a large number of babies that it currently has to transfer out to other facilities, primarily Mission Hospital. AdventHealth also implies that it currently cannot and does not treat babies with DRGs 792 and 793. This is misleading. **Exhibit 10** below shows the babies with DRGs 792 and 793 that were born and cared for at AdventHealth in the last four years. In fact, AdventHealth has kept and treated at its Hendersonville Hospital between 39 and 51 babies with these DRGs in each of the last four years.

**Exhibit 10**  
**Neonates with DRGs 792 and 793 Treated at AdventHealth**

<b>County</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY2023</b>	<b>Average</b>
Buncombe	8	7	9	15	<b>10</b>
Haywood	1	-	-	1	<b>1</b>
Henderson	24	24	34	27	<b>27</b>
Madison	-	-	-	-	-
McDowell	-	-	-	-	-
Polk	3	3	1	2	<b>2</b>
Rutherford	11	1	-	-	<b>3</b>
Transylvania	4	4	5	4	<b>4</b>
Yancey	-	-	-	-	-
<b>Total Service Area</b>	<b>51</b>	<b>39</b>	<b>49</b>	<b>49</b>	<b>47</b>

*Source: HiDi market data.*

*Need for the Service is Not Justified by Neonatal Transfers*

AdventHealth suggests that it is transferring large volumes of patients to Mission Hospital and other more distant Level IV NICU providers on page 38 of its application. The information presented here is misleading for several reasons.



Mission Hospital, with 51 Level IV neonatal acute care beds, is the only provider of neonatal acute care services in the area.<sup>7</sup> During FFY2022, Mission Hospital's neonatal acute care beds provided 13,625 days of care, which equates to 73.2 percent occupancy. When a neonatal bed is not readily available at Mission Hospital, patients must travel to Charlotte, Greenville, SC, or Tennessee where there are neonatal acute care services. The following table summarizes the distances (in miles) from a sampling of cities in the service area to the locations of available neonatal acute care beds.

*Source: AdventHealth application p38.*

First, Level II/III services are available at three additional hospitals in Western North Carolina that serve the catchment area and are ignored by AdventHealth including Harris Regional, UNC Blue Ridge - Morganton, and Atrium Health Cleveland. In addition, there are also Level IV neonatal care units located in Spartanburg and Greenville, SC where AdventHealth identifies patient origin for 2022-2023 newborn deliveries on Application page 40. AdventHealth ignores that OB patients it serves from Greenville and Spartanburg County are likely to be served closer to home if they have to be transferred to the Level IV units in these counties.

In addition, AdventHealth does not transfer babies as frequently as it implies in its application. The statement above, and in other places throughout the application, is highly misleading; it implies that AdventHealth is frequently transferring babies to Mission Hospital that it could serve if it had a higher level of care, yet AdventHealth provides no actual transfer data.

Based on Mission's internal data, AdventHealth transferred on average approximately 42 neonates and/or expectant mothers per year to Mission Health between 2021 and 2023. See **Exhibit 11**. In the same three years, Mission only declined transfer requests for 5 total combined OB and neonatal patients. It is impossible to understand how the proposed program will serve more than 200 neonates per year in Year 3 when AdventHealth is currently transferring an average of 13 babies per year for neonatal care and only about 42 neonatal and high-risk mothers combined. These figures also include patients who need high-risk delivery support or Level IV NICU service that AdventHealth cannot and will not provide.

**Exhibit 11**

**AdventHealth Henderson Neonatal and OB Transfers and Declines with Mission Health**

	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>Average 21-23</b>
AdventHealth Neonatal Transfers Accepted by Mission	18	9	13	13.3
AdventHealth Neonatal Transfers Declined by Mission	0	1	0	0.3
AdventHealth OB Transfers Accepted by Mission	39	18	23	26.7
AdventHealth OB Transfers Declined by Mission	2	2	0	1.3
<b>Total OB/Neonatal Transfers and Declines</b>	<b>59</b>	<b>30</b>	<b>36</b>	<b>41.7</b>

*Source: Mission internal transfer center data.*

At most, AdventHealth's own internal data shows an average of 47 Level II/III DRG patients they are already serving year after year, plus an average of 40 high risk mothers and neonates transferred to Mission each year for a total of 87 patients at most. This number includes transferred patients who need a higher level of care than AdventHealth will offer.

**Exhibit 12** compares the three ways in which Mission has reasonably calculated the demand for AdventHealth’s proposed Level II/III program based on actual service area utilization, statewide Level II/III utilization, and the actual patients already served and transferred by AdventHealth. These analyses result in a range of 19.2% to 23.8% occupancy of the proposed unit, which are all remarkably consistent and less than half of the utilization projected by AdventHealth based on theoretical market volume, unreasonable growth rates, and unsubstantiated market share. The proposed project cannot support a five-bed unit when it has not shown the ability to support a unit at all with a census of approximately one (1) comprised mostly of patients it is already serving. Moreover, it does not need five additional acute care beds to create an underutilized unit when it has ample capacity to convert existing acute care beds to a smaller, more reasonably sized neonatal unit.

**Exhibit 12**  
**Summary of Alternative Projection Analyses Based on Actual Data**

	Discharges	Days	ADC	% Occupancy
Service Area Ratio of Level II/III Discharges to Births (AdventHealth Tables 2 and 3)	78	368	1.0	20.2%
Statewide Ratio of Level II/III Days to Births (All Providers)	93	435	1.2	23.8%
Statewide Ratio of Level II/III Days to Births (Providers with 10 or Less Beds)	75	351	1.0	19.2%
Average of Patients Already Served + Transferred Babies and High Risk Mothers*	87	409	1.1	22.4%
<b>AdventHealth Projections</b>	<b>212</b>	<b>1,020</b>	<b>3</b>	<b>55.9%</b>

*\*Includes transfers of Level IV neonates and high-risk mothers with conditions not appropriately treated at AdventHealth even with Level II/III care.*

*AdventHealth’s Asheville Hospital Proposal Undermines this Project*

These neonates to be served at AdventHealth in Henderson County will be further diluted when and if AdventHealth implements its proposed hospital in Buncombe County. In 2022, AdventHealth applied for and received conditional approval to build an acute care hospital in Asheville, Buncombe County which will include an OB unit.<sup>3</sup> AdventHealth fails to consider any shift in patients from AdventHealth Hendersonville to its Asheville hospital and does not identify whether these neonates will be transferred to Mission, which is likely closer to home, or to its Hendersonville Hospital. **According to its application for the Buncombe County hospital, AdventHealth wanted to bring its proposed services (including OB) closer to the homes of residents currently traveling to Hendersonville for care.** In addition, the story that AdventHealth highlights at the beginning of its neonatal application demonstrates the need for neonatal care close to home. Does AdventHealth intend to transfer its neonatal patients further away from home to its new unit? AdventHealth makes no effort to account for patients who will

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<sup>3</sup> Project ID #B-12233-22 is currently under appeal. It should be noted that AdventHealth does not have site entitlement to the proposed site included in this application.

undoubtedly shift from AdventHealth Hendersonville to the Buncombe County hospital upon its implementation and therefore includes these patients in its neonatal patient projections.  
*AdventHealth's Acute Care Bed Utilization Does Not Support the Need for More Beds*

AdventHealth is applying to add five new acute care beds for a project that it cannot support with either reasonably projected Level II/III utilization or its other acute care services. As shown in **Exhibit 12** AdventHealth's proposed Level II/III beds will be utilized at occupancy between 19% and 23% based on reasonable assumptions.

In addition to its over-projection of neonatal days, AdventHealth also overestimates its future general acute care bed utilization.<sup>4</sup> To project acute care days for the project horizon, it uses a CAGR of 4.3% to represent the growth in patient days for 2019-2023. However, it fails to notice the reduction of days from 2019 to 2021, even without considering the sharp decline in 2020 due to COVID.

The use of patient days to predict the growth rate conveniently omits consideration of total discharges and ALOS. In the same period (2019-2023), discharges had only a 1.9% CAGR. See **Exhibit 13**. However, ALOS grew 2.3% during this time period. The combination of these two factors resulted in an inflated total patient day growth rate. It is not reasonable to assume that ALOS will continue to grow at a rate of 2.3% per year.

**Exhibit 13**  
**AdventHealth Utilization and Growth for 2019-2023**

	<b>FFY2019</b>	<b>FFY2020</b>	<b>FFY2021</b>	<b>FFY2022</b>	<b>FFY2023</b>	<b>2019-2023 CAGR</b>
Discharges	3,290	2,839	3,008	3,172	3,547	1.9%
ALOS	3.5	3.1	3.7	4.1	3.8	2.3%
Days	11,398	8,839	11,096	12,984	13,467	4.3%
ADC	31.23	24.22	30.40	35.57	36.90	
Beds	62	63	64	65	66	
% Occupancy	50.4%	38.4%	47.5%	54.7%	55.9%	

*Source: 2020-2024 LRAs*

Based on reasonable assumptions, when AdventHealth's utilization is projected based on actual 2023 discharges grown at a CAGR of 1.9% (consistent with Advent's historical rate of growth for 2019-2023), and ALOS is held constant at 3.8, the results would be patient days totaling 14,795 in 2028 for a 65.4% occupancy. See **Exhibit 14**. Contrary to the AdventHealth's statement on Application page 64, AdventHealth will not soon meet the target occupancy of 66.7%. Nor does an occupancy rate of 65.4% justify the addition of 5 acute care beds.

<sup>4</sup> It should be noted that total patient days (only) are presented on page 63 of the application, but Form C-1b was not completed for the facility as a whole, and as a result the application is incomplete, given that the application is necessitated by the addition of five acute care beds.

**Exhibit 14**  
**Revised Projection Based on Admission Trend**

	FFY2023	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028
Discharges	3,547	3,614	3,683	3,753	3,824	3,897
ALOS	3.8	3.8	3.8	3.8	3.8	3.8
Days	13,467	13,723	13,983	14,249	14,519	14,795
ADC	36.90	37.60	38.31	39.04	39.78	40.53
Beds	62	62	62	62	62	62
% Occupancy	59.5%	60.6%	61.8%	63.0%	64.2%	65.4%

In addition, AdventHealth again fails to consider its Buncombe County hospital. AdventHealth shows on page 31 that Buncombe County residents comprise 36.7% of its total patients in the last full fiscal year. On page 33, AdventHealth projects Buncombe County patients will comprise 36.7% of total patients for the entire facility in the first three years of this project through 2028. It fails to consider any patient shift to the Buncombe County hospital, even though Buncombe County patients alone make up more than one-third of its total patient base.

*AdventHealth Lacks Support of Actual Clinical Providers for this Project*

AdventHealth’s Letters of Support (AdventHealth’s Exhibit I.2) further highlights the lack of true internal need for this project. With the exception of one letter from a pediatric hospitalist who sees newborns at AdventHealth, all other letters are community letters of support. Like Mission, these agencies and representatives agree that increased access to neonatal care is always a good thing. However, these letters originate from a large geographic area of community agencies, whose communities will not necessarily gain meaningful access to neonatal care through the proposed project.

More importantly, there is only one letter from a physician within AdventHealth supporting this project. There are no letters at all from obstetricians who deliver at AdventHealth to document that the proposed unit is actually needed. It is unusual that this project would be pursued without the support of current OB physicians and other clinical nursery staff. This further highlights the likelihood that the driving force for this project is additional general acute care beds and not the neonatal unit itself.

In summary, AdventHealth fails to show a need for additional acute care beds and fails to show a need for a five-bed neonatal care unit. It simply does not have the utilization to support either. Mission is in full support of expanding access to neonatal care, but fears that this project is simply a guise to add acute care beds when the 2024 SMFP shows that Henderson County has no need.

**Criterion (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.**

AdventHealth fails to demonstrate that its project is the most effective alternative. AdventHealth considered only two alternatives:

1. Do Nothing / Maintain Status Quo
2. Convert Existing Beds Acute Care Beds to Neonatal Acute Care Beds

While Mission believes that option two is viable, a third, better option exists which AdventHealth failed to consider: Right Size the Unit **and** Convert Existing Acute Care Beds to Neonatal Acute Care Beds.

As discussed and demonstrated in detail in the discussion of Criterion (3), the proposed neonatal care unit is oversized. There is no way that AdventHealth can support a five-bed neonatal care unit given its historical births, its current acute care bed count, and its proposed services for the project. While Mission fully supports additional access to neonatal care in Western North Carolina, more beds does not necessarily equal more access to care. AdventHealth should recalibrate the unit to reduce the proposed neonatal acute care beds to create a unit that will be more efficiently utilized.

AdventHealth has ample capacity – now and in the future – to convert existing acute care beds to neonatal acute care beds, even more so if the size of the unit is reduced. As shown in the discussion of Criterion (3), AdventHealth significantly over projected its future acute care utilization to demonstrate that it needs additional licensed beds for this project. The impetus behind this is likely two-fold. First, it allows AdventHealth to utilize a higher-level charge mechanism for some babies it is already serving that could be categorized as Level II. See **Exhibit 10**.

In addition, AdventHealth is utilizing a back door to obtain additional acute care beds. Licensure does not differentiate between licensed acute care beds and neonatal acute care beds; they are all combined as a licensed acute care bed count on the license. The 2024 SMFP shows a need for zero (0) acute care beds in Henderson County and resultingly does not allow AdventHealth to apply for additional acute care beds. However, neonatal acute care beds no longer fall under the purview of the SMFP and can be obtained without a quantitative need determined by the Agency. Should the proposed unit not be sustainable, which is likely, AdventHealth can potentially convert these beds to general acute care beds without a CON in the future.

AdventHealth has chosen an oversized and unneeded alternative that allows it to strategize and maximize its future structure and to give it options down the road. However, AdventHealth does this at the expense of the efficiency of its proposed neonatal unit and in a manner that likely fails to disclose its full intent.

AdventHealth should be found non-conforming with Criterion (4).

## **Criterion (5) Financial Feasibility**

### Projected Utilization/Financial Feasibility

As discussed in detail in Criterion (3), AdventHealth’s projected utilization for both neonatal acute care beds and general acute care beds is unreasonable, unsupported, and based on flawed methodology and theory. More importantly, neonatal acute care utilization is not tied at all to Advent’s actual births and historical OB/GYN utilization and transfers. As a result,

AdventHealth's financial projections are unreasonable, undocumented, and overstated. There is no way to verify that the proposed project is financially feasible based on AdventHealth's projected utilization as it results in far overstated revenues and unreliable financial feasibility.

#### Understated Operating Costs

As will be discussed under Criterion (7), AdventHealth has not considered the wide variety of clinical expertise that is required to operate the proposed unit and has therefore understated its staffing expense. It does not appear that AdventHealth has reviewed the required support services needed to operate a Level II/III program accredited by the American Academy of Pediatrics ("AAP").

As will be discussed in more detail, AdventHealth has not provided for expenses or staffing associated with a medical director/neonatologist, a clinical nurse specialist in neonatal medicine, a dietitian with neonatal experience, 24/7 pharmacy support from a pharmacist with neonatal pharmacology experience, a respiratory therapist with neonatal experience, a neonatal therapist (behavioral health), at least 1 registered dietician with specialized training in neonatal nutrition, a master's level social worker with perinatal or pediatric experience, pediatric ophthalmology support to monitor retinopathy associated with prematurity. See **Attachment B** for the standards required by the AAP. AdventHealth does not identify any costs associated with these required staff positions or the cost associated with specialist consultation.

In summary, AdventHealth should be found non-conforming with Criterion (5) as flaws and questionable information are contained throughout Advent's financial projections.

#### **Criterion (6) Unnecessary Duplication**

AdventHealth's proposed project does not properly consider all existing providers of neonatal care throughout and near its counties of patient origin shown on Application page 40. While it could provide a closer location to parts of Henderson, Polk, and Transylvania counties, it does not meaningfully increase access to much of its 9-county service area.

In its Application, AdventHealth also ignores existing providers of Level II/III neonatal care in western North Carolina and northern South Carolina. Harris Regional Hospital in Sylva (Jackson County), Atrium Health Cleveland (Cleveland County), and UNC Blue Ridge – Morganton (Burke County) are existing providers in western North Carolina, in addition to the Level IV NICU services provided at Mission Hospital. Furthermore, there are two other proximate neonatal acute care providers in Greenville and Spartanburg, South Carolina. However, AdventHealth wrongly states over and over again that Mission Hospital is the only provider in western North Carolina.

Again, increased access to neonatal services is always positive. However, access was not fully assessed by AdventHealth in its proposal. As a result, its oversized unit with inflated utilization projections will provide less access to the service area than AdventHealth has claimed.

For these reasons and those referenced in the associated discussions of Criteria (1), (3), (4), and (18a), AdventHealth should be found non-conforming with Criterion (6).

## Criterion (7) Staffing

On Application, page 47, AdventHealth describes its intended service offerings for the neonatal care unit as follows:

Based on a review of North Carolina licensure regulations for the organization of neonatal services, American Academy of Pediatrics (AAP) level of neonatal care requirements, existing clinical staff, and proposed scope of services, AdventHealth Hendersonville's clinical leadership determined it could safely accommodate discharges historically categorized by DRG 792 – Prematurity Without Major Problems and a portion of discharges historically categorized by DRG 793 – Full Term Neonate With Major Problems. AdventHealth Hendersonville's clinical leadership reviewed the ICD-10 codes and associated length of stay within the historical discharges for DRG 793 to identify the cohort of patients that could appropriately be served by the proposed project. A summary of the historical data is included in Exhibit C.4-2.

Source: Application p47

While AdventHealth never specifies, its service offerings align with the AAP definition of a Level II Special Care Unit.

### STANDARD V: LEVEL II SPECIAL CARE NURSERY (SCN) REQUIREMENTS

#### Level II SCN Requirements

- (a) The Level II SCN will provide comprehensive care of infants born  $\geq 32$  wk or with birth wt  $\geq 1500$  g who<sup>2</sup>:
1. are mild to moderately ill with physiologic immaturity or who have conditions that are expected to resolve quickly<sup>2</sup>;
  2. are not anticipated to require subspecialty services on an urgent basis<sup>2</sup>;
  3. require continuous positive airway pressure (CPAP) or short-term (less than 24 h) conventional mechanical ventilation for a condition expected to resolve rapidly or until transfer to a higher-level facility is achieved<sup>2</sup>; or
  4. are back transferred from a higher-level facility for convalescent care.<sup>2</sup>

The AAP publication which outlines the guidelines and requirements for a Level II Special Care Unit is included in **Attachment B**. Level II Special Care is outlined on pages 6-8 of the document.

AdventHealth's proposed staffing leaves many questions and fails to demonstrate that the proposed unit meets all AAP requirements for a Level II Special Care Unit. These include:

- The total FTEs on Form H include only four positions: Registered Nurses, Lactation Consultant, Respiratory Therapist, and Surgery Tech. In Year 1 of the project, except Registered Nurses, all other positions are equal to 0.1 FTE or less. By Year 3, the lactation consultant for the unit is equal to 0.3 FTE and the Respiratory Therapist and Surgery Tech are still equal to 0.1 FTE or less. As described below, respiratory therapy is significantly understaffed, and other necessary staffing requirements have not been considered.

Form H Staffing									
Neonatal Acute Care Beds	1st Full FY			2nd Full FY			3rd Full FY		
Include employees, contract employees and temporary employees but not independent contractors	# of FTEs	Average Annual Salary per 1 FTE**	Total Salary *	# of FTEs	Average Annual Salary per 1 FTE**	Total Salary *	I	Average Annual Salary per 1 FTE**	Total Salary *
	E	F	G=E*F	H	I	J=H*I	K	L	M=K*L
Registered Nurses	8.5	\$85,485	\$722,810	8.5	\$88,050	\$747,049	8.5	\$90,691	\$771,615
Lactation Consultant	0.1	\$101,519	\$14,997	0.2	\$104,563	\$21,904	0.3	\$107,711	\$27,330
Respiratory Therapist	0.0	\$85,214	\$1,717	0.0	\$87,779	\$2,694	0.0	\$90,406	\$3,556
Surgery Tech	0.0	\$65,636	\$2,644	0.1	\$67,596	\$4,150	0.1	\$69,618	\$5,476
<b>Total</b>	<b>8.7</b>		<b>\$742,167</b>	<b>8.8</b>		<b>\$775,797</b>	<b>8.9</b>		<b>\$807,976</b>

Source: Application p112

- First, Respiratory Therapy is a key component to providing Level II/III care (aligning with the AAP Level II standards). As shown below, a Level II SCU must have a respiratory care leader and staff available for immediate 24/7 onsite care when needed. AdventHealth only projects to have 0.1 FTE in Year 3 for its respiratory therapist. 0.1 FTE is equal to four hours a week. In the case of a full five-bed unit, this is equivalent to **48 minutes per week of care per baby or 6.9 minutes per day**.

<b>Respiratory Therapy</b>
(w) The respiratory care leader will: <ol style="list-style-type: none"> <li>1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. have sufficient time allocated to oversee the respiratory therapists (RTs) who provide care in the level II SCN;</li> <li>3. provide oversight of annual simulation and skills verification, which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;</li> <li>4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and</li> </ol>
5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.
(x) Respiratory care practitioners assigned to the SCN will: <ol style="list-style-type: none"> <li>1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal or pediatric respiratory care certification preferred;</li> <li>2. be on-site 24/7 and immediately available when an infant is supported by assisted ventilation or CPAP;</li> <li>3. be able to attend deliveries and assist with resuscitation as requested;</li> <li>4. demonstrate a current status of NRP completion;</li> <li>5. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the SCN; and</li> </ol>

Source: AAP Guidelines for Neonatal Care pp.7-8

- In addition, AdventHealth also undervalues lactation services. Lactation services are a vital component of care for neonates and their mothers, who generally need to pump to feed their babies at this level of care. The AAP provides the following guidelines for lactation assistance:

<b>Lactation and Breastfeeding Support</b>
(aa) The facility will: <ol style="list-style-type: none"> <li>1. have personnel with the knowledge and skills to support lactation available at all times;</li> <li>2. have a certified lactation counselor (CLC), international board-certified lactation consultant (IBCLC) preferred, available for on-site consultation on weekdays and accessible by telehealth or telephone 24/7; and</li> <li>3. operationally review CLC and/or IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup></li> </ol>

Source: AAP Guidelines for Neonatal Care p8



- With a maximum allocation of a 0.3 FTE lactation consultant, there is no way AdventHealth can meet this level of care.
- There are other staffing and support areas required by the AAP that AdventHealth omits. These include, but are not limited to:
  - Neonatal Medical Director
  - Neonatologist
  - Privileged Care Providers
  - Nursing Leadership
  - Neonatal Therapists
- There are also staff positions currently in place at AdventHealth that the Application omits addressing whether the current staff have specialized neonatal training and can serve the unit or whether additional staffing will be required. This includes:
  - Social Workers
  - Dieticians
  - Pharmacy

**With regard to staffing, AdventHealth treats this project as if it is just another nursing unit and fails to recognize the specialized staffing and requirements this unit will require.** As a result, its staffing and associated expenses are largely underestimated.

### **Criterion (8) Support Services**

As described above in relation to Criterion (7), it is clear that AdventHealth already has these functions in place for the hospital as a whole. However, the proposed neonatal care unit will have specialized needs and requirements for some support staff including management, staff training, dietary, social services, and discharge planning. See **Attachment B**. AdventHealth does not describe any steps it will take to ensure that existing staff have the skills and training necessary to serve the neonatal care unit or to recruit additional staff who do. This is necessary to ensure quality of care for the proposed project.

### **Criterion (13) Medically Underserved Population**

AdventHealth does not disclose charity care in its projected payor mix. See **Exhibit 15**. However, as would be expected, there is a huge contrast in payor mix between general inpatient care and neonatal acute care beds. It is not surprising that both Medicaid and insurance percentages are significantly higher for neonates than for adult care, as neonates do not qualify for Medicare and are more likely to qualify for Medicaid due to pediatric medically fragile conditions.

**Exhibit 15**

<b>Projected Payor Source 3rd FFY</b>		
<b>Payor Source</b>	<b>Percentage of Total Patients Served</b>	
	<b>Facility</b>	<b>Neonatal Acute Care Beds</b>
Self-Pay	4.10%	5.80%
Charity Care	Included in Self-Pay	Included in Self-Pay
Medicare	55.50%	
Medicaid	8.70%	56.70%
Insurance	29.20%	37.50%
Workers Compensation		
TRICARE		
Other	2.50%	
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Source: Application p87

While charity care was bundled with self-pay by AdventHealth in its payor mix, it can be calculated and compared using the totals on Form F.2b. As a percentage of gross revenue, AdventHealth proposes to provide less charity care to its neonatal patients than to general inpatients. AdventHealth estimates that charity care for neonates will equal 2.27% of total gross revenue in the first three project years, while it estimates that charity care for general inpatients will equal 4.27% of total gross revenue for the same time period. See **Exhibits 16 and 17**. While AdventHealth projects to provide care to a higher level of Medicaid neonates, as medically fragile infants can often qualify for Medicaid, it is questionable that it projects a lower level of charity care for those with insurance and self-pay given the acuity and cost of care.

**Exhibit 16**

**Projected Charity Care as a Percentage of Gross Revenue – Proposed Neonatal Beds**

	<b>FFY1</b>	<b>FFY2</b>	<b>FFY3</b>
<b>Charity Care</b>	\$ 70,777	\$ 111,343	\$ 147,938
<b>Total Gross Revenue</b>	\$ 3,120,204	\$ 4,908,558	\$ 6,521,842
<b>Charity Care as a % of Total Gross Revenue</b>	2.27%	2.27%	2.27%

Source: Form F.2b, Application p108

**Exhibit 17**

**Projected Charity Care as a Percentage of Gross Revenue – General Acute Care Beds**

	<b>FFY1</b>	<b>FFY2</b>	<b>FFY3</b>
<b>Charity Care</b>	\$ 5,464,347	\$ 5,867,981	\$ 6,301,865
<b>Total Gross Revenue</b>	\$ 127,970,652	\$ 137,423,444	\$ 147,584,653
<b>Charity Care as a % of Total Gross Revenue</b>	4.27%	4.27%	4.27%

Source: Form F.2b, Application p109

**Criterion (18a) AdventHealth’s Project will Not be Cost Effective, Offer Quality Care, Increase Access, or Improve Competition**

As discussed in detail above regarding Criteria (1) and (3), the project is not cost-effective because the proposed unit is oversized, and its projected utilization is highly overstated. The proposed project will not serve the number of patients it proposes and will not be cost-effective. In addition, the outlay to establish the proposed service is not justified by the small number of patients it will ultimately serve. As referenced earlier, this expenditure is likely more about obtaining the option to have additional acute care beds in the future than it is about establishing neonatal care at a hospital that only delivered 548 babies in 2023.

There is no denying that care closer to home and the ability to keep parents and babies closer together during the neonatal care period results in better overall outcomes and experiences. However, the remainder of AdventHealth’s response to the quality-of-care component is vague and theoretical. AdventHealth first discusses the availability of AdventHealth’s 24/7 OB/GYN hospitalists who manage OB care and gynecological emergencies. While this is vital to delivery outcomes, it ignores the fact that these are not the physicians that will care for the neonates being served in the proposed unit. There is no discussion of the staffing quality and availability of the clinical staff who will be caring for the infants in the proposed neonatal care unit.

In addition, AdventHealth provides general quality policies to show its commitment to quality but does not address or provide any draft policies or initiatives unique to its proposed neonatal care unit. Moreover, AdventHealth makes no assertions to seek any form of accreditation or to meet AAP requirements for the proposed unit. Its application does not demonstrate that it has any understanding or plans for the level of care that it proposes to offer regarding staffing, quality, and availability. See discussions of Criteria (7) and (8).

Regarding access to underserved groups, AdventHealth states:

The proposed project will promote access to healthcare services in the service area by the medically underserved. AdventHealth Hendersonville has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. AdventHealth Hendersonville will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient’s ability to pay. Please see discussion in Section C and the policies in Exhibit L.4.

*Source: Application p93*

These “specific strategies” are called into question by the charity care comparison presented previously in **Exhibits 16 and 17**. It is unusual that AdventHealth is taking extra measures to provide charity care to the proposed patient base, but the proposed charity care would be a lesser percentage of gross revenues than the charity care provided to the patient population at large. AdventHealth has not adequately demonstrated that it will increase access to financially underserved populations with this project.

In conclusion, AdventHealth’s project will not create meaningful competition or increase access in most of its nine service area counties. AdventHealth fails to account for multiple other nearby providers of Level II/III neonatal care and considers only Mission as an alternative to its project for its proposed service area.

AdventHealth should be found non-conforming with Criterion (18a)

**Criteria and Standards – Advent’s Project Does Not Address Performance Standards for Acute Care Beds**

As there is no mechanism for reviewing this project as anything other than a change in licensed bed capacity, then AdventHealth is requesting to add to its licensed bed capacity. As such, the acute care criteria and standards apply, which AdventHealth has not addressed.

\* \* \*

For all these reasons, AdventHealth is non-conforming with multiple criteria should be denied.

**Attachment A**  
**Washington Post Article**

# Millennials aren't having kids. Here's why.

We found some answers when looking into a different mystery: What's going on with only children?



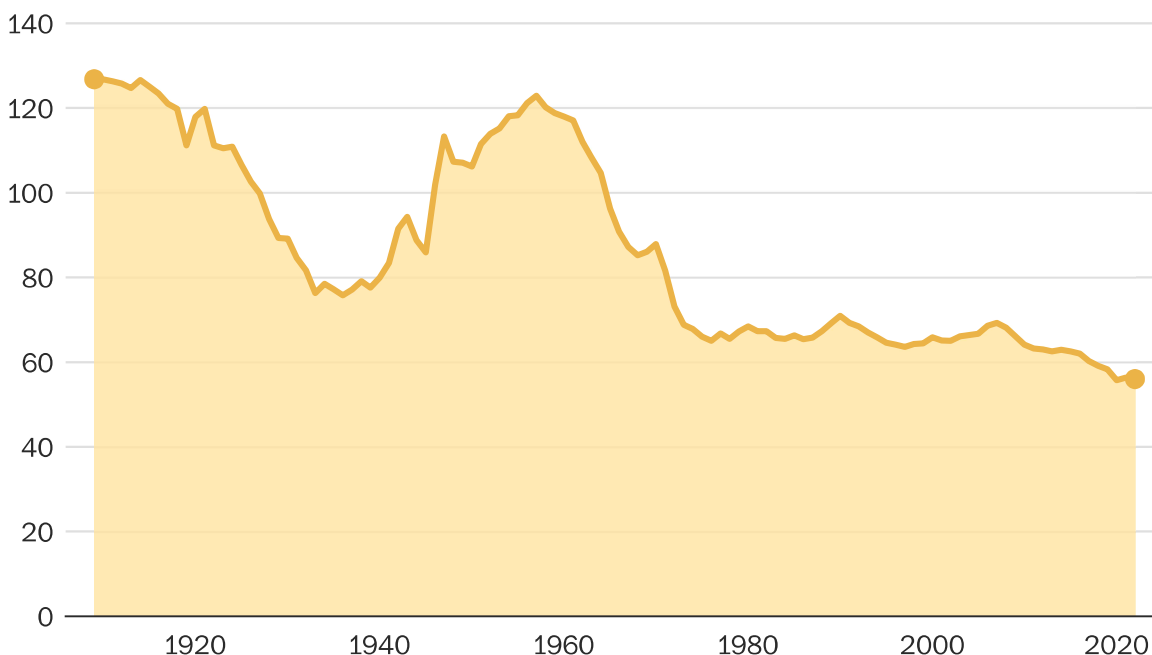
Analysis by [Andrew Van Dam](#)  
Staff writer | + Follow

November 3, 2023 at 6:00 a.m. EDT

The U.S. birthrate languishes at its lowest level in history. So when our friend and colleague [Herman Wong](#) suggested running the numbers on only children, we lit up with the cheap joy of answering a question to which we already knew the answer. With fewer kids overall, Americans are surely cranking out one-hit wonders in record numbers, right?

## America's birthrate remains mired near record lows

Annual live births per 1,000 women ages 15 to 44



Not so fast!

Every two years, the Census Bureau quietly appends a battery of fertility-related questions to its workhorse monthly questionnaire, the Current Population Survey, our go-to source for everything from the unemployment rate to Americans' moving habits. It's smaller than the immense annual American Community Survey, but it's one of the few major surveys that asks how many times American women have given birth.

## Department of Data



We here at the Department of Data are dedicated to exploring the weird and wondrous power of the data that defines our world. [Read more.](#)

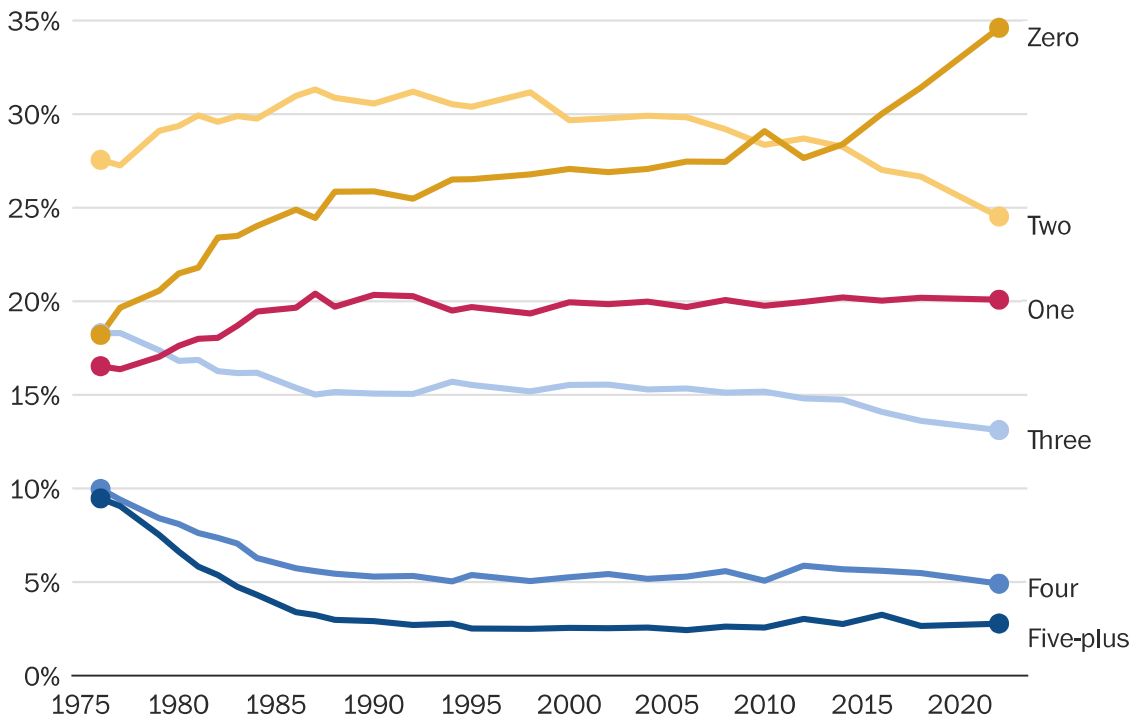
As we analyzed the latest figures, from 2022, our brains spun in our skulls: Since the mid-1980s, the rate at which we produce only children has remained absolutely flat. Something like 1 in 5 American women ages 25 to 44 are one and done.

That's bizarre, given birthrates! But let's zoom out and look at the whole universe of possible family sizes.

First, we noted that families with three or more kids plunged in the 1980s, as birth control, education and greater opportunity helped women pile into the workforce. That's also when only children rose to their current level. Families shifted again after the Great Recession when, among women 25 to 44, even having two children lost its luster. The number of women who had zero children soared. Only children held steady.

## Only children stay steady; zero-child families become the norm

Number of times women have given birth in their lifetime, average, ages 25 to 44



Note: We omitted 2020, due to pandemic-related disruptions.

Source: Census Bureau's Current Population Survey Fertility Supplement via IPUMS

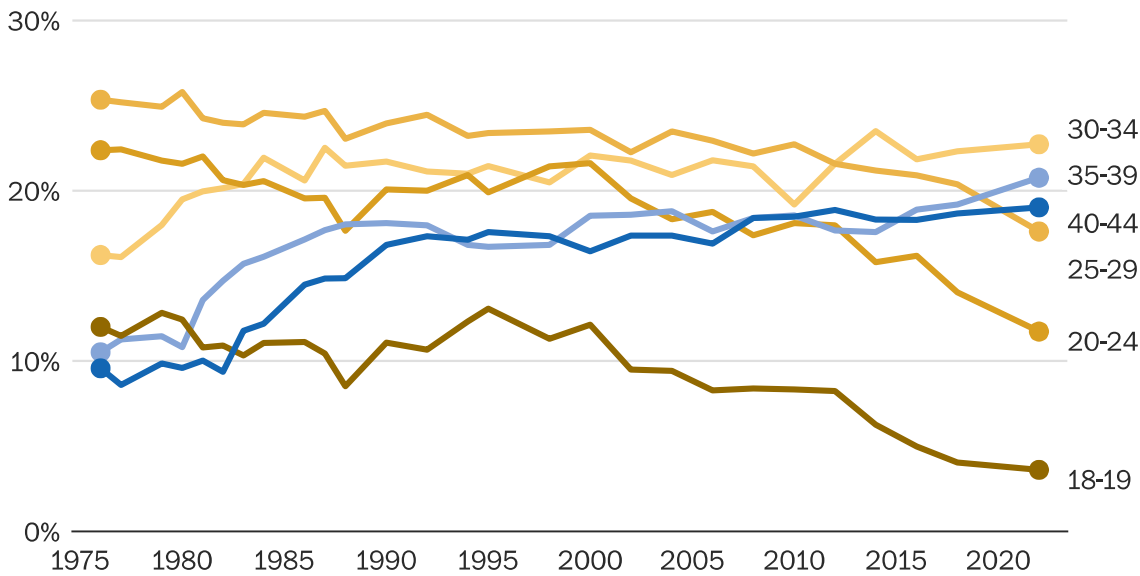
DEPARTMENT OF DATA / THE WASHINGTON POST

To be sure, this is partly because women are starting their families later and thus having second children later. But even among women in their early 40s, the share of only children has barely budged in more than three decades, crawling from 17 percent in 1990 to 19 percent in 2022.



## The flat overall line masks shifts in age groups

Share of women who have given birth only once, by age



Note: We omitted 2020, due to pandemic-related disruptions.

Source: Census Bureau's Current Population Survey Fertility Supplement via IPUMS

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That suggests a simple explanation: If people want kids, they want more than one. A consistent minority stops at one, be it for biological, philosophical or logistical reasons. But otherwise children seem to be a multiple-or-nothing proposition.

Our friends at Gallup confirmed this. A poll this summer found that almost nobody — just 3 percent of Americans — considers one child to be the ideal family size.

## (Almost) nobody thinks you should have just one child

What do you think is the ideal number of children for a family to have?

View more

Source: Gallup telephone poll of 2,028 U.S. adults from June 1 to 22 and July 3 to 27, 2023, with a margin of error of plus or minus 3 percentage points

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Even if you poll people who currently have one child, only 6 percent of them consider one to be the loveliest number. Zero is even less popular.

## How many kids you think are ideal, based on how many you currently have

What do you think is the ideal number of children for a family to have?

Zero children is ideal	One	Two	Three	Four	Five or more	No opinion
	0	20	40	60	80	100
Currently have zero						
Currently have one						
Currently have two						
Currently have three						
Currently have four or more						

Note: Numbers may not total to 100 due to rounding.

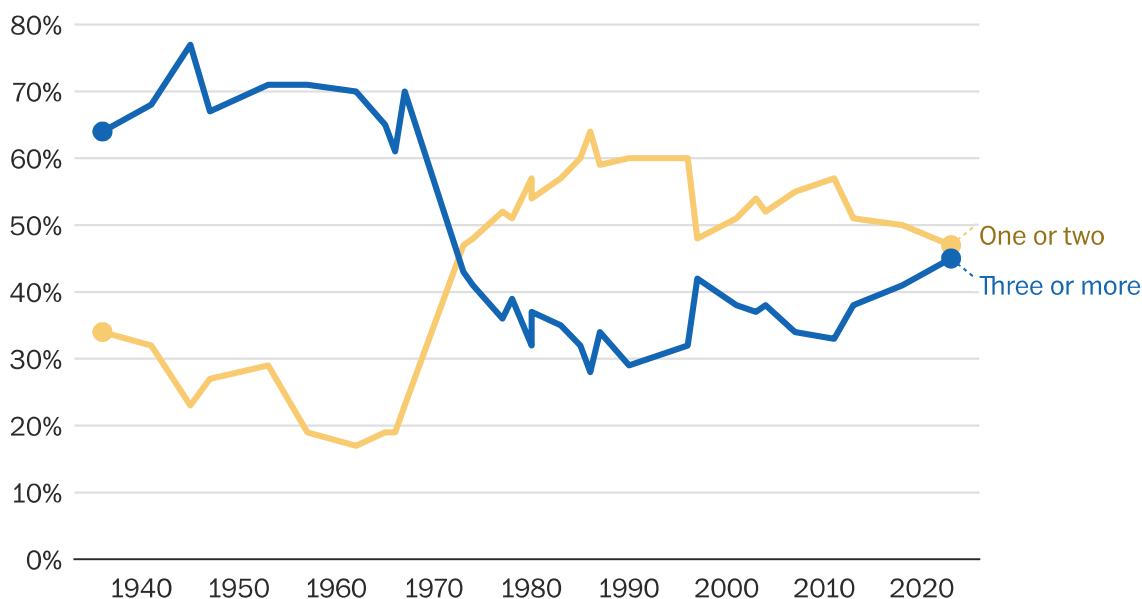
Source: Gallup telephone poll of 2,028 U.S. adults from June 1 to 22 and July 3 to 27, 2023, with a margin of error of plus or minus 3 percentage points

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About three quarters of us think two (44 percent) or three (29 percent) children would be ideal. And the parents who have that many kids are much more likely to have the precise number of kids they think is ideal. That contrasts sharply with parents with fewer kids, who almost always think more would be ideal, and parents with four or more kids, about half of whom think the ideal family is probably smaller than theirs. Whoops.

## Bigger families are coming back in style

What do you think is the ideal number of children for a family to have?



Source: Gallup telephone polls, most recently of 2,028 U.S. adults from June 1 to 22 and July 3 to 27, 2023, with a margin of error of plus or minus 3 percentage points

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University of Texas psychologist Toni Falbo has studied only children such as herself since the mid-1970s, when they were legitimately rare. She told us that (largely false) stereotypes have led parents to believe that having just one child amounted to “mistreating your child by not providing them with another sibling.”

There’s evidence that only children may be more likely to divorce than people from large families, and may have higher body mass indexes in adolescence, Falbo told us. But she’s found little backing for the persistent belief that only children struggle socially, especially after kindergarten.

“It turns out only children are not more selfish than others. They aren’t lonelier than others,” Falbo said. “Ironically, in many ways, they’re less lonely than other people because they’re accustomed to being alone.”

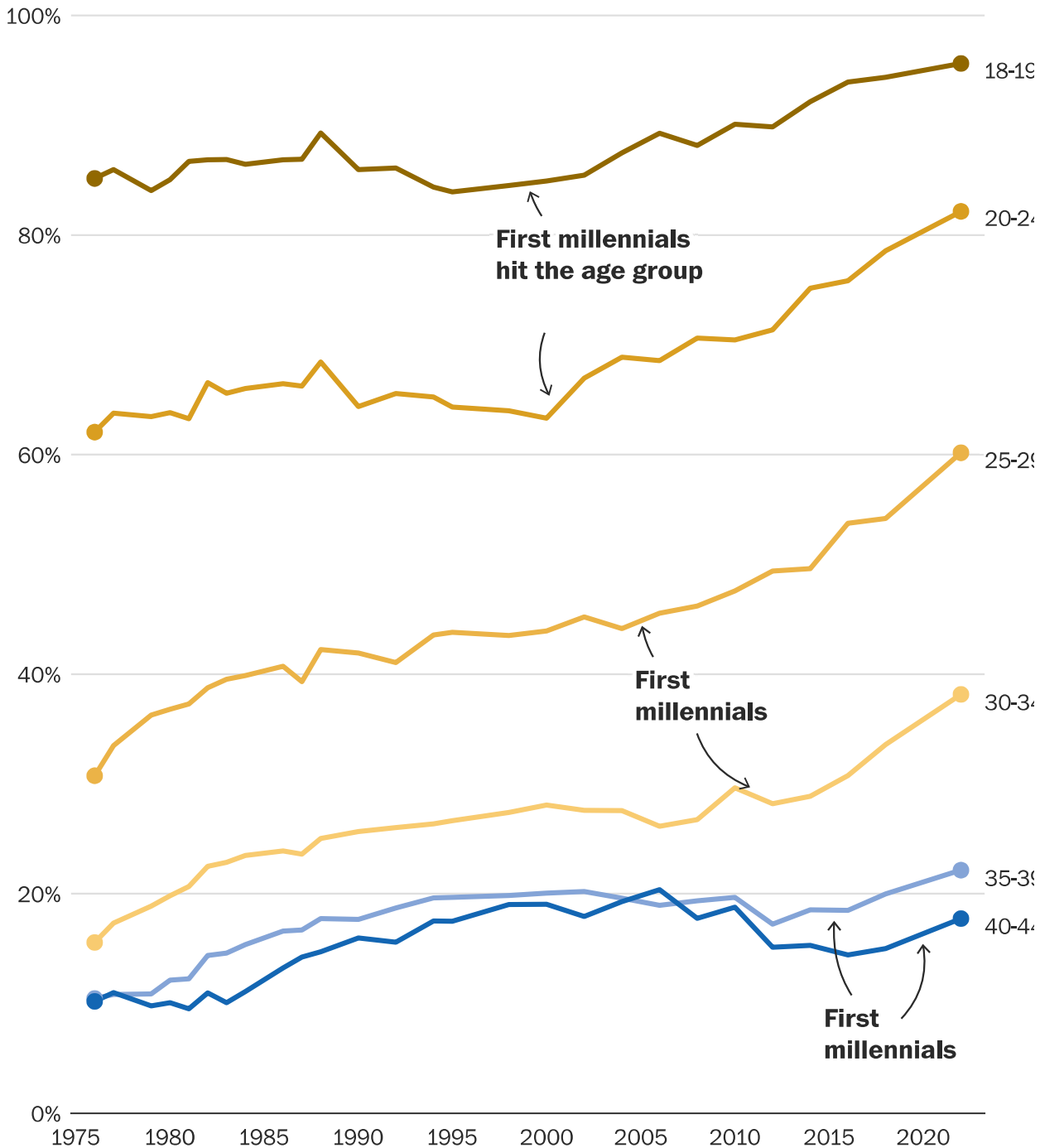
So why are people choosing none over one? The biggest determinants of childlessness seem to be youth, marriage (or lack thereof) and higher education. The shift toward zero kids came fastest among younger women, especially those in their 20s, though we now see it across the age spectrum.

But look deeper at that data and you'll spot something wild. Women in their early 20s embraced childlessness first, with a sharp rise beginning around 2002. That happens to be when the first millennials, born in 1981, entered that age group. For women in their later 20s, the jump in childlessness happened in 2006, just as the first millennials arrived.

As you ascend the age spectrum, the millennial echo follows. When the oldest millennials hit their 40s, even 40-year-olds become more likely to go childless.

## A generational turning point in childlessness

Share of women who have never given birth, by age



Source: Census Bureau's Current Population Survey Fertility Supplement via IPUMS

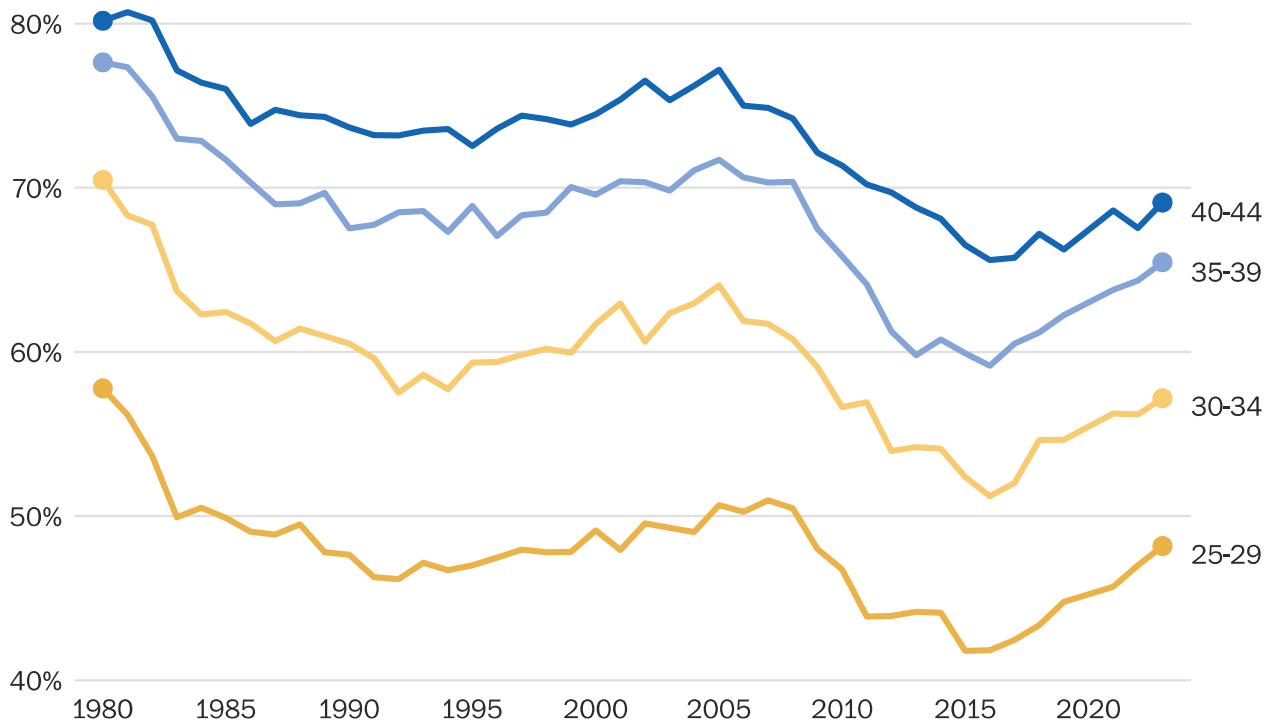
Generations are squishy, man-made distinctions. Outside the baby boom, it's rare to see such a vivid generational turning point. We'd love to have a perfect explanation for it. Send us your theories!

For now, we can tell you that marriage rates have steadily declined, and unmarried folks are less likely to have kids. The same goes for that other major marker of building your own household: a building. Millennials were late to homeownership, which made it harder to start families.

But neither offers a full explanation. Both married and unmarried Americans have shifted toward childlessness in the millennial era. And levels of childlessness have actually accelerated among millennials as their homeownership rates have recently grown.

## The great millennial homeownership rebound

Share of women whose households own their own home



Note: We omitted 2020, due to pandemic-related disruptions.

Source: Census Bureau's Current Population Survey Annual Social and Economic Supplement via IPUMS

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Instead, just about every source we consulted pointed to the broader economic climate. Hammered by the Great Recession, soaring student debt, precarious gig employment, skyrocketing home prices and the covid-19 crisis, millennials probably faced more economic headwinds in their childbearing years than any other generation. And, as sociologist Karen Benjamin Guzzo, director of the Carolina Population Center at the University of North Carolina, told us, it put them behind on everything you're supposed to line up before you have kids.

“We have a pretty strong set of prerequisites: You absolutely should finish school, and have a decent job, and you should make a decent income, and you should be in a good partnership, and you should live on your own,” Guzzo told us. “That takes a while to accomplish, especially in this day and age. Some people may feel like they’re never going to be in a good place.”

And, unlike previous generations, millennials had the means to delay pregnancy thanks to affordable, long-acting birth-control options, said Alison Gemmill, a demographer at the Johns Hopkins Bloomberg School of Public Health.

“Historically, one of the reasons why we think the U.S. has had such a high fertility rate compared to other countries was related to unintended and unwanted pregnancies that resulted in births,” Gemmill told us. Now that it’s easier to avoid accidental pregnancies, more women are having kids later, or not at all.

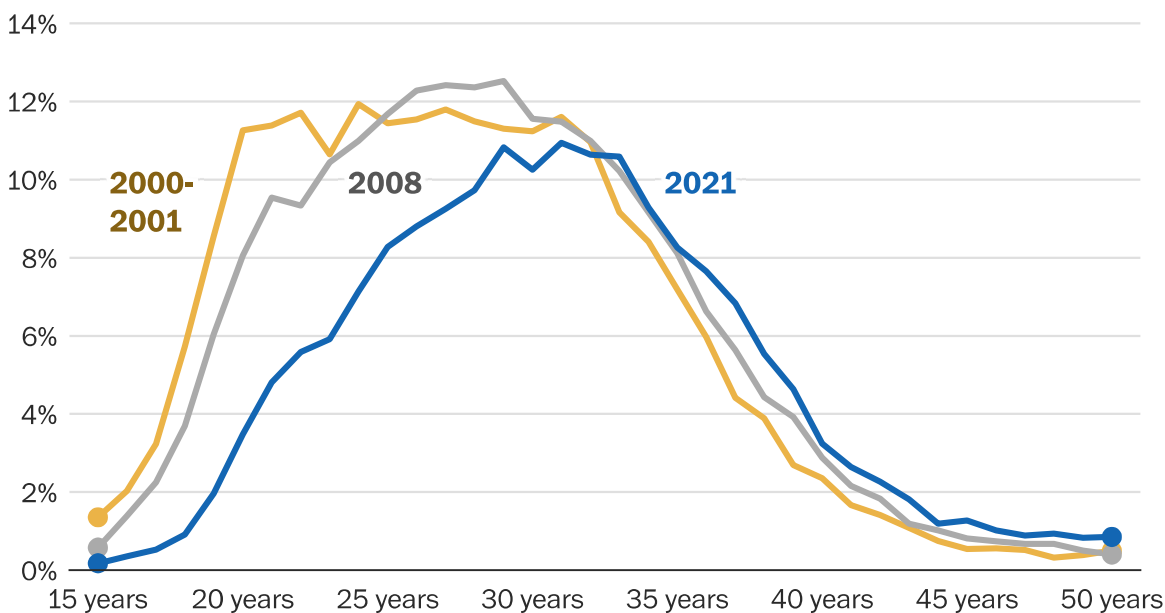
Sociologist Sarah Hayford directs Ohio State’s Institute for Population Research and has, with Guzzo, studied the [living daylight](#)s out of another key data source, the National Center for Health Statistics’ [National Surveys of Family Growth](#). She thinks millennials may still come around on kids.

“A big part of the uptick in childlessness is delay rather than permanent childlessness,” Hayford told us. “Even among women in their thirties, a lot will go on to have a child.”

If women are able to follow through on their delayed family plans, much of the rise in childlessness could be erased, according to a [2020 analysis](#) of the same data set by Gemmill and Caroline Sten Hartnett of the University of South Carolina. But with older millennials in their 40s, time for a reversal may be running out.

## The rise in older births hasn't made up for the fall in younger ones

Share of women in each age group who had a child in the past year



Source: Census Bureau’s American Community Survey via IPUMS

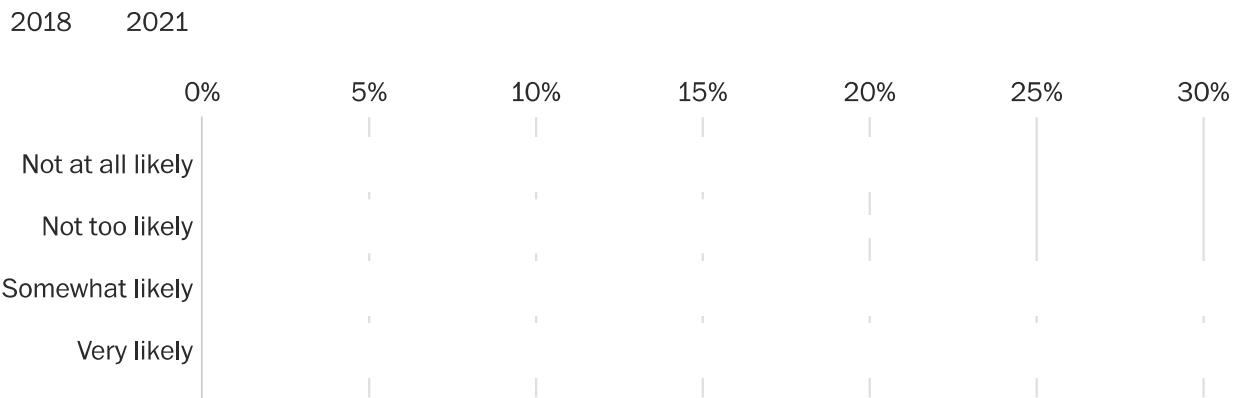
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When that almost mythical perfect time to have children does arrive, some women will find they don't have the means. "In the United States, we overestimate our ability to get pregnant later or how readily available medically assisted reproduction might be," Guzzo said. "I mean, it is available, but it's crazy expensive. Your average person can't afford it. It's often not covered by insurance."

Meanwhile, a [2021 poll from our friends at Pew Research](#) found that about 44 percent of childless adults ages 18 to 49 said they were not too likely, or not at all likely, to have children, a sharp increase from the 37 percent who said the same thing in 2018.

## Preference for procreation plummets post-pandemic

Thinking about the future, how likely is it that you will have children someday?



Source: [Pew Research Center online survey of 1,617 childless U.S. adults ages 18 to 49 conducted Oct. 18 to 24, 2021, with a margin of error of plus or minus 4 percentage points](#)

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And a hefty 56 percent said they just didn't want kids. (The remainder pointed to medical reasons, financial reasons and lack of a partner. The state of the world and climate change came in a distant fifth and sixth out of seven.)



## Childless Americans just don't want kids

Why non-parents ages 18 to 49 say it's not too likely, or not at all likely that they'll have kids, 2021

### WHY FOLKS AREN'T LIKELY TO HAVE KIDS

Just don't want kids	56%
Some other reason	43

### OF THOSE WHO CITED SOME OTHER REASON

Medical reasons	19
Financial reasons	17
No partner	15
Age	10
State of the world	9
Climate change/the environment	5
Partner doesn't want kids	2
Other	12
No answer	19

Source: [Pew Research Center online survey of 1,617 childless U.S. adults ages 18 to 49 conducted Oct. 18 to 24, 2021, with a margin of error of plus or minus 4 percentage points](#)

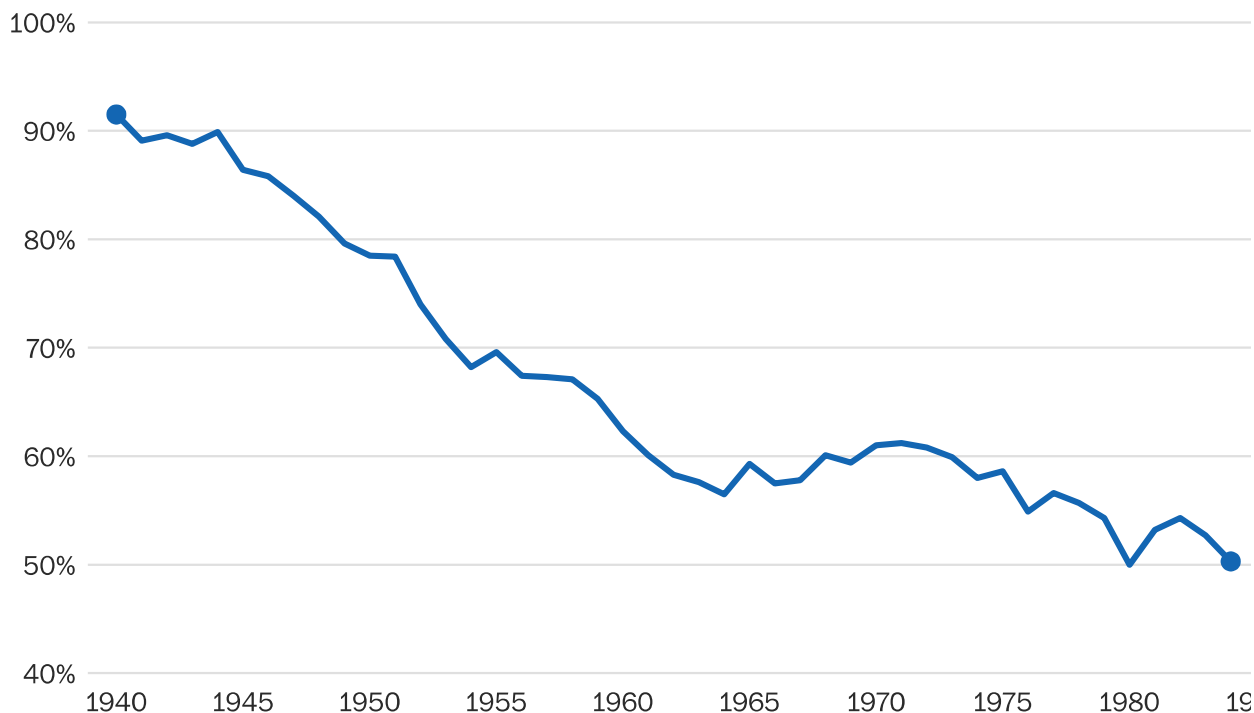
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When we asked about childless couples in an [earlier column](#), many readers pointed to the rise of same-sex marriage. But the [latest Census Bureau estimates](#), from 2021, show that fewer than 1 in 100 U.S. households are led by same-sex couples. Even if none of those couples had kids, an absurd assumption, it wouldn't come close to explaining the rise in childlessness.

After consulting our own household — which notably includes a brilliant dog but zero children — we began to wonder if it may have something to do with millennials being the first generation that isn't likely to do better than their parents, [according to Opportunity Insights](#). A [recent WSJ/NORC poll](#) found that 78 percent of Americans aren't confident their children will have better lives than they did.

## It used to be easier to raise a kid who'd be better off than you

Share of children earning more than their parents, by birth year



Source: [Opportunity Insights](#)

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We have little data to back up this speculation, but many of our sources wholeheartedly agreed. About 90 percent of kids born in 1944 outdid their parents; even negligent mothers and fathers could produce a surefire success. For kids born in 1984, that number was just 50 percent. These days, when the outlook may be even bleaker, there's intense pressure to pump your kids up with every available ounce of organic superfood, superior schooling and extracurricular enrichment to give them a slim shot at getting ahead.

So the decision to avoid having children may amount to a kind of performance anxiety in the face of intense expectations and weak governmental and social support, Guzzo said: "If I don't do everything right, then my kid will end up living on my couch forever or be a serial killer. ... I don't know if or when I'll have what it takes to be a 'good' parent.

"The stakes are so high. I don't want to screw it up."

***Ahoy there! The Department of Data needs your queries.*** Who's most likely to live with their adult siblings? Where are hailstorms getting more dangerous? What did the stress caused by the Beltway sniper do to expectant mothers in the region? Just ask!

*If your question inspires a column, we'll send an official Department of Data button and ID card. This week, we'll make the trek all the way across the newsroom to deliver a button to Herman Wong, The Post's deputy general-assignment editor ... or at least we would if he wasn't out on paternity leave with his first — and so far only! — child.*

**Attachment B**  
**AAP Guidelines**



# Standards for Levels of Neonatal Care: II, III, and IV

Ann R. Stark, MD, FAAP, DeWayne M. Pursley, MD, MPH, FAAP, Lu-Ann Papile, MD, FAAP, Eric C. Eichenwald, MD, FAAP, Charles T. Hankins, MD, MBA, FAAP, Rosanne K. Buck, RN, MS, NNP-BC, C-ONQS, Tamara J. Wallace, DNP, APRN, NNP-BC, Patricia G. Bondurant, DNP, RN, Nicole E. Faster, MSN, RN, RNC-NIC

## OVERVIEW

Establishment of risk-appropriate care was first proposed in 1976 when leaders in perinatal health proposed a model system of regionalized care for obstetrical and neonatal patients, including definitions of graded levels of hospital care.<sup>1</sup> Risk-appropriate care, in which infants with mild to complex critical illness or physiologic immaturity are cared for in a facility with the personnel and resources appropriate for their needs and condition, results in improved outcomes. This concept is supported by the American Academy of Pediatrics (AAP) policy statement “Levels of Neonatal Care,” which provides a review of data supporting a tiered provision of neonatal care and reaffirms the need for nationally consistent standards of care to improve neonatal outcomes.<sup>2</sup>

The work of the AAP NICU Verification Program began in 2013 when the state of Texas mandated that all Texas facilities caring for newborns required a neonatal level of care designation to receive Medicaid payment for neonatal services and announced a plan to engage survey agencies to verify levels of neonatal care. The AAP was identified as 1 of 2 Texas-approved survey agencies to pilot the verification survey process in 2016, and the NICU Verification Program was officially launched. Since 2016, the NICU Verification Program has provided third-party surveys by experienced and credentialed neonatologists, neonatal nurses, and pediatric surgeons to assess compliance with state-specific risk-appropriate neonatal care standards.

Since then, discussions were initiated with the Georgia Department of Public Health in 2019 to provide NICU verification surveys in Georgia. Additionally, the AAP NICU Verification Program is named as the approved neonatal survey agency for neonatal care services in Missouri’s code of state regulations for neonatal care designation. The AAP continues to be approached by additional states and

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independent facilities for verification services outside Texas, Georgia, and Missouri.

Although all states regulate health care facilities, specifications for levels of neonatal care and adherence to requirements vary widely.<sup>3,4</sup> Data indicate that facilities often assess themselves at a higher level than an independent observer, yet only a few states require verification by a third-party surveying agency or health department official. Recognizing that a national neonatal verification program is vital to high-quality and equitable care, the AAP NICU Verification Program has developed the “Standards for Levels of Neonatal Care: II, III, and IV,” which have the potential to improve the quality and consistency of risk-appropriate neonatal care and is critical to the future growth of the AAP NICU Verification Program.

The AAP Standards for Levels of Neonatal Care are considered a complementary implementation tool as they are based on existing AAP policy; evidence-based literature; standards of professional practice from national neonatal, perinatal, and surgical organizations; published data; and, when no data existed, expert opinion. Developed by the AAP NICU Verification Program Leadership Team with the support of AAP staff, the Standards codify the minimum components of care expected for each level of neonatal care from Special Care Nursery (Level II), to complex subspecialty care including surgery (Level IV NICU). The NICU Verification

Program also convened a virtual stakeholder meeting in September 2020, which included national leaders in neonatal intensive care, neurodevelopmental follow-up care, pediatric surgery, and quality and patient safety. The Section on Neonatal-Perinatal Medicine (SONPM) Clinical Leaders Group (CLG) and Follow-up Group provided additional input to the Standards, and published standards from nursing, pediatric surgery, and therapist organizations have been integrated as well.

The lack of standardized or state-specific risk-appropriate neonatal care policies is a barrier to the delivery of regulated and high-quality neonatal care. By establishing and implementing risk-appropriate neonatal care standards, the NICU Verification Program believes that the AAP will improve neonatal outcomes by ensuring that every infant receives care in a facility with the personnel and resources appropriate for the newborn’s needs and condition. Although the Standards are identified as minimum requirements for each level of neonatal care, the AAP NICU Verification Program encourages facilities to go beyond the minimum. The AAP NICU Verification Program upholds the AAP Equity Agenda and is committed to supporting efforts to improve health outcomes by encouraging facilities to further assess the health disparities of their patients, families, and community. The AAP values equity, diversity, and inclusivity and recognizes that family-centered

care is essential for best outcomes and encourages facilities to amplify their focus on family members and staff to elevate the quality of neonatal care and improve the health outcomes of the nation’s most vulnerable population.<sup>3,4</sup>

The AAP “Standards for Levels of Neonatal Care II, III, and IV” (the “Standards”) were developed through the cooperative efforts of the AAP NICU Verification Program Leadership Team and the Committee on Fetus and Newborn (COFN), the SONPM, and the SONPM CLG. The Standards delineate the components of care expected for each level of neonatal care from Special Care Nursery (Level II), to complex subspecialty care including surgery (Level IV NICU) by setting forth standards for institutional commitment, neonatal programing, personnel, ancillary services, patient and family care resources, and equipment required for each level of neonatal care. Compliance with the Standards will not guarantee that a particular neonatal program is in compliance with applicable state law or other requirements. In addition, the Standards are not designed to be an educational resource for clinicians related to treatment decisions or standards of patient care. Rather, the Standards set forth the minimum components to be included in any neonatal program desiring to be recognized as providing a particular level of neonatal care.

## **STANDARD I: INSTITUTIONAL COMMITMENT**

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- (a) The facility's organized medical staff and institutional governing body must demonstrate an institutional commitment to the neonatal program and will:
1. include a commitment of the facility's governing body supporting the level-specific provisions of neonatal services as described in the neonatal program description;
  2. include allocation of sufficient personnel and resources to attain optimal neonatal care;
  3. reaffirm the neonatal program at least every 3 years; and
  4. verify the neonatal program description is current at the time of neonatal verification.
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## **STANDARD II: NEONATAL PROGRAM DESCRIPTION**

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- (a) The facility will provide a detailed description of the neonatal services provided that includes a comprehensive explanation of the scope of services available to all neonatal and obstetrical patients that is consistent with accepted professional standards of practice and clinical care; defines the neonatal population served; and supports the health, safety, and optimal care of all patients.
1. The comprehensive description of neonatal services will include, at a minimum:
    - i. identification of the resources used to develop the facility's neonatal policies and procedures for the neonatal services it provides;
    - ii. description of the review and revision schedule for all neonatal medical practice guidelines, neonatal nursing policies, and ancillary care team policies that does not exceed 3 years;
    - iii. written guidelines for consultation, triage, stabilization, and transfer of newborns and/or pregnant or antepartum persons who receive care at the facility;
    - iv. provisions to facilitate continuity of care for high-risk neonatal patients from delivery to discharge;
    - v. delineation of roles, responsibilities, and authority of the medical, nursing, and ancillary patient care directors;
    - vi. physician, advanced practice nurse, and/or other medical care provider staffing plan for neonatal coverage;
    - vii. plan for nurse staffing including provisions for flexibility and change in census and acuity;
    - viii. completion of an annual educational needs assessment to evaluate the ongoing educational needs of all staff participating in the care of newborns;
    - ix. annual educational plan for all staff participating in the care of newborns that includes didactic education, simulation, competency, and skills validation;
    - x. appropriate allocations for family-centered care including providing parents with reasonable access to their infants and encouraging advocacy, shared decision-making, and participation in their child's care;
    - xi. assurance of equitable care for all neonatal patients and families and provisions for promoting an environment of cultural humility;
    - xii. capability of neonatal care team members to have the knowledge and skills to provide lactation support;
    - xiii. a process to assess and establish appropriate on-going care for all newborns after discharge;
    - xiv. a description of the Neonatal Patient Safety and Quality Improvement Program (NPSQIP); and
    - xv. established evacuation policies and procedures to guarantee that obstetrical and neonatal patients receive, or are transferred to, the appropriate level(s) of care.
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### **STANDARD III: NEONATAL PATIENT SAFETY AND QUALITY IMPROVEMENT PROGRAM (NPSQIP)**

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#### **NPSQIP Core Components:**

- (a) The facility will have a system for identification and review of significant events that could indicate threats to patient safety, with a goal of learning from identified events and mitigating future risk of recurrence, including:
  - 1. a list of specific triggers or safety indicators that warrant a record review, with the goal of identifying significant safety events such as errors, adverse events, near misses, complications, and mortalities;
  - 2. a process for systematic multidisciplinary review of selected cases or safety events, using acceptable failure mode and effect analysis tools with a goal of identifying interventions to improve systems and reduce future safety risks; and
  - 3. a process for monitoring the implementation of identified interventions.
- (b) The facility will have a dashboard or equivalent that is used to summarize and track quality indicators relevant to newborn care, including:
  - 1. a list of selected quality measures relevant to the facility with a process for obtaining data needed for each selected neonatal quality measure;
  - 2. a platform to display performance on the selected quality measures, including a process for updating data with a frequency that allows for appropriate identification of performance concerns;
  - 3. benchmarking of performance, when possible, with internal or external benchmarks; and
  - 4. a multidisciplinary forum for review of the dashboard or equivalent.
- (c) The facility will have a structured approach to quality improvement (QI) that seeks to improve care quality and outcomes.<sup>5</sup> Quality outcomes include care that is safe, efficient, effective, timely, equitable, and patient centered.<sup>6</sup> Approaches will include:
  - 1. a clear process for determining current QI initiatives, with a goal that the unit is engaged in at least 1 to 2 such initiatives at any given time;
  - 2. identification of a multidisciplinary QI team for each initiative, with a designated team lead;
  - 3. use of structured improvement methods or framework to guide improvement efforts; and
  - 4. a multidisciplinary quality committee that meets regularly to identify and review QI initiatives.
- (d) The facility will maximize efforts to standardize and improve care through the use of guidelines and policies that align with research-driven and evidence-based best practices, including:
  - 1. a process for identifying topics for guideline or policy development;
  - 2. a process for developing guidelines and policies that incorporate evidence-based recommendations;
  - 3. a platform for making guidelines and policies readily available to clinical providers; and
  - 4. a process for periodic review of guidelines and policies to guarantee they remain updated, and evidence based.
- (e) The facility will have multidisciplinary involvement in quality and safety activities, including:
  - 1. involvement of all disciplines represented in the neonatal quality and safety activities as appropriate and as described above; and
  - 2. for level IV facilities, involvement of subspecialty services with significant presence in the neonatal unit.
- (f) The neonatal-specific unit will coordinate with hospital quality and safety activities, including:
  - 1. structured collaboration with the obstetrics and pediatric surgery departments, if applicable, to identify and implement opportunities for shared quality and safety efforts;
  - 2. participation in hospital-level quality and safety activities to confirm alignment of neonatal quality goals with hospital priorities;
  - 3. alignment with hospital activities and reporting of quality measures to national organizations; and
  - 4. participation in efforts to guarantee everyday readiness for external assessments by regulatory organizations.
- (g) The facility will participate in larger communities of perinatal safety and quality, including:
  - 1. collaboration between transferring and receiving hospitals to examine and improve population-level quality and safety through structured activities such as transport review and sharing of clinical protocols; and
  - 2. for level III and IV facilities, participation in regional, state, or national databases that allows benchmarking of performance.

#### **NPSQIP Additional Best Practices:**

- (h) Encourage and support the integration of family into quality improvement and patient safety initiatives.
  - (i) Explicit efforts to identify inequities and target equity in quality measures.
  - (j) A process for random chart audits and peer review.
  - (k) Neonatal team training for safety and Just Culture.
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### **STANDARD IV: GENERAL PROGRAM REQUIREMENTS**

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#### **Family-Centered Care Core Components:**

- (a) The facility will:
  - 1. allow all parents to have reasonable access to their infants at all times;
  - 2. have access to the services, personnel, and equipment needed to provide the appropriate level of care for all infants;
  - 3. support the physiologic, developmental, and psychosocial needs of infants and their families;
  - 4. have a process to screen every family for social determinants, depression, and cultural needs; and
  - 5. refer patients and families to appropriate resources as needed.

#### **Family-Centered Care Additional Best Practices:**

- (b) Implement the utilization of primary nursing.
- (c) Involve family in daily and multidisciplinary patient care rounds.

- (d) Implement and support a family advisory council.
- (e) Establish a process to evaluate potential health disparities of the patient population served.
- (f) Implement a coordinated process to assess and address the emotional needs of families.
- (g) Engage in shared decision-making by involving family in discharge planning, including transport discussions.
- (h) Provider and staff training on shared decision-making and how to engage in difficult and inclusive conversations.
- (i) Explicit efforts to support lactation and the needs of breastfeeding<sup>a</sup> individuals.

**Lactation and Neonatal Nutrition**

- (j) The facility will:
  1. have personnel with the knowledge and skills to support lactation available at all times;
  2. have pumping equipment and secure human milk storage facilities available;
  3. have policies and procedures in place to support:
    - i. the initiation and maintenance of lactation;
    - ii. early initiation of milk expression;
    - iii. safety, preparation, storage, and use of human milk and formula;
    - iv. long-term pumping and transition to breastfeeding; and
    - v. the utilization of donor human milk, if available.
  4. provide annual education to all direct care providers on the importance of, and support of lactation (ie, pumping, mixing, safe storage, misappropriation, and proper identification); and
    - i. all direct care providers have didactic education, skills verification, and competency on the proper mixing of human milk and formula;
  5. establish a program for breastfeeding and lactation support, including data collection.

**Neonatal Resuscitation**

- (i) The facility must have written policies and procedures specific to the resuscitation and stabilization of newborns based on current standards of professional practice.<sup>7</sup>
  1. At least 1 person with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7.<sup>7</sup>
  2. A full range of neonatal resuscitative equipment, supplies, and medications must be immediately available at all times.<sup>7</sup>
  3. If the facility provides obstetrical delivery services:
    - i. Each birth will be attended by at least 1 AAP Neonatal Resuscitation Program (NRP) trained provider whose only responsibility is the management of the newborn and initiating resuscitation.<sup>7</sup>
    - ii. In the event of identified antepartum and intrapartum risk factors, at least 2 NRP trained providers should be present at birth and be responsible solely for the management and resuscitation of the newborn.<sup>7</sup> Additional qualified providers should be available depending on the anticipated risk, number of newborns, and the obstetrical setting.<sup>7</sup>
    - iii. If advanced resuscitation measures are anticipated, a fully qualified neonatal resuscitation team should be present at the time of birth.<sup>7</sup>

**Radiology**

- (j) When obtaining imaging in neonatal and obstetrical patients, radiology services will incorporate the “as low as reasonably achievable” principle.<sup>8</sup>

**Policies and Procedures**

- (k) The facility will have written:
  1. neonatal, medical, and ancillary care guidelines, policies, and procedures that are established on evidence-based literature, and best-practice standards, that are monitored and tracked for adherence, reviewed at least every 3 years, and revised as needed;
  2. a policy that mandates the escalation of concern and the urgent presence of a privileged care provider at the bedside, including a method to track adherence;
  3. policies and procedures that define the criteria for neonatal team presence at a delivery and identify a method to track adherence, if applicable;
  4. policies and procedures for the triage, stabilization, and transfer of obstetrical patients to the appropriate level of care, if applicable;
  5. policies and procedures for consultation by telehealth and telephone, if applicable;
  6. policies and procedures for intrafacility and interfacility neonatal transport;
  7. policies and procedures for transfer to a higher level of neonatal care or for services not available at the facility, if applicable;
  8. policies and procedures for car seat safety observation before discharge; and
  9. policies and procedures for disaster response, including evacuation of obstetrical and neonatal patients to the appropriate level(s) of care.

**Staff Privileges**

- (l) The facility will have:
  1. specified requirements for all privileged care providers participating in the care of neonatal patients, and have a credentialing process for delineation of privileges;
  2. a process to verify that all ancillary care services, clinical staff, and support staff have relevant neonatal training and expertise; and
  3. a mechanism in place for medical, nursing, and ancillary care leadership to review and approve these credentials and track adherence.

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<sup>a</sup> The word chestfeeding may be used by nonbinary, transgender, and other parents to identify how they feed their infants. It may refer to human milk or human milk substitute feeding, from a person who lactates or not. Because of this broad and variable definition, chestfeeding and breastfeeding are not always synonymous, and the words are not interchangeable. Published literature findings on breastfeeding may not hold the same outcomes for chestfeeding. Throughout this document, the words breastfeeding and human milk will be used.

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## STANDARD V: LEVEL II SPECIAL CARE NURSERY (SCN) REQUIREMENTS

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### Level II SCN Requirements

- (a) The Level II SCN will provide comprehensive care of infants born  $\geq 32$  wk or with birth wt  $\geq 1500$  g who<sup>2</sup>:
1. are mild to moderately ill with physiologic immaturity or who have conditions that are expected to resolve quickly<sup>2</sup>;
  2. are not anticipated to require subspecialty services on an urgent basis<sup>2</sup>;
  3. require continuous positive airway pressure (CPAP) or short-term (less than 24 h) conventional mechanical ventilation for a condition expected to resolve rapidly or until transfer to a higher-level facility is achieved<sup>2</sup>; or
  4. are back transferred from a higher-level facility for convalescent care.<sup>2</sup>

### Neonatal Medical Director

- (b) The neonatal medical director (NMD) will:
1. be a board eligible or certified neonatologist or a board-certified pediatrician with sufficient training and expertise to assume responsibility of care for infants who require level II care, including endotracheal intubation, assisted ventilation, and CPAP management, or equivalent<sup>5</sup>;
    - i. if the neonatologist or pediatrician is certified by The American Board of Pediatrics, they will meet maintenance of certification (MOC) requirements;
  2. complete annual continuing medical education (CME) specific to neonatology; and
  3. demonstrate a current status of NRP completion.

### Neonatologists

- (c) If the NMD and/or on-site provider is not a neonatologist, the privileged care provider must maintain a consultative relationship with a board certified or eligible neonatologist at a higher-level neonatal facility; and
1. the facility must have a written policy or guideline that defines the criteria for neonatologist consultation at a higher-level neonatal facility.

### Privileged Care Providers

- (d) Privileged care providers with pediatric- or neonatal-specific training qualified to manage the care of infants with mild to moderate critical conditions, including emergencies, will<sup>5</sup>:
1. be continuously available on-site, or on-call and available to arrive on-site within an appropriate time frame as defined by the facility's policies and procedures;
    - i. if the on-site or on-call provider is not a physician, a written policy will be in place that defines the criteria for notification and time frame for on-site physician presence, and a tracking mechanism for compliance is required;
    - ii. if an infant is maintained on a ventilator, a pediatric- or neonatal-specific privileged care provider who can manage respiratory emergencies will be immediately available on-site;
  2. demonstrate a current status of NRP completion;
  3. complete annual continuing education requirements specific to neonatology; and
  4. have credentials reviewed at least every 2 years by the NMD.
- (e) At least 1 person with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7<sup>7</sup>; and
1. demonstrate a current status of NRP completion.
- (f) The facility will establish a written policy for backup privileged care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent medical providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup>

### Nursing Leadership

- (g) The level II SCN nurse leader will:
1. be a registered nurse (RN) with experience and training in perinatal nursing and neonatal conditions, with nursing certification preferred<sup>5</sup>;
  2. have at least a Bachelor of Science in Nursing, Master's preferred;
  3. demonstrate a current status of NRP completion;
  4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level II SCN care;
  5. be responsible for inpatient activities in the level II SCN and, as appropriate, obstetrical, well newborn, and/or pediatric units;
  6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;
  7. provide oversight of annual neonatal-specific education, which includes low-volume, high-risk procedures consistent with the care provided in the level II SCN; and
  8. foster collaborative relationships with multidisciplinary team members, facility leadership, and higher-level facilities to create a diverse, equitable, and inclusive environment focused on the quality of care and patient care outcomes.<sup>5</sup>

### Clinical Nurse Staffing

- (h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup>

### Clinical Nurse Staff

- (i) Each clinical nurse will:
1. be an RN, with nursing certification specific to the care environment preferred;
  2. demonstrate a current status of NRP completion;
  3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level II SCN; and

4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.
- (j) If the facility utilizes licensed practical nurses (LPNs) or nonlicensed direct care providers to support the clinical nursing staff, the facility must:
1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;
  2. provide annual education specific to the care of the neonatal population served; and
  3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.

#### **Nursing Orientation and Education**

- (k) Level II SCN nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup>
- (l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.
- (m) Annual nursing education will address the annual needs assessment and incorporate simulation and skills verification of low-volume, high-risk procedures consistent with the types of care provided in the level II SCN and include education related to serious safety events.

#### **Clinical Nurse Educator**

- (n) The level II SCN clinical nurse educator or perinatal nurse educator will:
1. be an RN, with nursing certification specific to the care environment preferred;
  2. have at least a Bachelor of Science in Nursing, Master's preferred;
  3. demonstrate a current status of NRP completion;
  4. cultivate collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes<sup>5</sup>; and
  5. have experience and expertise to evaluate the educational needs of the clinical staff, develop didactic and skill-based educational tools, oversee education and skills verification, and evaluate retention of content, critical thinking skills, and competency relevant to level II neonatal care.<sup>9</sup>
- (o) The facility will have a dedicated individual with sufficient time allocated to perform the roles and responsibilities of the clinical nurse educator.

#### **Neonatal Transport**

- (p) The facility will have policies and procedures in place to identify a local neonatal transport program to facilitate neonatal transport to a higher-level neonatal facility.

#### **Pediatric Medical Subspecialists and Pediatric Surgical Specialists**

- (q) Policies and procedures will be in place for referral to a higher level of neonatal care when pediatric medical subspecialty or pediatric surgical specialty consultation and/or intervention is needed.

#### **Laboratory Services**

- (r) Laboratory services will have:
1. laboratory personnel on-site 24/7;
  2. the ability to determine blood type, crossmatch, and perform antibody testing;
  3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or cytomegalovirus (CMV)-negative blood;
  4. the ability to perform neonatal blood gas monitoring; and
  5. the ability to perform analysis on small volume samples.
- (s) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to verify timely and direct communication of all critical value results.

#### **Pharmacy**

- (t) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:
1. be available for consultation on-site, or by telehealth or telephone, 24/7;
  2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and
  3. participate in multidisciplinary care, as needed.
- (u) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level II SCN; and
1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.

#### **Diagnostic Imaging**

- (v) Radiology services will have:
1. appropriately trained radiology personnel continuously available on-site to meet routine diagnostic imaging needs and to address emergencies;
  2. personnel appropriately trained in ultrasonography, including cranial ultrasonography, on-call and/or available on-site to perform advanced imaging as requested; and
  3. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.

#### **Respiratory Therapy**

- (w) The respiratory care leader will:
1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;
  2. have sufficient time allocated to oversee the respiratory therapists (RTs) who provide care in the level II SCN;
  3. provide oversight of annual simulation and skills verification, which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;
  4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and

5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.
- (x) Respiratory care practitioners assigned to the SCN will:
1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal or pediatric respiratory care certification preferred;
  2. be on-site 24/7 and immediately available when an infant is supported by assisted ventilation or CPAP;
  3. be able to attend deliveries and assist with resuscitation as requested;
  4. demonstrate a current status of NRP completion;
  5. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the SCN; and
  6. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.

#### **Dietitian**

- (y) The facility must have, or have the ability to consult with, at least 1 registered dietitian or nutritionist who has specialized training in neonatal nutrition, who will<sup>5</sup>:
1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;
  2. establish policies and procedures to verify proper preparation and storage of human milk and formula; and
  3. have policies and procedures for dietary consultation for patients in the SCN.

#### **Neonatal Nutrition**

- (z) The facility will:
1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;
  2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for human milk, donor human milk, fortification of human milk and formula; and
  3. have policies and procedures in place for accurate verification and administration of human milk and formula, and to avoid misappropriation.

#### **Lactation and Breastfeeding Support**

- (aa) The facility will:
1. have personnel with the knowledge and skills to support lactation available at all times;
  2. have a certified lactation counselor (CLC), international board-certified lactation consultant (IBCLC) preferred, available for on-site consultation on weekdays and accessible by telehealth or telephone 24/7; and
  3. operationally review CLC and/or IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup>

#### **Neonatal Therapists**

- (bb) If the facility does not have in-house access to neonatal therapy expertise, the facility will have a formal process in place for providing on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family or psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served. The facility will have on-site access to the following as needed<sup>12</sup>:
1. an occupational or physical therapist with neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and
  2. at least 1 individual skilled in the evaluation and management of neonatal feeding and swallowing concerns, with neonatal therapy certification preferred.<sup>5</sup>
- (cc) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal therapist coverage based on the specific need and volume of the neonatal population served.<sup>12</sup>

#### **Social Worker**

- (dd) The SCN social worker will:
1. be a Master's prepared medical social worker with perinatal and/or pediatric experience.<sup>5</sup>
- (ee) The facility will:
1. provide 1 social worker for every 30 beds providing level II neonatal care and/or specialty and subspecialty perinatal care<sup>5</sup>;
  2. have a written description that clearly identifies the responsibilities and functions of the SCN social worker; and
  3. have social services available for each family with an infant in the SCN as needed.

#### **Pastoral Care**

- (ff) Personnel skilled in pastoral care will be available as needed and by family request, and will represent, or have the ability to consult, multiple religious affiliations representative of the population served.<sup>5</sup>

#### **Retinopathy of Prematurity**

- (gg) If the facility back transfers infants for convalescent care, the facility must have a process in place to appropriately identify infants at risk for retinopathy of prematurity to guarantee timely examination and treatment by having<sup>13</sup>:
1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity<sup>5,13</sup>; and
  2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity, if needed.<sup>5,13</sup>

### **Discharge and Follow-up**

(hh) Systems will be in place to establish preparation for SCN discharge, including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed.

1. The facility will:
    - i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk neonatal follow-up with appropriate developmental follow-up services; and
    - ii. have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.
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## **STANDARD VI: LEVEL III NICU REQUIREMENTS**

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### **Level III NICU Requirements**

(a) The Level III neonatal facility will:

1. provide comprehensive care for infants born at all gestational ages and birth weights, with mild to complex critical conditions or medical problems requiring sustained life support, hemodynamic support, and/or conventional mechanical ventilation<sup>2</sup>;
2. have the ability to provide high-frequency ventilation, inhaled nitric oxide (iNO) delivery, and/or therapeutic hypothermia or have policies and procedures in place to facilitate neonatal transfer to a higher level of care<sup>2</sup>;
3. provide care for infants who are back transferred for convalescent care<sup>2</sup>; and
4. have sufficient experience based on patient volume and a systematic process to assess the quality of care provided to each very low birth weight infant, including a method to track specific quality indicators including obstetrical and neonatal transfers, review aggregate data using accepted methodology, and develop action plans as needed to improve patient outcomes.<sup>2,14</sup>

### **Neonatal Medical Director**

(b) The NMD will:

1. be a board eligible or certified neonatologist or equivalent;
  - i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;
2. complete annual continuing CME specific to neonatology; and
3. demonstrate a current status of NRP completion.

### **Neonatologists**

(c) The NICU neonatologists will:

1. be a board eligible or certified neonatologist or equivalent;
  - i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;
2. complete annual CME specific to neonatology;
3. demonstrate a current status of NRP completion;
4. have credentials that are reviewed by the NMD at least every 2 years; and
5. preferably be on-site and immediately available 24/7 or on-call and available to arrive on-site within an appropriate time frame, as defined by the facility's policies and procedures.
  - i. If a neonatologist is not on-site 24/7, a written policy will be in place that defines the criteria for notification and time frame for on-site presence, and a tracking mechanism for compliance is required.

### **Privileged Care Providers**

(d) Privileged care providers with neonatal-specific training qualified to manage the care of infants with mild to complex critical conditions, including emergencies, will be on-site 24/7 and<sup>5</sup>:

1. demonstrate a current status of NRP completion;
2. complete annual continuing education requirements specific to neonatology; and
3. have their credentials reviewed at least every 2 years by the NMD.

(e) At least 1 person with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7<sup>7</sup>; and

1. demonstrate a current status of NRP completion.

(f) The facility will establish a written policy for backup privileged care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent medical providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup>

### **Nursing Leadership**

(g) The level III NICU nurse leader will:

1. be an RN with experience and training in neonatal nursing and conditions, with nursing certification preferred<sup>5</sup>;
  2. have at least a Bachelor of Science in Nursing, Master's preferred;
  3. demonstrate a current status of NRP completion;
  4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level III NICU care;
  5. be responsible for inpatient activities in the NICU(s) and, as appropriate, obstetrical, well newborn, and/or pediatric units;
  6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;
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7. provide oversight of annual neonatal-specific education which includes low-volume, high-risk procedures consistent with the care provided in the level III NICU; and
8. foster collaborative relationships with multidisciplinary team members, facility leadership, and higher-level facilities to create a diverse, equitable, and inclusive environment to improve the quality of care and patient care outcomes.<sup>5</sup>

#### **Clinical Nurse Staffing**

- (h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup>

#### **Clinical Nurse Staff**

- (i) Each clinical nurse will:
1. be an RN, with nursing certification specific to the care environment preferred;
  2. demonstrate a current status of NRP completion;
  3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level III NICU; and
  4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.
- (j) If the facility utilizes LPNs or nonlicensed direct care providers to support the clinical nursing staff, the facility must:
1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;
  2. provide annual education specific to the care of the neonatal population served; and
  3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.

#### **Nursing Orientation and Education**

- (k) Level III NICU nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup>
- (l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.
- (m) Annual nursing education will address the annual needs assessment and incorporate simulation and skill verification of low-volume, high-risk procedures consistent with the types of care provided in the level III NICU and include education related to serious safety events.

#### **Clinical Nurse Specialist**

- (n) The clinical nurse specialist will:
1. be an RN, with neonatal nursing certification and clinical nurse specialist certification preferred<sup>5</sup>;
  2. have at least a Bachelor of Science in Nursing, Master's or Doctorate preferred<sup>5</sup>;
  3. demonstrate a current status of NRP completion<sup>5</sup>;
  4. foster continuous quality improvement in nursing care<sup>5</sup>;
  5. develop and educate staff to provide evidence-based nursing care<sup>5</sup>;
  6. be responsible for mentoring new staff and developing team building skills<sup>5</sup>;
  7. provide leadership to multidisciplinary teams<sup>5</sup>;
  8. facilitate case management of high-risk neonatal patients<sup>5</sup>; and
  9. cultivate collaborative relationships with multidisciplinary team members and facility leadership to improve the quality of care and patient care outcomes.<sup>5</sup>
- (o) The roles and responsibilities of the NICU clinical nurse specialist can be allocated to multiple individuals to perform this role.

#### **Clinical Nurse Educator**

- (p) The NICU clinical nurse educator will:
1. be an RN, with nursing certification specific to the care environment preferred;
  2. have at least a Bachelor of Science in Nursing, Master's preferred;
  3. demonstrate a current status of NRP completion;
  4. cultivate collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes<sup>5</sup>; and
  5. have experience and expertise to evaluate the educational needs of the clinical staff, develop didactic and skill-based educational tools, oversee education and skills verification, and evaluate retention of content, critical thinking skills, and competency relevant to level III neonatal care.<sup>9</sup>
- (q) The facility will have a dedicated individual with sufficient time allocated to perform the roles and responsibilities of the NICU clinical nurse educator.

#### **Neonatal Transport**

- (r) If the facility has a neonatal critical care transport program, it will have an identified director of neonatal transport services.<sup>5</sup> The director of neonatal transport services can be the neonatal medical director or another physician who is a pediatrician, board eligible or certified neonatologist, pediatric hospitalist, or pediatric medical subspecialist with expertise and experience in neonatal and infant transport.<sup>5</sup>
1. If the facility does not have its own transport program, the facility must have policies and procedures in place to identify a local neonatal transport program to facilitate transport.<sup>5</sup>
- (s) Responsibilities of the director of neonatal transport services include the following:
1. train and supervise staff<sup>5</sup>;
  2. provide appropriate review of all transport records<sup>5</sup>;

3. develop and implement policies and procedures for patient care during transport<sup>5</sup>;
4. develop guidelines for determining transport team composition and medical control and establish a mechanism to track adherence<sup>5</sup>;
5. establish policies and procedures to provide transport updates and outreach education<sup>5</sup>;
6. establish a program for evaluating performance by tracking data, identifying trends, and implementing quality improvement initiatives to address transport performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>5</sup>; and
7. report neonatal transport data and neonatal-specific reviews back to the NPSQIP.
8. The director of neonatal transport services may delegate specific requirements to other person(s) or group(s) but retains the responsibility of certifying that these functions are addressed appropriately.<sup>5</sup>

(t) The facility will:

1. establish minimum education, experience, and training requirements for all transport team members<sup>15</sup>;
2. select transport team members based on their experience and competence in the care of neonates and the transport team must collectively have the ability to provide a level of care that is similar to that of the admitting unit<sup>15</sup>; and
3. provide annual transport education to all transport team members that incorporates equipment training, didactic education, simulation, and skills verification of low-volume, high-risk procedures consistent with the types of care provided during neonatal transport.<sup>15</sup>

#### **Neonatal Outreach**

(u) The level III facility will provide multidisciplinary outreach education to referring facilities by assessing educational needs and evaluating clinical care and outcomes, including transport data, as part of collaboration with lower-level neonatal facilities, if applicable.<sup>5</sup>

#### **Pediatric Medical Subspecialists**

(v) The facility must have the ability to obtain pediatric medical subspecialist advice or formal consultation either on-site or by prearranged consultative agreement using telehealth technology and/or telephone consultation from a distant location from a broad range of pediatric medical subspecialists including, but not limited to<sup>2</sup>:

1. cardiology, pulmonology, infectious disease, neurology, ophthalmology, endocrinology, hematology, gastroenterology, nephrology, and genetics or metabolism.

(w) If the pediatric medical subspecialist is available for on-site consultation, they will:

1. have credentials to consult at the facility including documented training, certification, competencies, and CME specific to their subspecialty; and
2. document consultations in the medical record within an appropriate time frame and as defined by the facility's policies and procedures.

#### **Neonatal Surgical Program – Optional for Level III**

##### **Pediatric Surgeons**

(x) Pediatric surgeons and pediatric surgical specialists will be available on-site or at another closely related NICU facility.<sup>5</sup>

1. If pediatric surgery is not offered on-site at the facility, policies and procedures will be in place with a facility that provides surgical care to facilitate transfer of an infant when needed.
  - i. Infants requiring cardiovascular surgery or extracorporeal membrane oxygenation (ECMO) will be transferred to a facility that provides these services.
2. If pediatric surgery is accessible on-site, the surgeons will:
  - i. be available at the bedside within 1 hour of request or identified need<sup>16</sup>;
  - ii. have credentials to provide care at the facility, including documented training, certification, competencies, and continuing education specific to their pediatric surgery specialty<sup>16</sup>;
  - iii. establish a program for evaluating surgical performance by accurately tracking data, identifying trends, and implementing quality improvement initiatives to address surgical performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>16</sup>; and
  - iv. report neonatal surgical and anesthesia care back to the NPSQIP.

##### **Anesthesiologists**

(y) If pediatric surgery is performed on-site, anesthesia providers with pediatric expertise must<sup>16</sup>:

1. be on the medical staff and promptly available 24/7 to respond to the bedside within 1 hour of request or identified need<sup>16</sup>;
2. serve as the primary responsible anesthesia provider for all infants <24 mo of age and should serve as the primary anesthesiologist for children ≤5 y of age based on the American Society of Anesthesiologists (ASA) physical status classification<sup>16</sup>; and
3. be physically present for all neonatal surgical procedures for which they serve as the primary responsible anesthesia provider.<sup>16</sup>

##### **Laboratory Services**

(z) Laboratory services will have:

1. laboratory personnel on-site 24/7;
2. the ability to determine blood type, crossmatch, and perform antibody testing;
3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or CMV-negative blood;
  - i. policies and procedures will be in place to facilitate emergent access to blood and blood component therapy so that the NICU can provide hematologic interventions, if applicable;
4. the ability to perform neonatal blood gas monitoring;
5. the ability to perform analysis on small volume samples; and
6. access to perinatal pathology services, if applicable.

(aa) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to maintain timely and direct communication of all critical value results.

##### **Pharmacy**

(bb) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:

1. be available for consultation on-site, or by telehealth or telephone, 24/7;
2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and

3. participate in multidisciplinary care, including participation in patient care rounds.
- (cc) The facility will have neonatal appropriate total parenteral nutrition (TPN) available 24/7, and:
1. the facility will have a written policy and procedure for the proper preparation and delivery of TPN.
- (dd) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level III NICU, and:
1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.

#### **Diagnostic Imaging**

- (ee) Radiology services will have:
1. appropriately trained radiology personnel continuously available on-site to meet routine diagnostic imaging needs and to address emergencies;
  2. fluoroscopy available on-call 24/7;
    - i. if fluoroscopy is not offered on-site at the facility, policies and procedures will be in place to facilitate transfer of an infant to a higher level of care;
  3. personnel appropriately trained in the following techniques will be on-call and/or available on-site to perform advanced imaging as requested:
    - i. ultrasonography, including cranial ultrasonography;
    - ii. computed tomography (CT); and
    - iii. magnetic resonance imaging (MRI); and
  4. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.
- (ff) The facility will provide pediatric echocardiography and have the ability to consult with a pediatric cardiologist for timely echocardiography interpretation as requested.

#### **Respiratory Therapy**

- (gg) The respiratory care leader will:
1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;
  2. have sufficient time allocated to oversee the RTs who provide care in the level III NICU;
  3. provide oversight of annual simulation and skills verification which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;
  4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and
  5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.
- (hh) Respiratory care practitioners assigned to the NICU will:
1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal and pediatric respiratory care certification preferred;
  2. be on-site 24/7 and immediately available to supervise assisted ventilation, assist in resuscitation, and attend deliveries;
  3. demonstrate a current status of NRP completion;
  4. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the NICU; and
  5. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.

#### **Dietitian**

- (ii) At least 1 registered dietitian or nutritionist who has specialized training in neonatal nutrition will have dedicated time allotted to serve the NICU and will<sup>5</sup>:
1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;
  2. establish policies and procedures to verify proper preparation and storage of human milk and formula;
  3. participate in multidisciplinary care, including participation in patient care rounds; and
  4. have policies and procedures for dietary consultation for infants in the NICU.

#### **Neonatal Nutrition**

- (jj) The facility will:
1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;
  2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for human milk, donor human milk, fortification of human milk and formula; and
  3. have policies and procedures in place for accurate verification and administration of human milk and formula, and to avoid misappropriation.

#### **Lactation and Breastfeeding Support**

- (kk) The facility will:
1. have personnel with the knowledge and skills to support lactation available at all times;
  2. have an IBCLC available for on-site consultation on weekdays and accessible by telehealth or telephone 24/7; and
  3. operationally review IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup>

**Neonatal Therapists**

- (ll) The facility will provide on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family and psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served.<sup>12</sup>
- (mm) The facility will have on-site access to the following neonatal therapists who have dedicated time allocated to serve the NICU:
1. an occupational and/or physical therapist with neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and
  2. a speech language pathologist with neonatal expertise, skilled in the evaluation and management of neonatal feeding and swallowing concerns, and neonatal therapy certification preferred.<sup>5</sup>
    - i. If swallow studies are not offered on-site at the facility, policies and procedures will be in place to facilitate neonatal transfer to a higher level of care.
- (nn) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal therapist coverage based on the specific need and volume of the neonatal population served.<sup>12</sup>

**Social Worker**

- (oo) The NICU social worker will:
1. be a Master's prepared medical social worker with perinatal and/or pediatric experience.<sup>5</sup>
- (pp) The facility will:
1. provide 1 social worker for every 30 beds providing level III neonatal care and/or specialty and subspecialty perinatal care<sup>5</sup>;
  2. have a written description that clearly identifies the responsibilities and functions of the NICU social worker; and
  3. have social services available for each family with an infant in the NICU as needed.

**Pastoral Care**

- (qq) Personnel skilled in pastoral care will be available as needed and by family request, and will represent, or have the ability to consult, multiple religious affiliations representative of the population served.<sup>5</sup>

**Retinopathy of Prematurity**

- (rr) The facility must have a process in place to appropriately identify infants at risk for retinopathy of prematurity to guarantee timely examination and treatment by having<sup>13</sup>:
1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity<sup>5,13</sup>; and
  2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity.<sup>5,13</sup>

**Discharge and Follow-up**

- (ss) Systems will be in place to establish preparation for NICU discharge, including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed.
1. The facility will:
    - i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk neonatal follow-up with appropriate developmental follow-up services; and
    - ii. provide developmental follow-up services or have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.
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## STANDARD VII: LEVEL IV NICU REQUIREMENTS

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### Level IV NICU Requirements

(a) The level IV neonatal facility will:

1. provide comprehensive care for infants born at all gestational ages and birth weights, with mild to complex critical conditions or medical problems requiring sustained life support, hemodynamic support, conventional and high frequency mechanical ventilation, iNO delivery, and/or therapeutic hypothermia<sup>2</sup>;
2. have the capability to provide surgical repair of complex congenital or acquired conditions<sup>2</sup>;
3. have the ability to provide ECMO or policies and procedures in place to facilitate neonatal transfer to another unit or facility that provides ECMO<sup>2</sup>;
4. maintain a broad range of pediatric medical subspecialists, pediatric surgical specialists, and pediatric anesthesiologists<sup>2</sup>;
5. facilitate transport and provide outreach education to lower-level facilities<sup>2</sup>; and
6. have sufficient experience based on patient volume and a systematic process to assess the quality of care provided, including a method to track specific quality indicators and clinical diagnoses, review aggregate data using accepted methodology, and develop action plans as needed to improve patient outcomes.<sup>2,14</sup>

### Neonatal Medical Director

(b) The NMD will:

1. be a board-certified neonatologist or equivalent;
  - i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;
2. complete annual CME specific to neonatology; and
3. demonstrate a current status of NRP completion.

### Neonatologists

(c) The NICU neonatologists will:

1. be a board eligible or certified neonatologist or equivalent;
  - i. if the neonatologist is certified The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;
2. complete annual CME specific to neonatology;
3. demonstrate a current status of NRP completion;
4. have credentials that are reviewed by the NMD at least every 2 years; and
5. preferably be on-site and immediately available 24/7, or on-call and available to arrive on-site within an appropriate time frame, as defined by the facility's policies and procedures.
  - i. If a neonatologist is not on-site 24/7, a written policy will be in place that defines the criteria for notification and time frame for on-site presence, and a tracking mechanism for compliance is required.

### Privileged Care Providers

(d) Privileged care providers with neonatal-specific training qualified to manage the care of infants with mild to complex critical conditions, including emergencies, will be on-site 24/7 and<sup>5</sup>:

1. demonstrate a current status of NRP completion;
2. complete annual continuing education requirements specific to neonatology; and
3. have their credentials reviewed at least every 2 years by the NMD.

(e) At least 1 person with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7<sup>7</sup>; and

1. demonstrate a current status of NRP completion.

(f) The facility will establish a written policy for backup privileged care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent medical providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup>

### Nursing Leadership

(g) The level IV NICU nurse leader will:

1. be an RN with experience and training in neonatal nursing and conditions, with nursing certification preferred<sup>5</sup>;
2. have at least a Bachelor of Science in Nursing, Master's preferred;
3. demonstrate a current status of NRP completion;
4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level IV NICU care;
5. be responsible for inpatient activities in the NICU(s) and, as appropriate, obstetrical, well newborn, and/or pediatric units;
6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;
7. provide oversight of annual neonatal-specific education, which includes low-volume, high-risk procedures consistent with the care provided in the level IV NICU; and
8. foster collaborative relationships with multidisciplinary team members and facility leadership to create a diverse, equitable, and inclusive environment to improve the quality of care and patient care outcomes.<sup>5</sup>

### Clinical Nurse Staffing

(h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup>

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### **Clinical Nurse Staff**

- (i) Each clinical nurse will:
  1. be an RN, with nursing certification specific to the care environment preferred;
  2. demonstrate a current status of NRP completion;
  3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level IV NICU; and
  4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.
- (j) If the facility utilizes LPNs or nonlicensed direct care providers to support the clinical nursing staff, the facility must:
  1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;
  2. provide annual education specific to the care of the neonatal population served; and
  3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.

### **Nursing Orientation and Education**

- (k) Level IV NICU nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup>
- (l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.
- (m) Annual nursing education will address the annual needs assessment and incorporate simulation and skill verification of low-volume, high-risk procedures consistent with the types of care provided in the level IV NICU and include education related to serious safety events.

### **Clinical Nurse Specialist**

- (n) The clinical nurse specialist will:
  1. be an RN, with neonatal nursing certification and clinical nurse specialist certification preferred<sup>5</sup>;
  2. have at least a Master of Science in Nursing, Doctorate preferred<sup>5</sup>;
  3. demonstrate a current status of NRP completion<sup>5</sup>;
  4. foster continuous quality improvement in nursing care<sup>5</sup>;
  5. develop and educate staff to provide evidence-based nursing care<sup>5</sup>;
  6. be responsible for mentoring new staff and developing team building skills<sup>5</sup>;
  7. provide leadership to multidisciplinary teams<sup>5</sup>;
  8. facilitate case management of high-risk neonatal patients<sup>5</sup>; and
  9. cultivate collaborative relationships with multidisciplinary team members and facility leadership to improve the quality of care and patient care outcomes.<sup>5</sup>
- (o) The facility will have a dedicated full-time equivalent (FTE) allocated to perform the roles and responsibilities of the NICU clinical nurse specialist.

### **Clinical Nurse Educator**

- (p) The NICU clinical nurse educator will:
  1. be an RN, with nursing certification specific to the care environment preferred;
  2. have at least a Bachelor of Science in Nursing, Master's preferred;
  3. demonstrate a current status of NRP completion;
  4. cultivate collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes<sup>5</sup>; and
  5. have experience and expertise to evaluate the educational needs of the clinical staff, develop didactic and skill-based educational tools, oversee education and skills verification, and evaluate retention of content, critical thinking skills, and competency relevant to level IV neonatal care.<sup>9</sup>
- (q) The facility will have at least 1 dedicated FTE allocated to perform the roles and responsibilities of the NICU clinical nurse educator.

### **Additional Neonatal Support Personnel**

- (r) The facility will foster collaborative and consultative relationships with additional neonatal support personnel to facilitate comprehensive multidisciplinary care consistent with the types of care provided in the level IV NICU.

### **Neonatal Transport**

- (s) If the facility has a neonatal critical care transport program, it will have an identified director of neonatal transport services.<sup>5</sup> The director of neonatal transport services can be the neonatal medical director or another physician who is a pediatrician, board eligible or certified neonatologist, pediatric hospitalist, or pediatric medical subspecialist with expertise and experience in neonatal and infant transport.<sup>5</sup>
    1. If the facility does not have its own transport program, the facility must have policies and procedures in place to identify a local neonatal transport program to facilitate transport.<sup>5</sup>
  - (t) Responsibilities of the director of neonatal transport services include the following:
    1. train and supervise staff<sup>5</sup>;
    2. provide appropriate review of all transport records<sup>5</sup>;
    3. develop and implement policies and procedures for patient care during transport<sup>5</sup>;
    4. develop guidelines for determining transport team composition and medical control and establish a mechanism to track adherence<sup>5</sup>;
    5. establish policies and procedures to provide transport updates and outreach education<sup>5</sup>;
    6. establish a program for evaluating performance by tracking data, identifying trends, and implementing quality improvement initiatives to address transport performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>5</sup>; and
    7. report neonatal transport data and neonatal-specific reviews back to the NPSQIP.
    8. The director of neonatal transport services may delegate specific requirements to other person(s) or group(s) but retains the responsibility of certifying that these functions are addressed appropriately.<sup>5</sup>
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- (u) The facility will:
1. establish minimum education, experience, and training requirements for all transport team members<sup>15</sup>;
  2. select transport team members based on their experience and competence in the care of neonates and the transport team must collectively have the ability to provide a level of care that is similar to that of the admitting unit<sup>15</sup>; and
  3. provide annual transport education to all transport team members that incorporates equipment training, didactic education, simulation, and skills verification of low-volume, high-risk procedures consistent with the types of care provided during neonatal transport.<sup>15</sup>

#### **Neonatal Outreach**

- (v) The level IV facility will provide multidisciplinary outreach education to referring facilities by assessing educational needs and evaluating clinical care and outcomes, including transport data, as part of collaboration with lower-level neonatal facilities.<sup>5</sup>

#### **Pediatric Medical Subspecialists**

- (w) The facility must have on-site access to a broad range of pediatric medical subspecialties including, but not limited to<sup>2</sup>:
1. cardiology, pulmonology, infectious disease, neurology, ophthalmology, endocrinology, hematology, gastroenterology, nephrology, and genetics or metabolism; and
  2. the pediatric medical subspecialists must:
    - i. be readily accessible for in-person consultation;
    - ii. have credentials to consult at the facility, including documented training, certification, competencies, and continuing education specific to their subspecialty; and
    - iii. document consultations in the medical record within an appropriate time frame and as defined by the facility's policies and procedures.

#### **Neonatal Surgical Program – Required for Level IV**

##### **Pediatric Surgeons**

- (x) Pediatric surgeons and pediatric surgical specialists will:
1. be available at the bedside within 1 hour of request or identified need and be capable of performing major pediatric surgery, including surgery for complex conditions<sup>16</sup>;
    - i. if transplant or cardiac surgery is not offered on-site at the facility, policies and procedures will be in place to facilitate neonatal transport to a facility that provides appropriate surgical care;
  2. provide consultation to a broad range of pediatric surgical specialists including, but not limited to<sup>5,16</sup>.
    - i. general pediatric surgery, neurosurgery, urology, ophthalmology, otolaryngology, orthopedics, and plastic surgery;
  3. have credentials to provide care at the facility, including documented training, certification, competencies, and continuing education specific to their pediatric surgery specialty<sup>16</sup>;
  4. establish a program for evaluating surgical performance by accurately tracking data, identifying trends, and implementing quality improvement initiatives to address surgical performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>16</sup>; and
  5. report neonatal surgical and anesthesia care back to the NPSQIP.

##### **Anesthesiologists**

- (y) Pediatric anesthesiologists must:
1. be on the medical staff and promptly available 24/7 to respond to the bedside within 1 hour of request or identified need<sup>16</sup>;
  2. serve as the primary responsible anesthesia provider for all infants <24 mo of age and should serve as the primary anesthesiologist for children ≤5 y of age or based on the ASA physical status classification<sup>16</sup>; and
  3. be physically present for all neonatal surgical procedures for which they serve as the primary responsible anesthesia provider.<sup>16</sup>

##### **Laboratory Services**

- (z) Laboratory services will have:
1. laboratory personnel on-site 24/7;
  2. the ability to determine blood type, crossmatch, and perform antibody testing;
  3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or CMV-negative blood;
    - i. policies and procedures will be in place to facilitate emergent access to blood and blood component therapy so that the NICU can provide a full range of hematologic interventions;
  4. the ability to perform neonatal blood gas monitoring;
  5. the ability to perform analysis on small volume samples;
  6. the capability to process biopsies and perform autopsies; and
  7. access to perinatal pathology services, if applicable.

- (aa) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to maintain timely and direct communication of all critical value results.

##### **Pharmacy**

- (bb) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:
1. be available for consultation on-site, or by telehealth or telephone, 24/7;
  2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and
  3. participate in multidisciplinary care, including participation in patient care rounds.
- (cc) The facility will have neonatal appropriate TPN available 24/7; and
1. the facility will have a written policy and procedure for the proper preparation and delivery of TPN.
- (dd) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level IV NICU; and
1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.

### **Diagnostic Imaging**

- (ee) Radiology services will have:
1. appropriately trained radiology personnel continuously available on-site to meet routine diagnostic imaging needs and to address emergencies;
  2. fluoroscopy available on-call 24/7;
  3. personnel appropriately trained in the following techniques will be on-call and/or available on-site to perform advanced imaging as requested:
    - i. ultrasonography, including cranial ultrasonography;
    - ii. CT;
    - iii. MRI; and
  4. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.
- (ff) The facility will provide pediatric echocardiography and have the ability to consult with a pediatric cardiologist for timely echocardiography interpretation as requested.

### **Respiratory Therapy**

- (gg) The respiratory care leader will:
1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;
  2. have sufficient time allocated to oversee the RTs who provide care in the level IV NICU;
  3. provide oversight of annual simulation and skills verification, including neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;
  4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and
  5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.
- (hh) Respiratory care practitioners assigned to the NICU will:
1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal and pediatric respiratory care certification preferred;
  2. be on-site 24/7 and immediately available to supervise assisted ventilation, assist in resuscitation, and attend deliveries, if applicable;
  3. demonstrate a current status of NRP completion;
  4. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the NICU; and
  5. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.

### **Dietitian**

- (ii) The NICU will have at least 1 full-time NICU-dedicated registered dietitian or nutritionist available on-site who has specialized training in neonatal nutrition and will<sup>5</sup>:
1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;
  2. establish policies and procedures to verify proper preparation and storage of human milk and formula;
  3. participate in multidisciplinary care, including participation in patient care rounds; and
  4. have policies and procedures for dietary consultation for infants in the NICU.

### **Neonatal Nutrition**

- (jj) The facility will:
1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;
  2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for human milk, donor human milk, fortification of human milk and formula; and
  3. have policies and procedures in place for accurate verification and administration of human milk and formula, and to avoid misappropriation.

### **Lactation and Breastfeeding Support**

- (kk) The facility will:
1. have personnel with the knowledge and skills to support lactation available at all times;
  2. have an IBCLC available for on-site consultation on weekdays and accessible by telehealth or telephone 24/7; and
  3. operationally review IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup>

### **Neonatal Therapists**

- (ll) The facility will provide on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family or psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served.<sup>12</sup>
- (mm) The facility will have on-site access to the following neonatal therapists who have dedicated time allocated to serve the NICU:
1. an occupational and/or physical therapist with sufficient neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and
  2. a speech language pathologist with neonatal expertise, skilled in the evaluation and management of neonatal feeding and swallowing concerns, and neonatal therapy certification preferred.<sup>5</sup>
- (nn) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal therapist coverage based on the specific need and volume of the neonatal population served.<sup>12</sup>
-

**Child Life Services**

(oo) Child life services, or the equivalent, will be available for on-site consultation to support patient- and family-centered care by establishing and maintaining therapeutic relationships between patients, family members, multidisciplinary team members, and community resources.

**Social Worker**

(pp) The NICU social worker will:

- 1. be a Master's prepared medical social worker with perinatal and/or pediatric experience.<sup>5</sup>

(qq) The facility will:

- 1. provide at least 1 social worker for every 30 beds providing level IV neonatal care and/or specialty and subspecialty perinatal care, if applicable<sup>5</sup>;
- 2. have a written description that clearly identifies the responsibilities and functions of the NICU social worker; and
- 3. have social services available for each family with an infant in the NICU as needed.

**Pastoral Care**

(rr) Personnel skilled in pastoral care will be available as needed and by family request, and will represent, or have the ability to consult, multiple religious affiliations representative of the population served.<sup>5</sup>

**Retinopathy of Prematurity**

(ss) The facility must have a process in place to appropriately identify infants at risk for retinopathy of prematurity to guarantee timely examination and treatment by having<sup>13</sup>:

- 1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity<sup>5,13</sup>; and
- 2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity.<sup>5,13</sup>

**Discharge and Follow-up**

(tt) Systems will be in place to establish preparation for NICU discharge including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed.

1. The facility will:

- i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk neonatal follow-up with appropriate developmental follow-up services; and
- ii. provide developmental follow-up services or have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.

**APPENDIX: NEONATAL LEVELS OF CARE  
COMPARISON: LEVEL (II, III, AND IV)  
REQUIREMENTS**

Level II	Level III	Level IV
<b>Level of Neonatal Care Requirements</b>		
<p>(a) The Level II SCN will provide comprehensive care of infants born <math>\geq 32</math> wk or with birth wt <math>\geq 1500</math> g who<sup>2</sup>:</p> <ol style="list-style-type: none"> <li>1. are mild to moderately ill with physiologic immaturity or who have conditions that are expected to resolve quickly<sup>2</sup>;</li> <li>2. are not anticipated to require subspecialty services on an urgent basis<sup>2</sup>;</li> <li>3. require CPAP or short term (less than 24 h) conventional mechanical ventilation for a condition expected to resolve rapidly or until transfer to a higher-level facility is achieved<sup>2</sup>; or</li> <li>4. are back transferred from a higher-level facility for convalescent care.<sup>2</sup></li> </ol>	<p>(a) The Level III neonatal facility will:</p> <ol style="list-style-type: none"> <li>1. provide comprehensive care for infants born at all gestational ages and birth weights, with mild to complex critical conditions or medical problems requiring sustained life support, hemodynamic support, and/or conventional mechanical ventilation<sup>2</sup>;</li> <li>2. have the ability to provide high-frequency ventilation, iNO delivery, and/or therapeutic hypothermia or have policies and procedures in place to facilitate neonatal transfer to another unit or facility that provides these services<sup>2</sup>;</li> <li>3. provide care for infants who are back transferred for convalescent care<sup>2</sup>; and</li> <li>4. have sufficient experience based on patient volume and a systematic process to assess the quality of care provided to each very low birth weight infant, including a method to track specific quality indicators including obstetrical and neonatal transfers, review aggregate data using accepted methodology, and develop</li> </ol>	<p>(a) The Level IV neonatal facility will:</p> <ol style="list-style-type: none"> <li>1. provide comprehensive care for infants born at all gestational ages and birth weights, with mild to complex critical conditions or medical problems requiring sustained life support, hemodynamic support, conventional and high frequency mechanical ventilation, iNO delivery, and/or therapeutic hypothermia<sup>2</sup>;</li> <li>2. have the capability to provide surgical repair of complex congenital or acquired conditions<sup>2</sup>;</li> <li>3. have the ability to provide ECMO or have policies and procedures in place to facilitate neonatal transfer to another unit or facility that provides ECMO<sup>2</sup>;</li> <li>4. maintain a broad range of pediatric medical subspecialists, pediatric surgical specialists, and pediatric anesthesiologists<sup>2</sup>;</li> <li>5. facilitate transport and provide outreach education to lower-level facilities<sup>2</sup>; and</li> <li>6. have sufficient experience based on patient volume and a systematic process to assess the quality of care provided, including a method</li> </ol>

Level II	Level III	Level IV
	action plans as needed to improve patient outcomes. <sup>2,14</sup>	to track specific quality indicators and clinical diagnoses, review aggregate data using accepted methodology, and develop action plans as needed to improve patient outcomes. <sup>2,14</sup>
<b>Neonatal Medical Director</b>		
<p>(b) The NMD will:</p> <ol style="list-style-type: none"> <li>1. be a physician who is a board-eligible or -certified neonatologist or a board-certified pediatrician with sufficient training and expertise to assume responsibility of care for infants who require level II care, including endotracheal intubation, assisted ventilation, and CPAP management, or equivalent<sup>5</sup>;</li> <li>i. if the neonatologist or pediatrician is certified by The American Board of Pediatrics, they will meet MOC requirements;</li> <li>2. complete annual CME specific to neonatology; and</li> <li>3. demonstrate a current status of NRP completion.</li> </ol>	<p>(b) The NMD will:</p> <ol style="list-style-type: none"> <li>1. be a board-eligible or -certified neonatologist or equivalent;</li> <li>i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;</li> <li>2. complete annual CME specific to neonatology; and</li> <li>3. demonstrate a current status of NRP completion.</li> </ol>	<p>(b) The NMD will:</p> <ol style="list-style-type: none"> <li>1. be a board-certified neonatologist or equivalent;</li> <li>i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;</li> <li>2. complete annual CME specific to neonatology; and</li> <li>3. demonstrate a current status of NRP completion.</li> </ol>
<b>Neonatologists</b>		
<p>(c) If the NMD and/or on-site provider is not a neonatologist, the privileged care provider must maintain a consultative relationship with a board-certified or -eligible neonatologist at a higher-level neonatal facility; and</p> <ol style="list-style-type: none"> <li>1. the facility must have a written policy or guideline that defines the criteria for neonatologist consultation at a higher-level neonatal facility.</li> </ol>	<p>(c) The NICU neonatologists will:</p> <ol style="list-style-type: none"> <li>1. be a board-eligible or -certified neonatologist or equivalent;</li> <li>i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;</li> <li>2. complete annual CME specific to neonatology;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. have credentials that are reviewed by the NMD at least every 2 years; and</li> <li>5. preferably be on-site and immediately available 24/7, or on-call and available to arrive on-site within an appropriate time frame, as defined by the facility's policies and procedures. <ol style="list-style-type: none"> <li>i. If a neonatologist is not on-site 24/7, a written policy will be in place that defines the criteria for notification and time frame for on-site presence, and a tracking mechanism for compliance is required.</li> </ol> </li> </ol>	<p>(c) The NICU neonatologists will:</p> <ol style="list-style-type: none"> <li>1. be a board-eligible or -certified neonatologist or equivalent;</li> <li>i. if the neonatologist is certified by The American Board of Pediatrics, they will meet MOC requirements in neonatal-perinatal medicine;</li> <li>2. complete annual CME specific to neonatology;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. have credentials that are reviewed by the NMD at least every 2 years; and</li> <li>5. preferably be on-site and immediately available 24/7, or on-call and available to arrive on-site within an appropriate time frame as defined by the facility's policies and procedures. <ol style="list-style-type: none"> <li>i. If a neonatologist is not on-site 24/7, a written policy will be in place that defines the criteria for notification and time frame for on-site presence, and a tracking mechanism for compliance is required.</li> </ol> </li> </ol>
<b>Privileged Care Providers</b>		
<p>(d) Privileged care providers with pediatric- or neonatal-specific training qualified to manage the care of infants with mild to moderate critical conditions, including emergencies will<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. be continuously available on-site, or on-call and available to arrive on-site within an appropriate time frame, as defined by the facility's policies and procedures;</li> <li>i. if the on-site or on-call provider is not a physician, a written policy will be in</li> </ol>	<p>(d) Privileged care providers with neonatal-specific training qualified to manage the care of infants with mild to complex critical conditions, including emergencies, will be on-site 24/7 and<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. demonstrate a current status of NRP completion;</li> <li>2. complete annual continuing education requirements specific to neonatology; and</li> <li>3. have their credentials reviewed at least every 2 years by the NMD.</li> </ol>	<p>(d) Privileged care providers with neonatal-specific training qualified to manage the care of infants with mild to complex critical conditions, including emergencies, will be on-site 24/7 and<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. demonstrate a current status of NRP completion;</li> <li>2. complete annual continuing education requirements specific to neonatology; and</li> <li>3. have their credentials reviewed at least every 2 years by the NMD.</li> </ol>

Level II	Level III	Level IV
<p>place that defines the criteria for notification and time frame for on-site physician presence, and a tracking mechanism for compliance is required;</p> <p>ii. if an infant is maintained on a ventilator, a pediatric- or neonatal-specific privileged care provider who can manage respiratory emergencies will be immediately available on-site;</p> <ol style="list-style-type: none"> <li>2. demonstrate a current status of NRP completion;</li> <li>3. complete annual continuing education requirements specific to neonatology; and</li> <li>4. have their credentials reviewed at least every 2 years by the NMD.</li> </ol> <p>(e) At least 1 person with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7<sup>7</sup>; and</p> <ol style="list-style-type: none"> <li>1. demonstrate a current status of NRP completion.</li> </ol> <p>(f) The facility will establish a written policy for backup medical care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent privileged care providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup></p>	<p>(e) At least 1 person with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately on-site 24/7<sup>7</sup>; and</p> <ol style="list-style-type: none"> <li>1. demonstrate a current status of NRP completion.</li> </ol> <p>(f) The facility will establish a written policy for backup medical care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent privileged care providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup></p>	<p>(e) At least 1 person with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications must be immediately available on-site 24/7<sup>7</sup>; and</p> <ol style="list-style-type: none"> <li>1. demonstrate a current status of NRP completion.</li> </ol> <p>(f) The facility will establish a written policy for backup medical care provider coverage that establishes flexibility for variable census and acuity. This policy will document the criteria for notification and time frame for on-site presence, be based on allocating the appropriate number of competent privileged care providers to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9</sup></p>
<b>Nursing Leadership</b>		
<p>(g) The level II SCN nurse leader will:</p> <ol style="list-style-type: none"> <li>1. be an RN with experience and training in perinatal nursing and neonatal conditions, with nursing certification preferred<sup>8</sup>;</li> <li>2. have at least a Bachelor of Science in Nursing, Master's preferred;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level II SCN care;</li> <li>5. be responsible for inpatient activities in the level II SCN and, as appropriate, obstetrical, well newborn, and/or pediatric units;</li> <li>6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;</li> <li>7. provide oversight of annual neonatal-specific education, which includes low-volume, high-risk procedures consistent with the care provided in the level II SCN; and</li> </ol>	<p>(g) The level III NICU nurse leader will:</p> <ol style="list-style-type: none"> <li>1. be an RN with experience and training in neonatal nursing and conditions, with nursing certification preferred<sup>8</sup>;</li> <li>2. have at least a Bachelor of Science in Nursing, Master's preferred;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level III NICU care;</li> <li>5. be responsible for inpatient activities in the NICU(s) and, as appropriate, obstetrical, well newborn, and/or pediatric units;</li> <li>6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;</li> <li>7. provide oversight of annual neonatal-specific education, which includes low-volume, high-risk procedures consistent with the care provided in the level III NICU; and</li> </ol>	<p>(g) The level IV NICU nurse leader will:</p> <ol style="list-style-type: none"> <li>1. be an RN with experience and training in neonatal nursing and conditions, with nursing certification preferred<sup>8</sup>;</li> <li>2. have at least a Bachelor of Science in Nursing, Master's preferred;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. have sufficient experience and expertise to create, and/or support, a program that provides care to infants who require level IV NICU care;</li> <li>5. be responsible for inpatient activities in the NICU(s) and, as appropriate, obstetrical, well newborn, and/or pediatric units;</li> <li>6. coordinate with respective neonatal, pediatric, and obstetric care services, as appropriate;</li> <li>7. provide oversight of annual neonatal-specific education, which includes low-volume, high-risk procedures consistent with the care provided in the level IV NICU; and</li> </ol>

Level II	Level III	Level IV
<p>8. foster collaborative relationships with multidisciplinary team members, facility leadership, and higher-level facilities to create a diverse, equitable, and inclusive environment focused on the quality of care and patient care outcomes.<sup>5</sup></p>	<p>8. foster collaborative relationships with multidisciplinary team members, facility leadership, and higher-level facilities to create a diverse, equitable, and inclusive environment to improve the quality of care and patient care outcomes.<sup>5</sup></p>	<p>8. foster collaborative relationships with multidisciplinary team members and facility leadership to create a diverse, equitable, and inclusive environment to improve the quality of care and patient care outcomes.<sup>5</sup></p>
<p><b>Clinical Nurse Staffing</b></p>		
<p>(h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup></p>	<p>(h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup></p>	<p>(h) A written nurse staffing plan is in place that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RNs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adequacy and adherence.<sup>9,10</sup></p>
<p><b>Clinical Nurse Staff</b></p>		
<p>(i) Each clinical nurse will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with nursing certification specific to the care environment preferred;</li> <li>2. demonstrate a current status of NRP completion;</li> <li>3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level II SCN; and</li> <li>4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.</li> </ol> <p>(j) If the facility utilizes LPNs or nonlicensed direct care providers to support the clinical nursing staff, the facility must:</p> <ol style="list-style-type: none"> <li>1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;</li> <li>2. provide annual education specific to the care of the neonatal population served; and</li> <li>3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.</li> </ol>	<p>(i) Each clinical nurse will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with nursing certification specific to the care environment preferred;</li> <li>2. demonstrate a current status of NRP completion;</li> <li>3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level III NICU; and</li> <li>4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.</li> </ol> <p>(j) If the facility utilizes LPNs or nonlicensed direct care providers to support the clinical nursing staff, the facility must:</p> <ol style="list-style-type: none"> <li>1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;</li> <li>2. provide annual education specific to the care of the neonatal population served; and</li> <li>3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.</li> </ol>	<p>(i) Each clinical nurse will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with nursing certification specific to the care environment preferred;</li> <li>2. demonstrate a current status of NRP completion;</li> <li>3. participate in annual simulation and skills verification, which includes low-volume, high-risk procedures consistent with the types of care provided in the level IV NICU; and</li> <li>4. promote a family-centered approach to care, including but not limited to skin-to-skin care, appropriate developmental positioning based on gestational age, lactation and breastfeeding support, and engagement of families in their infant's care.</li> </ol> <p>(j) If the facility utilizes LPNs or nonlicensed direct care providers to support the clinical nursing staff, the facility must:</p> <ol style="list-style-type: none"> <li>1. have written criteria that define the LPNs' or nonlicensed direct care providers' scope of neonatal care;</li> <li>2. provide annual education specific to the care of the neonatal population served; and</li> <li>3. have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.</li> </ol>
<p><b>Nursing Orientation and Education</b></p>		
<p>(k) Level II SCN nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup></p> <p>(l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.</p> <p>(m) Annual nursing education will address the annual needs assessment and incorporate simulation and skills verification of low-</p>	<p>(k) Level III NICU nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup></p> <p>(l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.</p> <p>(m) Annual nursing education will address the annual needs assessment and incorporate simulation and skill verification of low-volume,</p>	<p>(k) Level IV NICU nursing orientation will incorporate didactic education, simulation, skills verification, and competency and will be tailored to the individual needs of the nurse based on clinical experience.<sup>9</sup></p> <p>(l) The facility will document an annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members.</p> <p>(m) Annual nursing education will address the annual needs assessment and incorporate simulation and skill verification of low-volume,</p>



Level II	Level III	Level IV
<p>volume, high-risk procedures consistent with the types of care provided in the level II SCN and include education related to serious safety events.</p>	<p>high-risk procedures consistent with the types of care provided in the level III NICU and include education related to serious safety events.</p>	<p>high-risk procedures consistent with the types of care provided in the level IV NICU and include education related to serious safety events.</p>
<p><b>Clinical Nurse Specialist</b></p>	<p>(n) The clinical nurse specialist will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with neonatal nursing certification and clinical nurse specialist certification preferred<sup>5</sup>;</li> <li>2. have at least a Bachelor of Science in Nursing; Master's or Doctorate preferred<sup>5</sup>;</li> <li>3. demonstrate a current status of NRP completion<sup>5</sup>;</li> <li>4. foster continuous quality improvement in nursing care<sup>5</sup>;</li> <li>5. develop and educate staff to provide evidence-based nursing care<sup>5</sup>;</li> <li>6. be responsible for mentoring new staff and developing team building skills<sup>5</sup>;</li> <li>7. provide leadership to multidisciplinary teams<sup>5</sup>;</li> <li>8. facilitate case management of high-risk neonatal patients<sup>5</sup>; and</li> <li>9. cultivate collaborative relationships with multidisciplinary team members and facility leadership to improve the quality of care and patient care outcomes.<sup>5</sup></li> </ol> <p>(o) The roles and responsibilities of the NICU clinical nurse specialist can be allocated to multiple individuals to perform this role.</p>	<p>(n) The clinical nurse specialist will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with neonatal nursing certification and clinical nurse specialist certification preferred<sup>5</sup>;</li> <li>2. have at least a Master of Science in Nursing; Doctorate preferred<sup>5</sup>;</li> <li>3. demonstrate a current status of NRP completion<sup>5</sup>;</li> <li>4. foster continuous quality improvement in nursing care<sup>5</sup>;</li> <li>5. develop and educate staff to provide evidence-based nursing care<sup>5</sup>;</li> <li>6. be responsible for mentoring new staff and developing team building skills<sup>5</sup>;</li> <li>7. provide leadership to multidisciplinary teams<sup>5</sup>;</li> <li>8. facilitate case management of high-risk neonatal patients<sup>5</sup>; and</li> <li>9. cultivate collaborative relationships with multidisciplinary team members and facility leadership to improve the quality of care and patient care outcomes.<sup>5</sup></li> </ol> <p>(o) The facility will have a dedicated FTE allocated to perform the roles and responsibilities of the NICU clinical nurse specialist.</p>
<p><b>Clinical Nurse Educator</b></p>	<p>(n) The level II SCN clinical nurse educator or perinatal nurse educator will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with nursing certification specific to the care environment preferred;</li> <li>2. have at least a Bachelor of Science in Nursing; Master's preferred;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. cultivate collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes<sup>5</sup>; and</li> <li>5. have experience and expertise to evaluate the educational needs of the clinical staff, develop didactic and skill-based educational tools, oversee education and skills verification, and evaluate retention of content, critical thinking skills, and competency relevant to level II neonatal care.<sup>9</sup></li> </ol> <p>(o) The facility will have a dedicated individual with sufficient time allocated to perform the roles and responsibilities of the clinical nurse educator.</p>	<p>(p) The NICU clinical nurse educator will:</p> <ol style="list-style-type: none"> <li>1. be an RN, with nursing certification specific to the care environment preferred;</li> <li>2. have at least a Bachelor of Science in Nursing; Master's preferred;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. cultivate collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes<sup>5</sup>; and</li> <li>5. have experience and expertise to evaluate the educational needs of the clinical staff, develop didactic and skill-based educational tools, oversee education and skills verification, and evaluate retention of content, critical thinking skills, and competency relevant to level IV neonatal care.<sup>9</sup></li> </ol> <p>(q) The facility will have at least 1 dedicated FTE allocated to perform the roles and responsibilities of the NICU clinical nurse educator.</p>

Level II	Level III	Level IV
<b>Additional Neonatal Support Personnel</b>		
<p><b>Neonatal Transport</b></p> <p>(p) The facility will have policies and procedures in place to identify a local neonatal transport program to facilitate neonatal transport to a higher-level neonatal facility.</p>	<p>(r) If the facility has a neonatal critical care transport program, it will have an identified director of neonatal transport services.<sup>5</sup> The director of neonatal transport services can be the neonatal medical director or another physician who is a pediatrician, board-eligible or -certified neonatologist, pediatric hospitalist, or pediatric medical subspecialist with expertise and experience in neonatal and infant transport.<sup>5</sup></p> <ol style="list-style-type: none"> <li>1. If the facility does not have its own transport program, the facility must have policies and procedures in place to identify a local neonatal transport program to facilitate transport.<sup>5</sup></li> </ol> <p>(s) Responsibilities of the director of neonatal transport services include the following:</p> <ol style="list-style-type: none"> <li>1. train and supervise staff<sup>5</sup>;</li> <li>2. provide appropriate review of all transport records<sup>5</sup>;</li> <li>3. develop and implement policies and procedures for patient care during transport<sup>5</sup>;</li> <li>4. develop guidelines for determining transport team composition and medical control, and establish a mechanism to track adherence<sup>5</sup>;</li> <li>5. establish policies and procedures to provide transport updates and outreach education<sup>5</sup>;</li> <li>6. establish a program for evaluating performance by tracking data, identifying trends, and implementing quality improvement initiatives to address transport performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>5</sup>; and</li> <li>7. report neonatal transport data and neonatal-specific reviews back to the NPSQIP.</li> <li>8. The director of neonatal transport services may delegate specific requirements to other person(s) or group(s) but retains the responsibility of certifying that these functions are addressed appropriately.<sup>5</sup></li> </ol> <p>(t) The facility will:</p> <ol style="list-style-type: none"> <li>1. establish minimum education, experience, and training requirements for all transport team members<sup>15</sup>;</li> <li>2. select transport team members based on their experience and competence in the care of neonates and the transport team must collectively have the ability to provide</li> </ol>	<p>(r) The facility will foster collaborative and consultative relationships with additional neonatal support personnel to facilitate comprehensive multidisciplinary care consistent with the types of care provided in the level IV NICU.</p> <p>(s) If the facility has a neonatal critical care transport program, it will have an identified director of neonatal transport services.<sup>5</sup> The director of neonatal transport services can be the neonatal medical director or another physician who is a pediatrician, board-eligible or -certified neonatologist, pediatric hospitalist, or pediatric medical subspecialist with expertise and experience in neonatal and infant transport.<sup>5</sup></p> <ol style="list-style-type: none"> <li>1. If the facility does not have its own transport program, the facility must have policies and procedures in place to identify a local neonatal transport program to facilitate transport.<sup>5</sup></li> </ol> <p>(t) Responsibilities of the director of neonatal transport services include the following:</p> <ol style="list-style-type: none"> <li>1. train and supervise staff<sup>5</sup>;</li> <li>2. provide appropriate review of all transport records<sup>5</sup>;</li> <li>3. develop and implement policies and procedures for patient care during transport<sup>5</sup>;</li> <li>4. develop guidelines for determining transport team composition and medical control, and establish a mechanism to track adherence<sup>5</sup>;</li> <li>5. establish policies and procedures to provide transport updates and outreach education<sup>5</sup>;</li> <li>6. establish a program for evaluating performance by tracking data, identifying trends, and implementing quality improvement initiatives to address transport performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>5</sup>; and</li> <li>7. report neonatal transport data and neonatal-specific reviews back to the NPSQIP.</li> <li>8. The director of neonatal transport services may delegate specific requirements to other person(s) or group(s) but retains the responsibility of certifying that these functions are addressed appropriately.<sup>5</sup></li> </ol> <p>(u) The facility will:</p> <ol style="list-style-type: none"> <li>1. establish minimum education, experience, and training requirements for all transport team members<sup>15</sup>;</li> <li>2. select transport team members based on their experience and competence in the care of neonates and the transport team must collectively have the ability to provide a level of care that is similar to that of the admitting unit<sup>15</sup>; and</li> <li>3. provide annual transport education to all transport team members, which incorporates equipment training, didactic education,</li> </ol>

Level II	Level III	Level IV
	<p>a level of care that is similar to that of the admitting unit<sup>15</sup>; and</p> <p>3. provide annual transport education to all transport team members, which incorporates equipment training, didactic education, simulation, and skills verification of low-volume, high-risk procedures consistent with the types of care provided during neonatal transport.<sup>15</sup></p>	<p>simulation, and skills verification of low-volume, high-risk procedures consistent with the types of care provided during neonatal transport.<sup>15</sup></p>
<b>Neonatal Outreach</b>	<p>(u) The level III facility will provide multidisciplinary outreach education to referring facilities by assessing education needs and evaluating clinical care and outcomes, including transport data, as part of collaboration with lower-level neonatal facilities, if applicable.<sup>5</sup></p>	<p>(v) The level IV facility will provide multidisciplinary outreach education to referring facilities by assessing education needs and evaluating clinical care and outcomes, including transport data, as part of collaboration with lower-level neonatal facilities.<sup>5</sup></p>
<b>Pediatric Medical Subspecialists</b>	<p>(q) Policies and procedures will be in place for referral to a higher level of neonatal care when pediatric medical subspecialty or pediatric surgical specialty consultation and/or intervention is needed.</p> <p>(v) The facility must have the ability to obtain pediatric medical subspecialist advice or formal consultation either on-site or by prearranged consultative agreement using telehealth technology and/or telephone consultation from a distant location, from a broad range of pediatric medical subspecialists including, but not limited to<sup>2</sup>:</p> <ol style="list-style-type: none"> <li>1. cardiology, pulmonology, infectious disease, neurology, ophthalmology, endocrinology, hematology, gastroenterology, nephrology, and genetics or metabolism.</li> </ol> <p>(w) If the pediatric medical subspecialist is available for on-site consultation, they will:</p> <ol style="list-style-type: none"> <li>1. have credentials to consult at the facility which includes documented training, certification, competencies, and continuing education specific to their subspecialty; and</li> <li>2. document consultations in the medical record within an appropriate time frame and as defined by the facility's policies and procedures.</li> </ol>	<p>(w) The facility must have on-site access to a broad range of pediatric medical subspecialties including, but not limited to<sup>2</sup>:</p> <ol style="list-style-type: none"> <li>1. cardiology, pulmonology, infectious disease, neurology, ophthalmology, endocrinology, hematology, gastroenterology, nephrology, and genetics or metabolism; and</li> <li>2. the pediatric medical subspecialists must: <ol style="list-style-type: none"> <li>i. be readily accessible for in-person consultation;</li> <li>ii. have credentials to consult at the facility, including documented training, certification, competencies, and continuing education specific to their subspecialty; and</li> <li>iii. document consultations in the medical record within an appropriate time frame and as defined by the facility's policies and procedures.</li> </ol> </li> </ol>
<b>Neonatal Surgical Program Pediatric Surgeons (Optional for level III, but required for level IV)</b>	<p>(x) Pediatric surgeons and pediatric surgical specialists will be available on-site or at another closely related NICU facility.<sup>5</sup></p> <ol style="list-style-type: none"> <li>1. If pediatric surgery is not offered on-site at the facility, policies and procedures will be in place with a facility that provides surgical care to facilitate transfer of an infant when needed. <ol style="list-style-type: none"> <li>i. Infants requiring cardiovascular surgery or ECMO will be transferred to a facility that provides these services.</li> </ol> </li> <li>2. If pediatric surgery is accessible on-site, the surgeons will:</li> </ol>	<p>(x) Pediatric surgeons and pediatric surgical specialists will:</p> <ol style="list-style-type: none"> <li>1. be available at the bedside within 1 hour of request or identified need and be capable of performing major pediatric surgery, including surgery for complex conditions<sup>16</sup>; <ol style="list-style-type: none"> <li>i. if transplant or cardiac surgery is not offered on-site at the facility, policies and procedures will be in place to facilitate neonatal transport to a facility that provides appropriate surgical care;</li> </ol> </li> <li>2. provide consultation to a broad range of pediatric surgical specialists including, but not limited to<sup>5,16</sup>;</li> </ol>

Level II	Level III	Level IV
	<ul style="list-style-type: none"> <li>i. be available at the bedside within 1 hour of request or identified need<sup>16</sup>;</li> <li>ii. have credentials to provide care at the facility, including documented training, certification, competencies, and continuing education specific to their pediatric surgery specialty<sup>16</sup>;</li> <li>iii. establish a program for evaluating surgical performance by accurately tracking data, identifying trends, and implementing quality improvement initiatives to address surgical performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>16</sup>; and</li> <li>iv. report neonatal surgical and anesthesia care back to the NPSQIP.</li> </ul>	<ul style="list-style-type: none"> <li>i. general pediatric surgery, neurosurgery, urology, ophthalmology, otolaryngology, orthopedics, and plastic surgery;</li> <li>3. have credentials to provide care at the facility, including documented training, certification, competencies, and continuing education specific to their pediatric surgery specialty<sup>16</sup>;</li> <li>4. establish a program for evaluating surgical performance by accurately tracking data, identifying trends, and implementing quality improvement initiatives to address surgical performance in a coordinated systematic approach within a culture of safety, equity, and prevention<sup>16</sup>; and</li> <li>5. report neonatal surgical and anesthesia care back to the NPSQIP.</li> </ul>
<p><b>Anesthesiologists</b></p>	<ul style="list-style-type: none"> <li>(y) If pediatric surgery is performed on-site, anesthesia providers with pediatric expertise must<sup>16</sup>:               <ul style="list-style-type: none"> <li>1. be on the medical staff and promptly available 24/7 to respond to the bedside within 1 hour of request or identified need<sup>16</sup>;</li> <li>2. serve as the primary responsible anesthesia provider for all infants &lt;24 mo of age and should serve as the primary anesthesiologist for children ≤5 y of age based on the ASA physical status classification<sup>16</sup>; and</li> <li>3. be physically present for all neonatal surgical procedures for which they serve as the primary responsible anesthesia provider.<sup>16</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>(y) Pediatric anesthesiologists must:               <ul style="list-style-type: none"> <li>1. be on the medical staff and promptly available 24/7 to respond to the bedside within 1 hour of request or identified need<sup>16</sup>;</li> <li>2. serve as the primary responsible anesthesia provider for all infants &lt;24 mo of age and should serve as the primary anesthesiologist for children ≤5 y of age or based on the ASA physical status classification<sup>16</sup>; and</li> <li>3. be physically present for all neonatal surgical procedures for which they serve as the primary responsible anesthesia provider.<sup>16</sup></li> </ul> </li> </ul>
<p><b>Laboratory Services</b></p> <ul style="list-style-type: none"> <li>(r) Laboratory services will have:           <ul style="list-style-type: none"> <li>1. laboratory personnel on-site 24/7;</li> <li>2. the ability to determine blood type, crossmatch, and perform antibody testing;</li> <li>3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or CMV-negative blood;</li> <li>4. the ability to perform neonatal blood gas monitoring; and</li> <li>5. the ability to perform analysis on small volume samples.</li> </ul> </li> <li>(s) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to verify timely and direct communication of all critical value results.</li> </ul>	<ul style="list-style-type: none"> <li>(z) Laboratory services will have:           <ul style="list-style-type: none"> <li>1. laboratory personnel on-site 24/7;</li> <li>2. the ability to determine blood type, crossmatch, and perform antibody testing;</li> <li>3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or CMV-negative blood;               <ul style="list-style-type: none"> <li>i. policies and procedures will be in place to facilitate emergent access to blood and blood component therapy so that the NICU can provide hematologic interventions, if applicable;</li> </ul> </li> <li>4. the ability to perform neonatal blood gas monitoring;</li> <li>5. the ability to perform analysis on small volume samples; and</li> <li>6. access to perinatal pathology services, if applicable.</li> </ul> </li> <li>(aa) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to maintain timely and direct communication of all critical value results.</li> </ul>	<ul style="list-style-type: none"> <li>(z) Laboratory Services will have:           <ul style="list-style-type: none"> <li>1. laboratory personnel on-site 24/7;</li> <li>2. the ability to determine blood type, crossmatch, and perform antibody testing;</li> <li>3. a blood bank capable of providing blood component therapy and irradiated, leukoreduced or CMV negative blood;               <ul style="list-style-type: none"> <li>i. policies and procedures will be in place to facilitate emergent access to blood and blood component therapy so that the NICU can provide a full range of hematologic interventions;</li> </ul> </li> <li>4. the ability to perform neonatal blood gas monitoring;</li> <li>5. the ability to perform analysis on small volume samples;</li> <li>6. the capability to process biopsies and perform autopsies; and</li> <li>7. access to perinatal pathology services, if applicable.</li> </ul> </li> <li>(aa) Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in</li> </ul>

Level II	Level III	Level IV
<b>Pharmacy</b>		place to maintain timely and direct communication of all critical value results.
<p>(t) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:</p> <ol style="list-style-type: none"> <li>1. be available for consultation on-site, or by telehealth or telephone, 24/7;</li> <li>2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and</li> <li>3. participate in multidisciplinary care, as needed.</li> </ol> <p>(u) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level II SCN; and</p> <ol style="list-style-type: none"> <li>1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.</li> </ol>	<p>(bb) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:</p> <ol style="list-style-type: none"> <li>1. be available for consultation on-site, or by telehealth or telephone, 24/7;</li> <li>2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and</li> <li>3. participate in multidisciplinary care, including participation in patient care rounds.</li> </ol> <p>(cc) The facility will have neonatal appropriate TPN available 24/7; and</p> <ol style="list-style-type: none"> <li>1. the facility will have a written policy and procedure for the proper preparation and delivery of TPN.</li> </ol> <p>(dd) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level III NICU; and</p> <ol style="list-style-type: none"> <li>1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.</li> </ol>	<p>(bb) The facility will have at least 1 registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:</p> <ol style="list-style-type: none"> <li>1. be available for consultation on-site, or by telehealth or telephone, 24/7;</li> <li>2. complete continuing education requirements specific to pediatric and neonatal pharmacology; and</li> <li>3. participate in multidisciplinary care, including participation in patient care rounds.</li> </ol> <p>(cc) The facility will have neonatal appropriate TPN available 24/7; and</p> <ol style="list-style-type: none"> <li>1. the facility will have a written policy and procedure for the proper preparation and delivery of TPN.</li> </ol> <p>(dd) The pharmacy will have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the level IV NICU; and</p> <ol style="list-style-type: none"> <li>1. have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.</li> </ol>
<b>Diagnostic Imaging</b>		
<p>(v) Radiology services will have:</p> <ol style="list-style-type: none"> <li>1. appropriately trained radiology personnel available on-site to meet routine diagnostic imaging needs and to address emergencies;</li> <li>2. personnel appropriately trained in ultrasonography, including cranial ultrasonography, will be on-call and/or available on-site to perform advanced imaging as requested; and</li> <li>3. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.</li> </ol>	<p>(ee) Radiology services will have:</p> <ol style="list-style-type: none"> <li>1. appropriately trained radiology personnel available on-site to meet routine diagnostic imaging needs and to address emergencies;</li> <li>2. fluoroscopy available on-call 24/7; <ol style="list-style-type: none"> <li>i. if fluoroscopy is not offered on-site at the facility, policies and procedures will be in place to facilitate transfer of an infant to a higher level of care;</li> </ol> </li> <li>3. personnel appropriately trained in the following techniques will be on-call and/or available on-site to perform advanced imaging as requested: <ol style="list-style-type: none"> <li>i. ultrasonography, including cranial ultrasonography;</li> <li>ii. CT;</li> <li>iii. MRI; and</li> </ol> </li> <li>4. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.</li> </ol> <p>(ff) The facility will provide pediatric echocardiography and have the ability to consult with a pediatric cardiologist for timely echocardiography interpretation as requested.</p>	<p>(ee) Radiology services will have:</p> <ol style="list-style-type: none"> <li>1. appropriately trained radiology personnel available on-site to meet routine diagnostic imaging needs and to address emergencies;</li> <li>2. fluoroscopy available on-call 24/7;</li> <li>3. personnel appropriately trained in the following techniques will be on-call and/or available on-site to perform advanced imaging as requested: <ol style="list-style-type: none"> <li>i. ultrasonography, including cranial ultrasonography;</li> <li>ii. CT;</li> <li>iii. MRI; and</li> </ol> </li> <li>4. the ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested.</li> </ol> <p>(ff) The facility will provide pediatric echocardiography and have the ability to consult with a pediatric cardiologist for timely echocardiography interpretation as requested.</p>
<b>Respiratory Therapy</b>		
<p>(w) The respiratory care leader will:</p> <ol style="list-style-type: none"> <li>1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. have sufficient time allocated to oversee</li> </ol>	<p>(gg) The respiratory care leader will:</p> <ol style="list-style-type: none"> <li>1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. have sufficient time allocated to oversee the</li> </ol>	<p>(gg) The respiratory care leader will:</p> <ol style="list-style-type: none"> <li>1. be a full-time respiratory care practitioner, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. have sufficient time allocated to oversee the</li> </ol>

Level II	Level III	Level IV
<p>the RTs who provide care in the level II SCN;</p> <ol style="list-style-type: none"> <li>3. provide oversight of annual simulation and skills verification, which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;</li> <li>4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and</li> <li>5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.</li> </ol> <p>(x) Respiratory care practitioners assigned to the SCN will:</p> <ol style="list-style-type: none"> <li>1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. be on-site 24/7 and immediately available when an infant is supported by assisted ventilation or CPAP;</li> <li>3. be able to attend deliveries and assist with resuscitation as requested;</li> <li>4. demonstrate a current status of NRP completion;</li> <li>5. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the SCN; and</li> <li>6. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.</li> </ol>	<p>RTs who provide care in the level III NICU;</p> <ol style="list-style-type: none"> <li>3. provide oversight of annual simulation and skills verification, which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;</li> <li>4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and</li> <li>5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.</li> </ol> <p>(hh) Respiratory care practitioners assigned to the NICU will:</p> <ol style="list-style-type: none"> <li>1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. be on-site 24/7 and immediately available to supervise assisted ventilation, assist in resuscitation, and attend deliveries;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the NICU; and</li> <li>5. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.</li> </ol>	<p>RTs who provide care in the level IV NICU;</p> <ol style="list-style-type: none"> <li>3. provide oversight of annual simulation and skills verification, which includes neonatal respiratory care modalities and low-volume, high-risk neonatal respiratory procedures;</li> <li>4. develop a written RT staffing plan that establishes flexibility for variable census and acuity. This plan and actual staffing will be based on allocating the appropriate number of competent RTs to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care needs<sup>9</sup>; and</li> <li>5. maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation.</li> </ol> <p>(hh) Respiratory care practitioners assigned to the NICU will:</p> <ol style="list-style-type: none"> <li>1. be a respiratory care practitioner with documented experience and training in the respiratory support of newborns and infants, with neonatal and pediatric respiratory care certification preferred;</li> <li>2. be on-site 24/7 and immediately available to supervise assisted ventilation, assist in resuscitation, and attend deliveries, if applicable;</li> <li>3. demonstrate a current status of NRP completion;</li> <li>4. participate in annual simulation and respiratory skills verification, which includes low-volume, high-risk procedures consistent with the types of respiratory care provided in the NICU; and</li> <li>5. have their credentials reviewed by the respiratory care leader annually for adequacy and adherence.</li> </ol>
<b>Dietitian</b>		
<p>(y) The facility must have, or have the ability to consult with, at least 1 registered dietitian or nutritionist who has specialized training in neonatal nutrition, who will<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;</li> <li>2. establish policies and procedures to verify proper preparation and storage of human milk and formula; and</li> <li>3. have policies and procedures for dietary consultation for infants in the SCN.</li> </ol>	<p>(ii) At least 1 registered dietitian or nutritionist who has specialized training in neonatal nutrition will have dedicated time allotted to serve the NICU and will<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;</li> <li>2. establish policies and procedures to verify proper preparation and storage of human milk and formula;</li> <li>3. participate in multidisciplinary care, including participation in patient care rounds; and</li> </ol>	<p>(ii) The NICU will have at least 1 full-time NICU-dedicated registered dietitian or nutritionist available on-site who has specialized training in neonatal nutrition and will<sup>5</sup>:</p> <ol style="list-style-type: none"> <li>1. collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;</li> <li>2. establish policies and procedures to verify proper preparation and storage of human milk and formula;</li> <li>3. participate in multidisciplinary care, including participation in patient care rounds; and</li> <li>4. have policies and procedures for dietary consultation for infants in the NICU.</li> </ol>

Level II	Level III	Level IV
	4. have policies and procedures for dietary consultation for infants in the NICU.	
<b>Neonatal Nutrition</b>		
(z) The facility will: <ol style="list-style-type: none"> <li>1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;</li> <li>2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for, human milk, donor human milk, fortification of human milk, and formula; and</li> <li>3. have policies and procedures in place for accurate verification and administration of human milk and formula and to avoid misappropriation.</li> </ol>	(jj) The facility will: <ol style="list-style-type: none"> <li>1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;</li> <li>2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for, human milk, donor human milk, fortification of human milk, and formula; and</li> <li>3. have policies and procedures in place for accurate verification and administration of human milk and formula and to avoid misappropriation.</li> </ol>	(jj) The facility will: <ol style="list-style-type: none"> <li>1. provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to human milk<sup>5</sup>;</li> <li>2. develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for, human milk, donor human milk, fortification of human milk, and formula; and</li> <li>3. have policies and procedures in place for accurate verification and administration of human milk and formula and to avoid misappropriation.</li> </ol>
<b>Lactation and Breastfeeding Support</b>		
(aa) The facility will: <ol style="list-style-type: none"> <li>1. have personnel with the knowledge and skills to support lactation available at all times;</li> <li>2. have a CLC, IBCLC preferred, available for on-site consultation on weekdays and accessible by telehealth or telephone 24/7; and</li> <li>3. operationally review CLC and/or IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup></li> </ol>	(kk) The facility will: <ol style="list-style-type: none"> <li>1. have personnel with the knowledge and skills to support lactation available at all times;</li> <li>2. have an IBCLC available for on-site consultation on weekdays, and accessible by telehealth or telephone 24/7; and</li> <li>3. operationally review IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup></li> </ol>	(kk) The facility will: <ol style="list-style-type: none"> <li>1. have personnel with the knowledge and skills to support lactation available at all times;</li> <li>2. have an IBCLC available for on-site consultation on weekdays, and accessible by telehealth or telephone 24/7; and</li> <li>3. operationally review IBCLC personnel on an annual basis to establish adequately trained lactation coverage based on the specific need and volume of the neonatal population served.<sup>11</sup></li> </ol>
<b>Neonatal Therapists</b>		
(bb) If the facility does not have in-house access to neonatal therapy expertise, the facility will have a formal process in place for providing on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family or psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served. The facility will have on-site access to the following as needed <sup>12</sup> : <ol style="list-style-type: none"> <li>1. an occupational or physical therapist with neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and</li> <li>2. at least 1 individual skilled in the evaluation and management of neonatal feeding and swallowing concerns, with neonatal therapy certification preferred.<sup>5</sup></li> </ol>	(ll) The facility will provide on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family or psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served. <sup>12</sup>	(ll) The facility will provide on-site consultative services by qualified neonatal therapists to address the 6 core practice domains (environment, family or psychosocial support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing) and to provide the appropriate care for the neonatal population served. <sup>12</sup>
(cc) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal therapist coverage based on the specific need and volume of the neonatal population served. <sup>12</sup>	(mm) The facility will have on-site access to the following neonatal therapists who have dedicated time allocated to serve the NICU: <ol style="list-style-type: none"> <li>1. an occupational and/or physical therapist with sufficient neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and</li> <li>2. a speech language pathologist with neonatal expertise, skilled in the evaluation and management of neonatal feeding and swallowing concerns, and neonatal therapy certification preferred.<sup>5</sup></li> </ol>	(mm) The facility will have on-site access to the following neonatal therapists who have dedicated time allocated to serve the NICU: <ol style="list-style-type: none"> <li>1. an occupational and/or physical therapist with sufficient neonatal expertise, and neonatal therapy certification preferred<sup>5</sup>; and</li> <li>2. a speech language pathologist with neonatal expertise, skilled in the evaluation and management of neonatal feeding and swallowing concerns, and neonatal therapy certification preferred.<sup>5</sup></li> </ol>
	(nn) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal	(nn) The facility will operationally review neonatal therapist personnel on an annual basis to maintain adequate multidisciplinary neonatal

Level II	Level III	Level IV
therapist coverage based on the specific need and volume of the neonatal population served. <sup>12</sup>		
<b>Child Life Services</b>		
(oo) Child life services, or equivalent, will be available for on-site consultation to support patient- and family-centered care by establishing and maintaining therapeutic relationships between patients, family members, multidisciplinary team members, and community resources.		
<b>Social Worker</b>		
(dd) The SCN social worker will: 1. be a Master's prepared medical social worker with perinatal and/or pediatric experience. <sup>5</sup>	(oo) The NICU social worker will: 1. be a Master's prepared medical social worker with perinatal and/or pediatric experience. <sup>5</sup>	(pp) The NICU social worker will: 1. be a Master's prepared medical social worker with perinatal and/or pediatric experience. <sup>5</sup>
(ee) The facility will: 1. provide 1 social worker for every 30 beds providing level II neonatal care and/or specialty and subspecialty perinatal care <sup>5</sup> ; 2. have a written description that clearly identifies the responsibilities and functions of the SCN social worker; and 3. have social services available for each family with an infant in the SCN as needed.	(pp) The facility will: 1. provide 1 social worker for every 30 beds providing level III neonatal care and/or specialty and subspecialty perinatal care <sup>5</sup> ; 2. have a written description that clearly identifies the responsibilities and functions of the NICU social worker; and 3. have social services available for each family with an infant in the NICU as needed.	(qq) The facility will: 1. provide at least 1 social worker for every 30 beds providing level IV neonatal care and/or specialty and subspecialty perinatal care, if applicable <sup>5</sup> ; 2. have a written description that clearly identifies the responsibilities and functions of the NICU social worker; and 3. have social services available for each family with an infant in the NICU as needed.
<b>Pastoral Care</b>		
(ff) Personnel skilled in pastoral care will be available as needed and by family request and will represent, or have the ability to consult, multiple religious affiliations representative of the population served. <sup>5</sup>	(qq) Personnel skilled in pastoral care will be available as needed and by family request and will represent, or have the ability to consult, multiple religious affiliations representative of the population served. <sup>5</sup>	(rr) Personnel skilled in pastoral care will be available as needed and by family request and will represent, or have the ability to consult, multiple religious affiliations representative of the population served. <sup>5</sup>
<b>Retinopathy of Prematurity</b>		
(gg) If the facility back transfers infants for convalescent care, the facility must have a process in place to appropriately identify infants at risk for retinopathy of prematurity to guarantee timely examination and treatment by having <sup>13</sup> : 1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity <sup>5,13</sup> ; 2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity, if needed. <sup>5,13</sup>	(rr) The facility must have a process in place to appropriately identify infants at risk for retinopathy to guarantee timely examination and treatment by having <sup>13</sup> : 1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity <sup>5,13</sup> ; and 2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity. <sup>5,13</sup>	(ss) The facility must have a process in place to appropriately identify infants at risk for retinopathy to guarantee timely examination and treatment by having <sup>13</sup> : 1. documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity <sup>5,13</sup> ; and 2. the ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity. <sup>5,13</sup>
<b>Discharge and Follow-up</b>		
(hh) Systems will be in place to establish preparation for SCN discharge, including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed. 1. The facility will: i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk	(ss) Systems will be in place to establish preparation for NICU discharge, including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed. 1. The facility will: i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk neonatal follow-up with	(tt) Systems will be in place to establish preparation for NICU discharge including postdischarge follow-up by general and subspecialty pediatric care providers, home care arrangements and community service resources, and enrollment in a developmental follow-up program as needed. 1. The facility will: i. have written medical, neurodevelopmental, and psychosocial criteria that automatically warrant high-risk neonatal follow-up



Level II	Level III	Level IV
<p>neonatal follow-up with appropriate developmental follow-up services; and</p> <p>ii. have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.</p>	<p>appropriate developmental follow-up services; and</p> <p>ii. provide developmental follow-up services or have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.</p>	<p>with appropriate developmental follow-up services; and</p> <p>ii. provide developmental follow-up services or have a written referral agreement with a developmental follow-up clinic or practice, when possible, to provide neurodevelopmental services for the neonatal population served.</p>

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