



February 26, 2015

Certificate of Need Program  
Tertiary Service Review  
Attn: Kyle Karinen, Office of Legal Services  
Washington State Department of Health  
P.O. Box 47873  
Olympia, WA 98504-7873

Dear Mr. Karinen:

Consistent with the Department of Health's January 6, 2015 notification regarding the Tertiary Health Service's Review, enclosed please find Seattle Children's Hospital's proposal to add Level IV neonatal services to the listing of tertiary services. We are confident that our Proposal is fully responsive to the January 6 notification and that the data provided demonstrates that the addition of Level IV neonatal services fully meets the criteria listed in WAC 246-310-035.

Thank you for the opportunity to submit this proposal, and please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Sanford M. Melzer", followed by a horizontal line and a small arrow pointing to the right.

Sanford M. Melzer, MD MBA  
Senior Vice President & Chief Strategy Officer

# **Proposal to Add Level IV Neonatal Services to the Listing of Tertiary Services Identified in Certificate of Need Rules WAC 246-310-020**

## **1. Executive Summary:**

In February 2013, partly in response to the American Academy of Pediatrics (AAP) recommendations to use uniform, nationally-applicable definitions and consistent standards of service for different levels of neonatal intensive care (*Pediatrics* 130: 587-97, 2012), the Washington State Department of Health revised and updated its *Perinatal and Neonatal Level of Care Guidelines (the Guidelines)*. This update resulted in the designation of a new neonatal level of care; Level IV.

According to the Guidelines, Level IV is defined as a Program with Level III capabilities and services, plus:

- Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions
- Maintains a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site
  - Provides a full spectrum of medical and surgical pediatric subspecialists available 24/7
    - Multi-disciplinary team for management of orthopedic and neurological anomalies
    - Surgical repair of complex conditions that may require cardiopulmonary bypass, ECMO, dialysis, tracheostomy, etc.
    - Neuro-developmental follow-up program
- Has a quality improvement program with comparisons to national benchmarks for level IV NICUs

Level IV is the highest neonatal level of care, involving infrastructure and resources that can manage a very small subset of very ill neonates (approximately 1% of all newborns). This Proposal provides the rationale and supporting data to demonstrate that Level IV neonatal services meets the criteria in WAC 246-310-035 and should be added to the list of tertiary services regulated by the Certificate of Need Program.

## 2. Current Environment:

Washington State's Certificate of Need Program currently regulates Level II and Level III neonatal services. The definitions of these two levels are found in WAC 246-310-020.

*B) Intermediate care nursery and/or obstetric services level II: ... A level II obstetric service is in an area designed, organized, equipped, and staffed to provide a full range of maternal and neonatal services for uncomplicated patients and for the majority of complicated obstetrical problems;*

*(C) Neonatal intensive care nursery and/or obstetric services level III... A level III obstetric service is in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communications, transfer, and transportation for a given region. Level III services provide leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research;*

At the time the CN definitions of Level II and Level III neonatal services were last modified (1993), there was no level of care designated by either the AAP or the Department of Health.

## 3. Level IV Neonatal Services Clearly Meets the Current Tertiary Services Definition:

The process for determining whether a service is tertiary is found at WAC 246-310-035:

- 2) *In determining whether a service is a tertiary service the department shall consider the degree to which the service meets the following criteria:*
  - (a) Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;*
  - (b) Whether the service requires immediate access to an acute care hospital;*
  - (c) Whether the service is characterized by relatively few providers;*
  - (d) Whether the service is broader than a procedure;*
  - (e) Whether the service has a low use rate;*
  - (f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and*
  - (g) Whether the service carries a significant risk or consequence.*

The remaining sections of this Proposal evaluate Level IV neonatal services against WAC 246-310-035. In summary, Level IV neonatal services meets every criterion contained in the tertiary service identification rule: it is dependent on the skills and coordination of specialties and subspecialists; it requires access to an acute care hospital; as of February 2015, only four hospitals statewide have been designated as Level IV; the use rate is exceptionally low as evidenced by the fact that approximately 1% of all newborns are classified as Level IV; published research demonstrates that volumes affect outcomes for these neonates, and risk (as measured by in-hospital mortality) is significant.

#### 4. Criterion Specific Analysis:

Below we have responded to each criterion in WAC 246-310-035 to demonstrate why Level IV neonatal services should be added to the list of tertiary services.

- (a) *Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;*

Pediatric subspecialists involved in the care of complex NICU patients include anesthesiology and pain medicine, bioethicists, craniofacial, critical care, dermatology, neurodevelopment, endocrinology/diabetes, gastroenterology, genetics, cardiology, interventional cardiology, hematology/oncology, immunology, infectious diseases, intestinal failure program, lab medicine, pathology, neonatology, nephrology, neurology, pulmonary, and radiology. Surgical subspecialists involved in the care of NICU patients include pediatric and thoracic surgery, brachial plexus, oral and maxillofacial surgery, intestinal failure and GI transplant, cardiac surgery, neurosurgery, ophthalmology, orthopedics, otolaryngology, plastic and craniofacial surgery, urology, vascular anomalies, and pelvic floor reconstruction.

The literature, especially the AAP Guidelines cited above, and the recently published *Optimal Resources for Children's Surgical Care in the United States (Optimal Resources)*, from the Task Force for Children's Surgical Care (2013), provides additional guidance. The *Optimal Resources* report defines Neonatal levels of care as follows:

*Level I, II, III, or IV Neonatal Intensive Care Unit (NICU) designations are consistent with current AAP recommendations.<sup>1</sup> Level III NICUs must provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgeons, pediatric anesthesiologists and pediatric ophthalmologists (this can be done at the site or at a closely related institution by prearranged consultative agreement). Level IV NICUs must maintain a full range of pediatric medical subspecialists, children's surgical subspecialists and pediatric anesthesiologists on site (index institution is the primary site of practice). (emphasis added)*

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1. McAteer J, LaRiviere C, Drugas GT. Influence of surgeon experience, hospital volume and specialty designation on outcomes in pediatric surgery: a systematic review. *JAMA Pesiatr* 2013;167(5):468-475.

**(b) Whether the service requires immediate access to an acute care hospital;**

Level IV neonates (as well as Level II and III) require immediate access to a hospital.

**(c) Whether the service is characterized by relatively few providers;**

There are four hospitals in the State that are currently recognized as Level IV NICU providers.

**(d) Whether the service is broader than a procedure;**

The reasons a neonate may be classified as Level IV are varied, and not limited to any single diagnosis or surgical procedure. Level IV neonates present with and need surgical repair of complex conditions such as hypoplastic left heart, congenital diaphragmatic hernia, chronic renal failure, tracheomalacia, cardiopulmonary bypass, ECMO, chronic dialysis and tracheostomy care. Seattle Children's reviewed its recent Level IV cases and found that these neonates were assigned to no less than 15 different DRGs. In addition to the two traditional Level III DRGs (DRG 790 and 791), our level IV neonates were assigned to, at least, the following DRGs (Table 1):

**Table 1  
Seattle Children's Hospital  
Level IV Patient DRGs**

<b>DRG</b>	<b>DRG Description</b>
1	Heart transplant or implant of heart assist system w MCC
3	ECMO or trach w MV 96+ hrs or PDX exc face, mouth & neck w maj O.R.
4	Trach w MV 96+ hrs or PDX exc face, mouth & neck w/o maj O.R.
29	Spinal procedures w CC
30	Spinal procedures w/o CC/MCC
167	Other resp system O.R. procedures w CC
228	Other cardiothoracic procedures w MCC
229	Other cardiothoracic procedures w CC
264	Other circulatory system O.R. procedures
391	Esophagitis, gastroent & misc digest disorders w MCC
640	Nutritional & misc metabolic disorders w MCC
662	Minor bladder procedures w MCC
682	Renal failure w MCC
689	Kidney & urinary tract infections w MCC
793	Full term neonate w major problems

*Source: Seattle Children's Hospital*

***(e) Whether the service has a low use rate;***

The current rule does not define what a low use rate is. Our experience, which is supported by national data, suggests that Level IV neonates are around 5% of non-normal newborns (total neonates less DRG 795). According to CHARS, in 2013, there were 23,524 Level II and Level III discharges, such that Level IV would be about 1,175 neonates statewide. In 2013, CHARS identifies a total of approximately 80,000 births. The Level IV volume represents about 1.4% of the total statewide births. This volume produces an extremely low use rate.

***(f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and***

The AAP and the *Optimal Resources for Children's Surgical Care in the United States* provide evidence about the benefit of a tiered provision of care and consistent standards to improve neonatal outcomes. A September 2012 Policy Statement on Levels of Neonatal Care published by the AAP states:

*The updated classification consists of basic care (level I), specialty care (level II) and subspecialty intensive care (Level III and IV). These definitions reflect the overall evidence for risk appropriate care through the availability of appropriate personnel, physical space, equipment technology and organization...*

***(g) Whether the service carries a significant risk or consequence.***

Again, significant risk or consequence is not defined. The AAP Policy Statement referenced above does reference risk appropriate stratification of neonates. In addition, using CHARS data, Table 2 demonstrates of the services currently regulated, Neonatal Level III has one of the highest rates of in-hospital mortality. Level IV is the most acutely ill of neonates and based on the data we can discern from CHARS, the mortality rate is in excess of 15%.

**Table 2**  
**In-Hospital Mortality Rates for Current Tertiary Services**

<b>Tertiary Services</b>	<b>In-Hospital Mortality</b>
Specialty Burn Services	1.3%
Intermediate Care nursery or Level II OB	0.0%
Neonatal Intensive Care and/or OB Level III	7.8%
Transplantation of Solid Organs (heart)	8.3%
Transplantation of Solid Organs (liver/intestine)	2.9%
Transplantation of Solid Organs (pancreas)	0.0%
Transplantation of Solid Organs (kidney/pancreas)	0.0%
Transplantation of Solid Organs (lung)	2.9%
Transplantation of Solid Organs (kidney)	0.0%
Transplantation of Solid Organs (bone marrow)	2.9%
Open Heart Surgery (age 15+)	3.0%
Elective PCI (age 15+)	0.6%
Inpatient Rehabilitation Level I	0.2%

Source: WA State CHARS

## 5. Conclusion:

In conclusion, the data strongly suggests that Level IV neonatal services meets each of the criteria contained in WAC 246-310-035 used to determine whether a service is tertiary. Because both Level II and Level III neonatal services are on the list of tertiary services, and because Level IV neonatal services is the most complex and requires the highest degree of infrastructure, it should be added to the list of tertiary services.