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December 28, 2018

John J. Dreyzehner, MD, MPH, FACEOM
Commissioner
Tennessee Department of Health
710 James Robertson Parkway
Nashville, TN 37243

Re: Response to Department's Request for Additional Information Dated December 13, 2018 (NICU Consolidation Plans)

Dear Commissioner Dreyzehner,

Ballad Health ("Ballad") is providing this third supplement to our original request dated November 12, 2018. This letter is in response to your correspondence dated December 13, 2018, in which you requested additional information on our proposed plans to consolidate the two Level III Neonatal Intensive Care Units ("NICUs") currently operating at Holston Valley Medical Center ("HVMC") and Niswonger Children's Hospital ("Niswonger"). For purposes of this letter, Niswonger and Johnson City Medical Center ("JCMC") may be used interchangeably, since Niswonger is on the license of JCMC. Obstetric services are provided at JCMC, while post-delivery services for children are provided at Niswonger, which is co-located inside JCMC.

In your letter, the Department asked Ballad to address fourteen subjects related to the consolidation plans. Each of these subjects is addressed below.

1. **How Ballad will manage high-risk pregnancies occurring in a non-NICU facility (for mother and child), for both pre- and post-delivery (continuum of care), particularly as it pertains to Holston Valley Medical Center (HVMC) were there to be a transition down to a Level I nursery[1];**

   RESPONSE: High-risk pregnancies are those pregnancies that carry a greater risk for the mother and/or the child. Sometimes the high-risk pregnancy is only expected to affect the mother *or* the child, while other times the high-risk pregnancy may affect the mother *and* the child. Each of these situations is handled slightly differently in all health systems, including Ballad.

[1] See 11/12 letter, page 4, last 3 bullets.

Background on Ballad's High-Risk Pregnancy and Delivery Services

Ten Ballad hospitals currently offer delivery services. Specialized care for high-risk pregnancies is offered by independent OB/GYNs at two of these hospitals: JCMC and HVMC. High-risk maternal fetal medicine coverage in the Kingsport market is provided by Dr. Kevin Visconti, who is employed through High Risk Obstetrical Consultants, an obstetric group located in Knoxville, Tennessee. East Tennessee State University ("ETSU") physicians provide the high-risk obstetric coverage in the Johnson City market.

If a high-risk pregnancy is identified in the Ballad service area outside of the Kingsport or Johnson City markets, the mother is typically referred to one of these two providers for high-risk maternal fetal care. Dr. Visconti, who covers Kingsport, currently holds medical staff privileges at both JCMC and HVMC and is able to deliver babies at both locations. *Where* Dr. Visconti performs a high-risk delivery is a decision he makes with the mother and when necessary, with the pediatrician who will be caring for the baby.

In addition to maintaining the same level of high-risk maternal fetal medicine coverage that exists in Kingsport and Johnson City today, Ballad is also committed to ensuring that babies are delivered in the most appropriate location based on the anticipated needs of both the mother and the baby.

If a high-risk pregnancy is identified during pregnancy and is only expected to affect the health of the mother, the mother will be referred to a high-risk maternal fetal medicine specialist in Kingsport or Johnson City as soon as the high risk is identified. The specialist will oversee the mother's care during the pregnancy and the specialist will determine the most appropriate hospital for delivery based on the anticipated needs of the mother.

Planned deliveries at less than 35 weeks for any reason are referred to a Level III or Level IV NICU facility. Although it is not always possible to prenatally anticipate the need for pediatric subspecialty services, when a provider detects a congenital anomaly in a fetus, the Tennessee Perinatal Guidelines recommend that the mother be referred to a pediatric subspecialist who can facilitate a coordinated plan for delivery in a facility with the necessary services.

Under the Tennessee Perinatal Care System Guidelines for Transportation, all of Ballad's hospitals with obstetric services and Level I Nurseries are required to stabilize newborn infants who have unexpected complications until that newborn can be transferred to a facility that can provide the appropriate level of neonatal care. ***Staff in all of Ballad's Level I nurseries are trained on how to resuscitate and stabilize newborn infants for transport per these guidelines***.

None of this will change after the proposed consolidation of NICU services.

Under the Proposed Plan

As is the case today, if a mother in labor presents at one of Ballad's hospitals other than JCMC or HVMC, the physician in charge of that mother's care will determine the most appropriate place for delivery based on the needs of the mother and the baby. The physicians at the local hospital will be able to communicate with the specialists at Niswonger in real-time and determine whether the mother should be transported to JCMC prior to delivery or if the baby should be delivered at the local hospital and transported to Niswonger after delivery. Transport of the mother with the baby *in utero* is almost always preferred if a NICU stay for a baby is anticipated. However, each situation is different and physicians must be able to make these decisions in real time. Ballad does not, and will not, interfere with physician judgment regarding the most appropriate location for a delivery.

If a physician determines that it is in the best interests of the mother and the baby for the delivery to occur at the local hospital with the baby transported to Niswonger after delivery, the Niswonger transport team will be dispatched to the local hospital by ambulance or air to assist with the delivery, stabilization, and transport of the newborn. It should be noted that conducting high-risk deliveries and stabilizing high-risk newborns are both services within the scope of all Ballad delivery facilities, and are services already provided to every hospital in the region, including hospitals not part of the Ballad system. In order to ensure there is adequate coverage for any potential high risk delivery, Rapid Response Teams will be developed at the Level I Nursery facilities. These Rapid Response Teams will consist of respiratory therapists and nurses who have received advanced training through Niswonger (functioning as the region's State-designated Perinatal Center, which according to the Tennessee Perinatal Guidelines and Standards is responsible for coordination of care and ongoing training within the regionalized system of care) in neonatal resuscitation and stabilization. The skills and competencies of the Rapid Response Team members will be evaluated quarterly with on-site training conducted at Niswonger as necessary.

If an infant is born at HVMC and needs services which can be provided by the Level I Nursery at HVMC in accordance with the Tennessee Perinatal Standards, that infant will remain at HVMC. If the physician in charge of that baby's care determines that the baby needs a level of care higher than the Level I Nursery, the infant will be transported either to Niswonger or to a Level IV NICU, just as if that infant were born at any other Ballad hospital.

It should be noted that all Ballad delivery hospitals except HVMC currently offer transport of high-risk pregnancies to JCMC if the infant is expected to need services at a level higher than that which would be provided at a Level I Nursery. In addition, all Ballad hospitals except HVMC currently offer transport of newborns to Niswonger if the infant is determined to need NICU services after birth. The proposed plan will simply add HVMC to the other nine Ballad hospitals that offer transport of mothers and/or babies to Niswonger if a level of care higher than Level I Nursery is needed.

The Tennessee Perinatal Standards for Level I nurseries articulate a requirement that all Level I nurseries have the capability to perform neonatal resuscitation at every delivery, provide care for preterm infants at 35-37 weeks gestation who are physiologically stable, and stabilize newborn infants who are less than 35 weeks of gestation who are ill until they can be transported to a facility where the appropriate level of neonatal care is provided. These standards are consistent with the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012.

Under our proposed plan, all infants will be part of a coordinated and integrated system for stabilization and transfer to the highest level of care needed for that child. The development of Rapid Response Teams for deliveries at HVMC will provide support for when there is an immediate need for newborn resuscitation or care.

Finally, this plan has a proven track record for each hospital in the region, whether the hospital has an organized obstetrics program or not. ***Neither Ballad, nor its predecessor organizations, has lost a baby during transport to Niswonger***. Throughout the region, babies are stabilized at the delivery hospital before they are transported to a different facility and the transport process is meticulously planned and executed by specialized transport teams. Other Ballad hospitals have successfully and routinely transported neonates to Niswonger since 2009 from distances of more than one hour away, and as far as two hours away. We fully expect that the short transport between HVMC and Niswonger will be equally successful for the roughly one hundred (100) babies that would be affected by this change each year.

2. **Estimated timeline for elements and completion of the proposed transitions, including expansion of telemedicine technology;**

RESPONSE: There are important steps to be taken prior to implementation of the proposed change. A NICU Transition Team has been created, and consists of highly qualified staff with experience in neonatology and the care of newborns. We discuss various elements for the proposed transition below.

- Staff Integration and Training—The NICU Transition Team leaders from Niswonger's NICU and HVMC's NICU have been identified and all individuals have agreed to serve. Beginning in November, all staff members of HVMC's NICU were invited to tour Niswonger's NICU and meet the staff members at this location. The NICU Transition Team began meeting in December to discuss how to integrate the best practices of both teams for the benefit of the combined unit. The NICU Transition Team is also addressing administrative policies for the combined unit, including time-off requests, scheduling, holidays, etc. After considering the existing policies and practices of both NICUs, the NICU Transition Team will recommend policies for the combined team. The Transition Team meetings and policy recommendations are expected to be completed by the end of March, 2019.

- Physician Contracting— ETSU physicians will be the providers of neonatology coverage for all Ballad hospitals. This alignment will advance Ballad's commitment to teaching and training medical residents, nurses and allied health professionals in the region. This is a positive change from the current arrangement, as it creates one integrated system covered by our academic partner. Historically, the NICU at HVMC has been staffed by a Florida-based company which does not participate in teaching programs at ETSU. This was not advantageous for our region, since training of physicians is an important contribution by ETSU. The low volumes at HVMC in both pediatrics and NICU, combined with the lack of specialists, were not conducive to ETSU training programs or residency rotations. Thus, there has been little academic benefit for the highly necessary training of pediatricians and primary care physicians who need access to the volume and specialized services which can only be provided regionally at Niswonger. Since our proposed consolidation plan was announced, ETSU's Medical Director for Neonatology, Dr. Shawn Hollinger, has been working with Ballad's Vice President of Pediatric Services to determine coverage needs throughout the system and to develop plans to provide neonatology coordination, telemedicine coverage for immediate consultative services, and other necessary protocols. These activities are expected to be completed by the end of June, 2019.

- Transport Team Expansion— The NICU Transition Team is working to determine the competency level of each of the NICU transport nurses currently located at HVMC. Additional transport training and skill check-offs will be completed for the nurses who are selected to serve on the new NICU Transport Team. Ballad intends to maintain the existing contracts with ground services and air transport providers. The Transport Team Expansion efforts are expected to be completed by the end of May, 2019.

- Niswonger Facility Needs— The current Niswonger NICU facilities will accommodate the combined volume of both NICUs. Niswonger currently has 39 NICU beds and 17 special care beds, which are specially provided for babies with Neonatal Abstinence Syndrome ("NAS") and other needs which are not medically critical. Once combined, Ballad expects to have an average daily census of 35 at Niswonger's NICU and operate at approximately 90% capacity. To date, there have been no facility needs or expansions identified to complete the proposed consolidation. Given the decline in births that our region is experiencing, and the fact that this decline is expected to continue, we believe the 39 NICU beds will be appropriate for the foreseeable future. With respect to the 17 special care beds only available at Niswonger, we note that *Niswonger has been highlighted nationally by the Joint Commission for its approach to managing infants with NAS.*

- Telemedicine Coverage for Deliveries— Ballad is in the process of developing a system-wide telemedicine plan for neonatology coverage at Ballad's delivery facilities. Ballad's plan is being modeled after a NICU telemedicine program that was developed by Mayo Clinic. The Mayo Clinic Model serves a catchment area of 15,000

square miles and 10 "spoke" hospitals. The shortest distance between the remote delivery facility and the NICU is 40 miles, the average is 85 miles, and the greatest distance is 125 miles. The Niswonger catchment area is significantly smaller (11,400 square miles) and the hospitals are much closer together. The shortest distance between the Ballad remote delivery facility and the NICU is 3.2 miles away, the average is 36.3 miles, and the greatest is 68.6 miles.

In the Mayo Clinic Model, the remote delivery facilities are required to have Neonatal Resuscitation Program-compliant staff and resources for resuscitation, internet and wireless availability, and providers educated on these services. Ballad's program will have the same requirements and the program will include case reviews and simulation training for remote delivery facility staff. Additionally, Mayo Clinic's program serves the states of Minnesota, Wisconsin and Iowa, all of which experience weather challenges much more severe than typically seen in Northeast Tennessee and Southwest Virginia. As a result, we believe that the Mayo Clinic NICU Telemedicine program provides an excellent model for Ballad's telemedicine coverage program. Ballad's Telemedicine Plan is expected to be completed by the end of June, 2019 with implementation to be completed by July 1, 2019.

If the proposed NICU consolidation plan is approved in the coming weeks, Ballad will begin to slowly transition volumes and anticipates consolidation will be completed by July 1, 2019.

3. **Potential impact on deliveries at 32-35 weeks gestation, infants treated for neonatal abstinence syndrome, and other mother-infant dyads who previously would have appropriately delivered and been treated at HVMC to include the number of affected families, travel distance, and length of stay;**

RESPONSE: For infants who are delivered at 32-35 weeks gestation, the Tennessee Perinatal Standards require that all Level I nurseries be able to stabilize newborn infants who are less than 35 weeks gestation. Ballad's care of infants delivered at 32-35 weeks gestation has been consistent with the Tennessee Perinatal Standards across all Ballad delivery facilities. All Ballad delivery hospitals will continue to meet these requirements going forward.

Ballad, like many health systems across the country, has seen an increase in the number of babies born with NAS. The provision of care for NAS infants is often confused with the need for NICU care. Certainly, some babies suffering from NAS do need NICU levels of care, but there are many babies suffering from NAS who do not need NICU levels of care. Using NICU resources for babies who do not actually need NICU levels of care is an inefficient use of resources and not medically appropriate.

Current research indicates that the local delivery hospital is the most appropriate place for treatment of babies with NAS who experience no other complications. Ballad is committed to following this approach. Considering the volume of babies presenting with NAS in the Kingsport market, Ballad's nursery care model will include the provision of NAS treatment at

the local delivery hospital unless a higher level of NICU services is needed. This approach was implemented eighteen (18) months ago in Abingdon, Virginia, and Ballad intends to replicate this program at other hospitals.

In June 2017, Johnston Memorial Hospital ("Johnston Memorial") began working with Niswonger to keep babies experiencing NAS at the local delivery hospital. Neonatologists at ETSU developed protocols that allow the local team at Johnston Memorial to monitor the withdraw scores of the babies and initiate medication treatment if necessary. When the treatment is initiated, the baby is placed on a cardiorespiratory monitor to assess for respiratory depression. If additional medication is added to the treatment regimen, or if the dosage of medication is increased, the baby may be transferred to Niswonger for higher level care. The Niswonger NICU providers deliver ongoing education and training for Johnston Memorial's physicians, nurses, and ancillary providers to ensure the most current research and practices are being used. Transfers only occur if the baby's condition worsens to the level of needing a subspecialty consult (i.e. neurology, gastroenterology) or if there is a need for inpatient therapy services. The number of babies transferred from JMH decreased significantly from 53 in 2016, to 28 in 2017 and 25 in 2018.

With the support of protocols, education, and training from Niswonger, Ballad's goal will be to keep as many of the NAS patients for care in Kingsport as possible, while utilizing the higher volume regional center at Niswonger when more intensive support is needed. This is the best practice, and one we believe will be most beneficial for patients. Physicians may always make the decision to transfer an infant to Niswonger if the physician determines that the baby needs more extensive services, but we believe the model currently in use at Johnston Memorial will allow us to keep more NAS babies close to home.

Ballad has reviewed the number of babies born at HVMC over the last year that required levels of care beyond a Level I Nursery. Once the HVMC NICU numbers are adjusted for NAS babies, which will largely remain at HVMC, and the babies transported to HVMC are removed (as those will be transported to Niswonger) there are approximately one hundred (100) babies that would be affected by the proposed NICU consolidation each year. These are babies who are delivered at HVMC that require Levels of care beyond Level I Nursery, and these babies (or mothers prior to delivery) would be transported to Niswonger for that care. Babies born at any other Ballad facility in need of Levels of care beyond Level I Nursery will continue to be transported to Niswonger, or to a Level IV NICU, just as they would today. The only change being proposed is that some of these infants previously cared for in the NICU at HVMC will now be taken to Niswonger where they will have access to more pediatric subspecialists and family resources than are currently available at HVMC's NICU.

It may be instructive to point out that the delivery volumes at HVMC are not inconsistent with other hospitals in our region. Niswonger has successfully cared for infants born at each of these hospitals who needed Levels of care beyond a Level I Nursery. In 2018, the volumes in each hospital were as follows:

Ballad Delivery Hospital	Nursery/NICU Designation	Number of Deliveries in FY 2018
Johnson City Medical Center	Level III	1,255
Franklin Woods Community Hospital	Level I	1,187
Holston Valley Medical Center	Level III	896
Bristol Regional Medical Center	Level I	825
Indian Path Community Hospital	Level I	710
Johnston Memorial Hospital	Level I	598
Greene County Hospitals (2)	Level I	577
Wise County Hospitals (2)	Level I	387
TOTAL		**6,435**

Of the more than 6,400 deliveries at Ballad facilities, 4,284 of those deliveries occurred at hospitals with Level I Nursery services in compliance with the Tennessee Perinatal Standards. We are not aware of any outcomes that would suggest these 4,284 babies who were born at Level I Nursery facilities suffered any disadvantage in care. Several of our delivery hospitals have a similar number of deliveries to HVMC, and are farther away from Niswonger than HVMC. Babies needing Levels of care beyond Level I Nursery have historically been transferred to Niswonger and will continue to be transferred to Niswonger in the future.

In evaluating patient information from the calendar year 2016 through October of 2018, Niswonger received over five hundred (500) babies transported from over thirty (30) different counties. Thirty eight (38) of those babies were from Hawkins County, Tennessee, more than one hundred (100) were from Sullivan County, Tennessee, and fifteen (15) were from Scott County, Virginia.

4. **Plan for evaluating the impact of the proposed NICU merger to include regular ongoing evaluation of transfer metrics, health outcomes of mothers and infants delivering at each of Ballad's facilities, travel distance of affected families and ongoing patient, staff and community satisfaction and input;**

RESPONSE: As the region's only children's hospital and the State's Northeast Tennessee Perinatal Center, Niswonger has far more quality and safety resources than HVMC. Under the medical directorship of Dr. Shawn Hollinger, Niswonger offers a robust quality program that encompasses both the transport team and the NICU services. Niswonger is a member of the Solutions for Patient Safety Network which is a collaborative of over 130 children's hospitals who collectively work to create a universally safe and healing environment for children on the journey to zero harm events. The quality goals of this network are:

- 40 percent reduction in Hospital-Acquired Conditions
- 20 percent reduction in 7-Day Readmissions
- 50 percent reduction in Serious Safety Events
- 25 percent reduction in DART—Days Away Restricted or Transferred

Niswonger is also a member of the collaborative's Patient Safety Organization which provides the opportunity to work with other children's hospitals to develop best practices for learning from safety events and sharing improvement opportunities.

The NICU at Niswonger is a member of the Vermont Oxford Network which is a nonprofit collaboration of health care professionals working together as an interdisciplinary community to change the landscape of neonatal care. Membership in this network allows for benchmarking in the world's largest neonatal database. Data abstractors within Ballad submit information on each patient to the database which can then be compared to other centers for determining quality projects and opportunities for improvement. Current quality projects underway at Niswonger include a developmental care initiative for midline positioning to decrease the incidence of intraventricular hemorrhage and kangaroo care initiatives that promote skin to skin contact.

In addition to Vermont Oxford, the NICU team at Niswonger is heavily involved in the Tennessee Initiative for Perinatal Quality Care ("TIPQC"). Most recently, the team participated in the project related to nutrition for very low birth weight babies, the antibiotic stewardship project and the late preterm infant readmission project.

Ensuring the presence of a robust quality program related to neonatal transport is also a current focus of the NICU team at Niswonger. The program is designed to ensure the safe transport of babies to and from the facility as well as safety of the team. The program is based on recommendations from the American Academy of Pediatrics and nursing literature.[2] Each transport is currently assessed for:

- Unplanned extubations (if applicable)
- Average mobilization time of transport team with a goal of 30 minutes
- Rate of transport-related injuries with a goal of zero
- Rate of equipment failure during transport with a goal of zero
- Unintended neonatal hypothermia upon arrival to destination with a goal of zero
- Patient (parent/guardian) satisfaction with transport team service

Currently the Niswonger team is developing a standardized communication handoff tool for use at the destination facility. New metrics that will be tracked include rate of serious safety events and rate of medication errors during transport.

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[2] Diehl, B.C. (2018). Neonatal Transport: current trends and practices. Critical Care Nursing Clinics of North America, 30, 597-606

Ballad will also begin the process of a physician-led oversight committee to ensure the appropriateness of deliveries at all Ballad facilities. This committee will review transfer cases to determine if the delivery occurred in the appropriate setting. Joint meetings between obstetric physicians and pediatricians have already started to promote increased communication among different disciplines so that care can be better coordinated.

Family input into the practices and services is foundational for children's hospitals. Niswonger currently uses the Family Advisory Council model to allow input into the practices and processes of the facility. We are currently in the process of updating the membership and expanding the group to include a larger sample of families from all areas of service and to allow family input into hospital committees. This council structure will be used as a means to receive input from families post-consolidation.

The NICU staff integration team will serve as the platform to ensure that team members are achieving shared governance of unit decisions. This model is currently in place among nursing departments for Niswonger and will serve as the mechanism for evaluating concerns and addressing issues as they arise.

5. **Rationale for not including actions in the NICU and Trauma Center proposals in any of the current drafts of the Health Services Plans that would be impacted by them if implemented;**

RESPONSE: Under the Terms of Certification ("TOC"), Ballad is required to spend a minimum of $308 million over a ten year period on certain initiatives. In connection with these spending requirements, the TOC requires Ballad to submit plans for the first three full Fiscal Years outlining how Ballad intends to invest the $308 million in six different areas. Four of these six plans were required to be submitted to the Department by July 31, 2018, a deadline which Ballad met. At the time these four plans were submitted, Ballad had not finalized any decisions with regards to the Trauma Center consolidation or the NICU consolidation, although the Tennessee Department of Health had already approved the consolidation of the Level I trauma centers in the TOC. As a result, the plans that were submitted July 31st addressed how Ballad intends to meet the spending commitments for behavioral health, children's services, rural health services and population health, and how Ballad intends to achieve the various population health and access Index metrics related to these four health service areas. Ballad submitted the revised drafts of these plans on August 24th. The final analysis on the Trauma Center consolidation and the NICU consolidation was completed in late October and the Ballad Board approved the two consolidations in mid-November.

At this time, none of the program proposals in any of the current drafts of the Health Services Plans are expected to be impacted by the NICU and Trauma consolidations. In fact, these two consolidations will help Ballad achieve some of the goals set forth in the Health Services Plans. For instance, a pediatric trauma program combined with higher, more consistent volumes in the NICU at Niswonger will help Ballad recruit pediatric specialists.

Running low-volume programs would hinder Ballad's ability to recruit and retain pediatric specialists, particularly in an environment with declining projected pediatric volumes. We believe the trauma consolidation and the NICU consolidation are consistent with best practices, necessary for successful achievement of elements of the Health Services Plans, will lead to the best chance for better outcomes for patients, and would not be possible but for the merger. As we continue our ongoing dialogue with the Department on this or any other matter, we remain open to a discussion with the Department about whether or how any expenditures related to implementation of these important initiatives would be counted as expenditures under the COPA.

6. **Management of infants born at >36 weeks gestation needing a higher level of care at the time of delivery but expected to stabilize in two to 24 hours;**

RESPONSE: As one of the State's five Regional Perinatal Centers, JCMC and Niswonger follow the Tennessee Perinatal Care System Guidelines for Transportation. Ballad intends to implement these Guidelines at all Ballad delivery facilities for issues related to maternal and fetal stabilization and transport.

Level I nurseries can (i) care for preterm infants at 35 to 37 weeks' gestation who are physiologically stable and (ii) stabilize newborn infants who are less than 35 weeks of gestation or who are ill until they can be transferred to a facility where the appropriate level of neonatal care is provided.[3]

If an infant is born at >36 weeks gestation at any Ballad facility and needs a higher level of care at the time of delivery, but is expected to stabilize in two to 24 hours, the local team of pediatric providers will manage the care in-person in conjunction with telemedicine neonatology support until the baby stabilizes. It is important to note that a baby will not be transported until he or she is stabilized. Once a baby is stabilized, the provider responsible for that baby's care will determine if the baby still needs higher level services. If the baby is still in need of higher level services, the Niswonger transport team will be dispatched by ambulance or air to facilitate the transfer. If the provider determines that the baby no longer needs higher level services after stabilization, the baby will remain at the Ballad facility where it was delivered. Additionally, HVMC will have a Rapid Response Team consisting of trained nurses and respiratory professionals who can respond to provide assistance if needed. This team's competency will be assessed quarterly and ongoing education will be provided at Niswonger.

Under the proposed consolidation plan, HVMC will continue to operate a Level I Nursery and Niswonger will operate a Level III NICU. Pediatricians, family practice physicians, and ETSU family practice residents will provide care to neonates at both HVMC and Niswonger.

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[3] *See* Tennessee Perinatal Care System Guidelines for Transportation which cites the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care, 7th edition, 2012.

Infants born at >36 weeks gestation at HVMC will be stabilized first. Only if the provider in charge of that baby's care determines that the baby needs NICU services will that baby be transferred to Niswonger.

7. **Estimated number of additional incoming transfers of infants and mothers to Niswonger Children's Hospital and assessment of Niswonger Children's Hospital facility and staff capacity, to include the numbers and sizes of patient care rooms;**

RESPONSE: As noted above, Niswonger can accommodate the incremental NICU volumes expected from the proposed consolidation. Once consolidated, Niswonger's NICU is expected to operate at 90 percent of capacity. Notably, prior to volumes of newborns declining four years ago, Niswonger's NICU average census was 35, which is what is expected in the consolidated unit. With volumes having declined in both units, the combined average census is expected to be 35.

The Niswonger NICU was chosen as the consolidated site because:

1. It is part of a larger, integrated children's hospital for babies and children with more staff and broader services.
2. It is supported by 25 pediatric specialties, including pediatric surgery.
3. It can absorb all the NICU volume from HVMC and operate at an occupancy that is more preferable in accordance with state policy and national best practice. If the two programs are consolidated, the Niswonger NICU will operate at 90 percent capacity, still lower than East Tennessee Children's Hospital's 95 percent occupancy.
4. With birth volumes declining, the volumes in both legacy NICUs have been declining, and this trend is expected to continue. Further dilution of the volumes is not acceptable for patient care.
5. Niswonger is the State's designated perinatal center, and has been given the highest level of certification for Perinatology by the Joint Commission.
6. Already, thousands of newborns have utilized NICU services since the inception of the program at Niswonger, and the Niswonger transport program has proven successful throughout the region for families traveling at distances often greater than one hour and as much as two hours. The consolidation will lead to a better chance for positive outcomes for children, based on the evidence, national recommendations and state policy, and provide families with greater access to resources.

As noted below, every HVMC NICU team member will be given the opportunity to transfer to the Niswonger NICU if they would like to continue working in the NICU environment and they meet the competencies required. There will be no staff lay-offs or reductions as a result of this consolidation.

The following table provides additional information on the numbers and sizes of patient care rooms:

	NICU Beds	Average Room Size (sqft)	Total Sq Ft
Niswonger Private NICU	8	258.5	4,681
Niswonger Main NICU	31	85.2 to 91.9 ft (per bed space)	5,472
Niswonger Special Care (NAS)	17	191	6,545

8. **Identification and management of opportunities to transfer convalescing and maturing infants no longer needing specialist services to nurseries closer to home;**

RESPONSE: Management of convalescing and maturing neonates is a recognized function of a Level I Nursery. If the proposed NICU consolidation is approved, all of Ballad's delivery facilities will have Level I nurseries and be able to manage these babies. However, the decision as to when an infant may be transported from a NICU to a local hospital is a decision that is made by the physicians treating that baby, not a decision made by a hospital. In order for an infant to be transported from a NICU to another hospital, a physician in the NICU must sign off on the transfer and a local pediatrician must assume responsibility for the care of that infant. Today, the process of transferring babies from HVMC'c NICU or Niswonger's NICU back to a local delivery facility for convalescence/maturation is not used regularly. This is a recognized opportunity for additional cooperation going forward, and Ballad will work cooperatively with local pediatricians to evaluate the opportunities to do this when medically appropriate.

Convalescing is ideal for NAS babies who need higher level services early on, but only require Level I Nursery care once stabilized. Ballad will include convalescence in its overall plan for NAS care and encourage more providers to transfer NAS babies back home once it is safe to do so.

9. **Plan to minimize transportation barriers for families of NICU babies, particularly those with extended stays;**

RESPONSE: It is important to note that the overwhelming majority of NICU admissions in the region already occur at Niswonger, and there will be no impact on these families as a result of the proposed consolidation. In the past two years, more than 500 infants have been transported to Niswonger from outside Washington County, Tennessee. Many of these families currently travel past HVMC to Niswonger due to the level of care their child needs.

In a rural, sprawling community like ours, transportation needs are a recognized concern and one that Niswonger has been confronting for several years. Families may face travel barriers when their child is in the hospital – not just for NICU services, but generally. We believe the consolidation of NICU services at Niswonger will actually help alleviate the transportation burden many families face and Ballad is committed to supporting the expansion of community services to further address these issues.

The existing resources available for families at Niswonger's NICU are much more substantial than resources available for families at HVMC's NICU. For instance, Niswonger has a long-standing affiliation with the Southern Appalachian Ronald McDonald House, which is located on the same campus as Niswonger. Families who meet the Ronald McDonald House requirements can stay at the lodge free of charge. Niswonger also offers seventeen (17) single-family patient rooms where families can actually stay in the room with their baby for the entire hospitalization if they so choose. If a private room and/or the Ronald McDonald House is not available, Ballad has relationships with local hotels where families can stay at a discounted rate.

There are also existing programs in our service area that offer transportation to low-income families when a family member is hospitalized. A local business grant in Greene County allows funding to be allocated for transportation needs of any Greene County child traveling out of the county for health care services. To further address transportation issues for families, the Ballad Health Foundation is formulating a transportation grant program which will offer assistance to families who need to travel back and forth between home and the hospital. We anticipate that this program will be available in 2019.

10. Impact on Ballad staff (e.g., re-locations, layoffs, etc.) and existing contractual arrangements with providers;

RESPONSE: There are currently 21.4 FTEs working at the HVMC NICU, which includes both licensed and unlicensed team members. Under the proposed plan, every HVMC NICU team member will be given the opportunity to transfer to the Niswonger NICU if they would like to continue working in the NICU environment and meet the competencies required. There will be no staff lay-offs or reductions as a result of this consolidation. If a team member chooses not to relocate to Niswonger for employment, there are vacant positions in all of Ballad's facilities, including HVMC. Pediatric nurses will still be needed at HVMC to manage patients in the Level I Nursery. There are also staffing needs in obstetrics and the newborn nursery at HVMC. As noted above, the NICU Transition Team is currently evaluating policies and practices in place at both NICUs to determine the best options for the consolidated facility.

Neonatology coverage at HVMC is currently provided by a Florida-based physician contracting company, Mednax. The Mednax contract is set to expire at the end of December, and it is anticipated to be extended temporarily as this decision is contemplated. Mednax employs three neonatologists at HVMC. One of the three Mednax neonatologists

plans to retire in the coming months. If the NICU consolidation is approved, the Mednax contract will be terminated and ETSU will assume responsibility for neonatology services at Ballad. The remaining two neonatologists currently practicing at HVMC under the Mednax contract will be invited to apply for neonatology positions with ETSU to cover the Niswonger NICU. Going forward, Ballad's arrangement with ETSU will ensure that the Niswonger NICU is fully covered with highly competent physicians, and Ballad will be able to expand its partnership with ETSU for a better coordinated regional program of training for physicians and allied health professionals.

11. The monthly diversion numbers for HVMC 32-35 week gestation deliveries to Niswonger in the two fiscal years prior to the merger, and for the period after the merger through today;

RESPONSE: The decision to transfer a baby from a hospital where it was delivered to a NICU is governed by two factors: (i) the family's preference and (ii) the pediatrician at the delivery facility's preference. Once a NICU facility is chosen, the hospital where the baby was delivered places a call to the MD Connect system. That system links the referring physician with the neonatologist at the NICU facility of choice to accept the patient transfer. Once the patient is accepted, the transport team is deployed. At any time during the process, the transferring physician and/or transferring facility can request transfer to a different NICU facility. Currently, the only difference between how a team from HVMC's NICU is deployed and how a team from Niswonger's NICU is deployed is that HVMC offers ground transport only while Niswonger offers ground transport and air transport.

Ballad has not, and does not, divert babies from one facility to another. If a decision is made to send a baby to a higher or lower level of care, that decision is made by the physician at the referring facility.

For the two fiscal years prior to the merger, HVMC sent zero (0) babies of any gestational age to Niswonger, while sending 20 babies to hospitals in Knoxville, Tennessee, Charlottesville, Virginia, and Nashville, Tennessee. Physicians practicing at HVMC, a Wellmont Health System hospital, did not routinely send babies needing a higher level of care to Niswonger, a Mountain States Health Alliance hospital. Since the merger closed, there have been two (2) babies transferred from HVMC to Niswonger: one patient was a 39.6-week neonate transferred in July of 2018 for head cooling and the other was a 38.5-week neonate transferred for a surgical consult. Both of these babies required Level III NICU services and the family and/or the pediatrician in charge of that baby's care at HVMC determined that Niswonger was the best NICU facility for that baby's needs. If these two babies had been born prior to the merger, it is likely that both would have been sent outside the region to Knoxville, Charlottesville, or Nashville for Level III care. Providing families with a high-quality Level III NICU in our community will help more babies receive care closer to home.

12. Clarification of changes in transfer protocols and other changes for newborns previously transferred to HVMC;

RESPONSE: The proposed NICU consolidation will not require any changes in transport protocols. Today, the decision-making process is governed by the Tennessee Perinatal Care System Guidelines for Transportation. After the proposed consolidation, transport decisions will be governed the same way.

Once a pediatrician and a family make a decision to move a baby to a facility with a higher level of care, the current Ballad process for neonate transfers will be initiated through MD Connect and the transport team at Niswonger will be deployed by ambulance or air to facilitate the transfer. HVMC will stop receiving transfers from other facilities, but the consolidated Niswonger transport team will facilitate all NICU transfers in a coordinated fashion throughout the region. Historically, HVMC's NICU received the vast majority of its transfers (approximately 70-80 babies annually) from three (3) outlying facilities (Indian Path Community Hospital, Lonesome Pine Hospital, and Bristol Regional Medical Center). All three of these local hospitals also refer to Niswonger. Many of the babies historically transferred to HVMC were experiencing NAS. Ballad plans to work with the local facilities to facilitate NAS care locally when possible and transfer infants to Niswonger when higher levels of care are needed. As for babies that were historically transferred to HVMC for non-NAS-related NICU services, we believe Niswonger is the more appropriate facility under the Tennessee Perinatal Standards to care for these infants because, among other things as articulated in #14 below, subspecialty care is not available at HVMC's NICU. Given that these facilities are already routinely transferring babies to Niswonger, there is no need for any changes to the transport protocols for these three facilities. We will deploy the same processes used today and as described herein.

13. The financial analysis for the project, including the monetary investment to be made (e.g., for telemedicine, patient transportation, other) and how the investment relates to the financial commitments under the Terms of Certification; and

RESPONSE: The annual net operating loss at the HVMC NICU is approximately $1.5 million, which represents approximately ten percent (10%) of the total annual net operating loss at HVMC. It is reasonable to expect the NICU losses to continue to grow as volumes continue to decline. The elimination of this loss will allow Ballad to invest in other areas of pediatric care, including the investment in the Children's Health Plan, which provides for new Pediatric Emergency facilities in Kingsport and additional pediatric specialists to serve the region. Thousands of children will benefit from these investments. Additionally, based on current data and need, we are projecting the following monetary investments will be made which will benefit the entire region, including HVMC:

Category	Annual Expense
Telemedicine equipment and software for Kingsport market	$51,840
Provider fees, including increased neonatal nurse practitioner	$350,000

coverage for transports, neonatology telemedicine on call fees, and neonatology on call fees or in person responses to Kingsport market as needed	
Staff education and training	$5,000
Additional transport team costs	$50,000

As noted above, we remain open to a discussion with the Department about whether or how any expenditures related to implementation of these important initiatives would be counted as expenditures under the COPA.

14. Consideration of alternative models of service delivery, such as transitioning the HVMC NICU to a Level II instead of Level I.

RESPONSE: HVMC's NICU is licensed for fifteen (15) Level III NICU beds, but does not meet the State guidelines to serve as a Level III NICU. The HVMC NICU is operating with an average daily census of eight (8), in our view, dangerously low by NICU standards.[4] Maintaining a low volume NICU of any level can create safety and quality risks for the patients. The State of Tennessee Certificate of Need Standards for Neonatal Intensive Care Units suggest that the appropriate occupancy rate for NICUs is 80% or greater.[5] The establishment of the 80% threshold is intended to ensure optimal utilization of resources and to support high quality due to volumes and the other relevant aspects of the State Perinatal Plan (availability of specialties, skill levels, etc.). HVMC's NICU operates currently at 53% of capacity, while Niswonger's NICU operates at 69%. By comparison, East Tennessee Children's Hospital operates at 95% of capacity. The evidence shows that volumes beget sustainability of skills. The absence of volumes, particularly without specialty support, is far less than adequate for the best patient care. Frequent repetition of skills creates proficiency. Stretching of skills creates greater proficiency. There is simply not enough volume to meet the acceptable standards required to ensure skill competence.

To make this situation worse, the volume of births in our region continues to decline. Over the last four years, births in our region have declined by more than 7%, including an 11% decline in births in Kingsport and an 18% decline at HVMC.

Downgrading HVMC's NICU to a Level II NICU would not solve the volume problem that HVMC is facing. The number of babies categorized as Level II at HVMC is small. In FY 2018, there were a total of 133 "Level II" patients at HVMC, which equals an average daily census of five (5). Based on our assessment, the acuity of many of these Level II babies may not support that level of utilization (e.g. NAS babies). A certain volume of patients is required to

[4] The State of Tennessee State Health Plan Certificate of Need Standards and Criteria for Neonatal Intensive Care Units requires a Level III NICU to maintain at least 15 beds as this number is considered to be the minimum necessary to support economical operation of these services.

[5] The State of Tennessee State Health Plan Certificate of Need Standards and Criteria for Neonatal Intensive Care Units at 3.

keep skills sharp and HVMC's NICU does not have sufficient volume of Level III or Level II patients to support anything higher than a Level I Nursery.

There are other hospitals in the region with comparable, or even higher, delivery volumes which do not have a Level II or Level III NICU. Those hospitals operate within the standards set forth in the State Perinatal Plan. The continued dilution of the HVMC and Niswonger volumes through the operation of two NICUs will result in further separation between the ongoing operation of a NICU at HVMC and the State Health Plan's suggested 80% occupancy rate.

Shifting volume from Niswonger's NICU to HVMC's NICU was also not a viable alternative. Niswonger is currently operating at 69% capacity. Diluting the volume at two Level III NICUs puts both facilities in an unacceptable volume range and could compromise patient care.

Low volumes also make it very difficult to staff two NICUs with subspecialists. Under the *Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities*, Level III NICUs are expected to make "a broad range of pediatric medical subspecialists and pediatric surgical specialists" readily accessible on-site or by prearranged consultative agreements. HVMC does not meet this requirement; there are few pediatric medical specialties, and no pediatric surgical specialties immediately available. Niswonger, located 24 miles from HVMC, has far more specialists immediately available, provides 24/7 in-house neonatologist/neonatology Nurse Practitioner coverage, and 24/7 pediatric residency coverage. It is not possible to replicate the neonatology and specialty coverage of a children's hospital at a hospital with lower pediatric volumes, particularly when the projected pediatric volume for the region is declining.

It should be noted that the highest volume of babies admitted to the NICU at HVMC are categorized as "term" or "near term" babies. Based on the evidence from Niswonger's experience with the initiatives of the TIPQC, we believe there is opportunity to reduce potentially unnecessary utilization of NICU services for term or near-term babies at HVMC. The Family Birth Center at JCMC is an active participant in the late preterm initiatives of Tennessee's TIPQC program. This program focuses on stabilization of newborns, reducing the risk of respiratory distress, reducing the risk of hypoglycemia, reducing the risk of sepsis, addressing feeding difficulties, maintaining breastfeeding, and providing seamless transition to outpatient care. HVMC does not participate in the late preterm initiatives of TIPQC.

Through the implementation of late preterm protocols at JCMC, there has been a significant decrease in NICU admission for this patient class. Hypoglycemia was addressed through a specific glucose gel protocol. Three and a half months after this protocol was implemented at JCMC, there was a decrease in invasive blood draws by 37.5%, and only two (2) out of thirty (30) babies needing treatment for hypoglycemia were transferred to the NICU. ***Twenty-eight (28) NICU admissions at JCMC were avoided once this protocol was implemented***. We believe there are significant opportunities at HVMC to avoid term and late-pre term admissions and reduce the number of transfers to a NICU.

Based on current and projected volumes, the data, research, and state guidelines all indicate that the most appropriate model for our region is to consolidate the Level III services at Niswonger and move HVMC to a Level I Nursery. HVMC and Ballad's nine other delivery facilities will be supported by Rapid Response Teams and telemedicine consultations along with the development of an inpatient NAS unit at HVMC.

A Note About the Decision Process

The Ballad Board approved the consolidation of the HVMC NICU and the Niswonger NICU after considerable analysis and several months of evaluation. The process was led by a Subcommittee of the Board composed of doctors, community leaders, a former Virginia State Senator and business owners. After considering all of the information available, the Subcommittee recommended unanimously that Ballad consolidate the two Level III NICUs into a single Level III NICU at Niswonger. The Subcommittee's recommendation was presented to the Board which reviewed the recommendation in a special Board Workshop and at two separate Board meetings.

The Ballad Board was concerned that the low volumes at HVMC's NICU could create a question of compliance with state standards for operation of a Level III NICU. By consolidating the two NICUs, the Board saw an opportunity to address the low volume issue at HVMC's NICU and create a stronger Level III NICU at Niswonger for all patients of the region. The coordinated effort to create a higher volume, integrated and coordinated system of Perinatal Care is more consistent with state policy and documented best practices. This is unquestionably a **benefit** of the merger that will lead to the increased likelihood of positive outcomes for newborns, the improved sustainability of the training programs for pediatrics at ETSU, and improved sustainability of the region's Children's hospital.

After discussing this matter extensively, our Board voted unanimously to move forward with the NICU consolidation. We strongly believe this plan is what is in the best interest of our patients and we hope you will agree.

Please let us know if you have any additional questions or need any other information.

Sincerely,

Alan Levine

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