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S.C. SUPREME COURT

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

Medical University Hospital Authority, d/b/a
MUSC Shawn Jenkins Children's Hospital
and Pearl Tourville Woman's Pavilion,

Petitioner,

v.

South Carolina Department of Health and
Environmental Control and Trident Medical
Center, LLC, d/b/a Summerville Medical
Center,

Respondents.

Docket No. 21-ALJ-07-0107-CC

FINAL ORDER

Trident Medical Center, LLC, d/b/a
Summerville Medical Center,

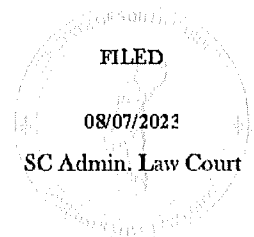
Petitioner,

v.

South Carolina Department of Health and
Environmental Control and Medical
University Hospital Authority, d/b/a MUSC
Shawn Jenkins Children's Hospital and Pearl
Tourville Woman's Pavilion,

Respondents.

Docket No. 21-ALJ-07-0259-CC
(Consolidated)

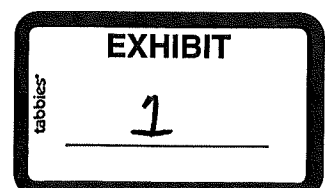


Appearances:

For Petitioner/Respondent Medical University Hospital Authority, d/b/a MUSC Shawn Jenkins Children's Hospital and Pearl Tourville Women's Pavilion: Daniel J. Westbrook, Esq.; Travis Dayhuff, Esq.; and Caroline Warner, Esq.

For Respondent/Petitioner Trident Medical Center, LLC, d/b/a Summerville Medical Center: David B. Summer, Jr., Esq.; William R. Thomas, Esq.; J. Evan Phillips, Esq.; Ashley W. Johnson, Esq.

For Respondent South Carolina Department of Health and Environmental Control:



Vito M. Wicevic, Esq.; Jessamine L. Grice, Esq.; Ashley C. Biggers, Esq.; Jenny R. Pittman, Esq.

STATEMENT OF THE CASE

This consolidated case came before the South Carolina Administrative Law Court (“ALC” or “Court”) pursuant to two requests for contested case hearings. Medical University Hospital Authority d/b/a MUSC Shawn Jenkins Children’s Hospital and Pearl Tourville Women’s Pavilion (“MUSC”) requested a contested case hearing to challenge a February 21, 2021 decision by the South Carolina Department of Health and Environmental Control (“DHEC”) to approve a Certificate of Need (“CON”) application from Trident Medical Center, LLC d/b/a Summerville Medical Center (“SMC”), which sought to establish a Level III neonatal intensive care unit (“NICU”) ¹ at its hospital in Summerville, South Carolina by converting six of its Level II intermediate care bassinets to Level III intensive care bassinets. SMC likewise requested a contested case hearing to challenge DHEC’s April 26, 2021, approval of a CON application filed by MUHA, which sought to add 3 Level II intermediate care bassinets ² and six Level III intensive care bassinets to its Shawn Jenkins Children’s Hospital in Charleston, South Carolina. This Court consolidated the two contested cases, which were tried over twelve days in August, September, and October of 2022.

During the hearing, the parties presented eighteen witnesses, both fact and expert, entered over 150 trial exhibits into the Record, and introduced over 150 demonstrative exhibits in support of their respective positions. After careful consideration of the testimony, evidence, applicable law, and the parties’ arguments and proposed orders, the Court upholds the Department’s decisions approving both projects.

ISSUES

1. Whether the Department erred in finding that MUHA’s and SMC’s Projects were not competing applications?;

1. The Department defines a Level III neonatal intensive care unit as a “subspecialty perinatal center”. Accordingly, both terms are used interchangeably throughout this Order.

2. A CON is not required for the addition of Level II intermediate care bassinets.

2. Whether MUHA's and SMC's respective Level III projects comply with the applicable *2020 South Carolina Health Plan* ("Health Plan")³ standards governing neonatal services, and in particular, whether Standards 1(d) and 1(e), operate retrospectively?;

3. Whether SMC must prove its compliance with the neonate management licensing requirements found in S.C. Code Ann. Reg. 61-16, Section 1306(C) at this stage of the proceedings?;

4. Whether MUHA's and SMC's respective Level III projects are consistent with the project review criteria ("PRC") considered the most important in the Health Plan and as set forth at S.C. Code Ann. Regs. 61-15 governing documentation of compliance with the need outlined in the Health Plan (§ 802.1); Distribution (Accessibility)(§ 802.3); Record of the Applicant (§ 802.13); Adverse Effects on Other Facilities (§ 802.23), and the PRC, Community Need Documentation (§ 802.2), identified by the Department in its decision to approve the projects?;

5. Whether SMC's project complies with the Department's findings under S.C. Code Reg. 61-15 § 501?;

6. Whether the various studies introduced during the contested case hearing related to very low birth weight baby ("VLBW") thresholds and outcomes are reliable given the increased access to subspecialists and advances in medicine?

7. Whether SMC's CON application for NICU at issue in the instant case differs from its CON application in 2017 for the same services, which the Department denied?; and,

8. Whether SMC's and MUHA's Projects meet the goals and purposes of the State Certification of Need and Health Facility Licensure Act ("CON Act") set forth in S.C. Code Ann. § 44-7-120?

STANDARD OF REVIEW

1. The South Carolina Administrative Procedures Act ("APA") authorizes the ALC to conduct contested case hearings arising from certain agency decisions. S.C. Code Ann. §§ 1-23-505(3), 600(A) (2005 & Supp. 2022); § 44-1-60(G) (2018); § 44-7-210(E) (2018). Since DHEC's approval of SMC's CON application and its approval of the MUHA CON application constituted final agency decisions under subsection 44-7-210(E), the Court has jurisdiction over the respective contested cases challenging these decisions.

3. Enacted March 13, 2020, for all but Chapter 3, which was enacted June 12, 2020.

2. Because MUHA and SMC are CON applicants and reside within the geographic areas served or to be served by each other's projects, they are "affected persons" for the purposes of participating in a contested case related to the Department's Decision. S.C. Code Ann. § 44-7-130(1)(2018). Accordingly, both parties have standing to participate in this contested case proceeding. *See* § 44-1-60(G)(2018) (identifying right of applicants, permittees, licensees, or affected persons to request a contested case hearing with the ALC).

3. A contested case hearing conducted before this Court in a CON matter is a trial *de novo*, in which "the whole case is tried as if no trial whatsoever had been had in the first instance," and the administrative law judge conducting the hearing is the sole finder of fact, who "must make sufficiently detailed findings supporting the denial or grant of a permit application." *Marlboro Park Hosp.*, 358 S.C. 573, 579, 595 S.E.2d 851, 854 (Ct. App. 2004) (quoting *Blizzard v. Miller*, 306 S.C. 373, 412 S.E.2d 406 (1991) and *Converse Power Corp. v. S.C. Dep't of Health & Envtl. Control*, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002)).

4. The trial judge who observes a witness is in the best position to judge the witness's demeanor and veracity and to evaluate the credibility of his testimony. *Woodall v. Woodall*, 322 S.C. 7, 10, 471 S.E.2d 154, 157 (1996); *Wallace v. Milliken & Co.*, 300 S.C. 553, 556, 389 S.E.2d 448, 450 (Ct. App. 1990). Therefore, the weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. *S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co.*, 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992).

5. An expert is granted wide latitude in determining the basis of his or her opinion, and where an expert's testimony is based upon facts sufficient to form an opinion, the trier of fact must weigh its probative value. *Small v. Pioneer Machinery, Inc.*, 329 S.C. 448, 470, 494 S.E.2d 835, 846 (Ct. App. 1997). In general, the trier of fact may give an expert's testimony the weight he or she determines it deserves. *Florence County Dep't of Soc. Servs. v. Ward*, 310 S.C. 69, 425 S.E.2d 61 (Ct. App. 1992). Further, the trier of fact may accept the testimony of one expert over that of another. *S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co.*, 308 S.C. 216, 417 S.E.2d 586 (1992).

6. MUHA, as the moving party challenging the Department's Decision to approve SMC's Project, bears the burden of proof. S.C. Code Ann. § 44-7-210(E) (2018); S.C. Code Ann. Regs. 61-15 § 403(1) (Supp. 2005); *see also Leventis v. S.C. Dep't of Health & Envtl. Control*, 340 S.C. 118, 132-33, 530 S.E.2d 643, 651 (Ct. App. 2000) (holding that the burden of proof in

administrative proceedings generally rests upon the party asserting the affirmative of an issue). Similarly, SMC bears the burden of proof in its case against MUHA.

7. Each respective party must, therefore, prove its case by a preponderance of the evidence. *Nat'l Health Corp. v. S.C. Dep't of Health & Envtl. Control*, 298 S.C. 373, 379, 380 S.E.2d 841, 844 (Ct. App. 1989) (indicating the preponderance of the evidence standard applies in CON disputes). Preponderance of the evidence means “evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole show that the fact sought to be proved is more probable than not.” *BLACK'S LAW DICTIONARY* 1182 (6th ed. 1990).

PROCEDURAL BACKGROUND

1. On August 6, 2020, SMC filed its CON application for the SMC Project under the 2020 Health Plan. On January 27, 2021, the Department issued its letter deeming SMC's CON application complete. The Department identified the following priority project review criteria for its review of SMC's CON application: (a) compliance with the need outlined in the 2020 SHP; (2) community need documentation; (3) distribution (accessibility); (4) record of the applicant; and (5) adverse effects on other facilities.

2. On November 6, 2020, MUHA notified the Department of its status as an affected person and its opposition to the SMC Project. MUHA asserted that because it had also filed a CON application for 6 NICU bassinets, its CON application should be considered “competing” with SMC's application.

3. On February 22, 2021, the Department issued its decision letter approving SMC's CON application (“SMC Decision”). In the SMC Decision, the Department did not find SMC's CON application competing with MUHA's CON application under S.C. Code Ann. Regs. § 61-15 § 103(6).

4. On November 3, 2020, MUHA submitted a CON application for the MUHA Project under the 2020 Health Plan.

5. On January 22, 2021, SMC notified the Department that it was an affected person opposed to the approval of MUHA's CON application. SMC asserted that its application should not be considered competing with MUHA's application. SMC further stated that if the applications were considered competing, SMC's application was comparatively superior to MUHA's Project.

6. On March 3, 2021, MUHA requested a final review conference regarding DHEC's approval of SMC's CON application. DHEC denied MUSC's request.

7. On April 26, 2021, the Department issued its decision letter approving MUHA's CON application. In the MUHA Decision, the Department found MUSC's CON application complied with the 2020 Health Plan and the same project review criteria. DHEC additionally did not find MUHA's application competing with SMC's application. On April 26, 2021, following the denial of its Request for Final Review ("RFR") by the South Carolina Board of Health and Environmental Control (Board), MUHA petitioned the ALC for contested case review against DHEC and SMC.

8. On July 21, 2021, SMC, following its RFR denial by the Board, petitioned the ALC for contested case review against the Department and MUHA.

9. On August 25, 2021, MUHA filed a Motion to Consolidate the above referenced cases pursuant to SCALC Rule 19(D). The Court granted the Motion to Consolidate on September 9, 2021.

10. On September 13, 2021, MUHA moved this Court for summary judgment on the basis that SMC's CON application did not satisfy the following portion of S.C. Code Ann. Regs. 61-16 § 1306(C), which will be referred to herein as "the minimum average transfer requirement":

Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate⁴ admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. (Emphasis added.)

Id.

11. SMC opposed MUHA's Motion for Summary Judgment, which the Court denied on May 4, 2022.

12. On October 14, 2021, SMC moved this Court pursuant to S.C. Code Ann. § 1-23-600(H)(4) to lift the automatic stay imposed under S.C. Code Ann. § 1-23-600(H)(2) so that it could begin operating the 6 Level III bassinets which were approved by the DHEC Staff. MUHA

4. Under Chapter 3 of the State Health Plan, "neonate" refers to the first twenty-eight days after a baby's birth.

opposed the motion. On December 8, 2021, the Court denied SMC's Motion to Lift the Automatic Stay.

13. The case proceeded to trial on the dates referenced *supra*.

FINDINGS OF FACT

Based on the testimony, exhibits, and arguments presented at the hearing, and considering the credibility of the witnesses and the accuracy of the evidence, this Court makes the following Findings of Fact by a preponderance of the evidence:

I. THE PARTIES

SMC

1. SMC is a 124-bed hospital located at 295 Midland Parkway in Summerville, South Carolina that provides a comprehensive range of services. SMC is the only hospital in Dorchester County, South Carolina, and SMC will grow to 174 beds upon the completion of a 50-bed expansion. SMC currently is a licensed Level II special care nursery and operates 16 Level II bassinets.

2. SMC is part of Trident Health System, which operates under the same corporate entity, and includes a 296-bed acute care sister hospital, Trident Medical Center ("TMC") that is located in Charleston County about 6 miles away from SMC. Trident Health operates a Level II trauma center and provides complex medical services primarily to Charleston, Dorchester, and Berkeley Counties (the "Tri-County Area"), one of the busiest emergency rooms in the state of South Carolina and the busiest dedicated pediatric emergency department in the Charleston area. In the last ten years SMC has invested over \$100 million in its campus and has plans to invest another \$75 - \$80 million in the next two years.

3. SMC and TMC are part of Health Care America ("HCA"), a for-profit hospital corporation which operates 53 affiliated hospitals across the nation with 1,933 Level III NICU bassinets.

4. In 2017, Trident Health received CON approval to consolidate at SMC all women's and perinatal services provided at both SMC and TMC. The consolidation was completed in 2019, and SMC is now the second largest perinatal program in Perinatal Region ("PR") V, and one of the largest in South Carolina. SMC has a pediatric intensive care unit, a dedicated pediatric emergency department and several pediatric subspecialties on its campus. In addition to women's and children's services, SMC offers a variety of specialty services to better serve its community

such as bariatric services, orthopedic services, and robotic surgery, and it will soon begin offering cardiac catheterization services.

5. SMC's Level II nursery designation means that in addition to providing services for normal uncomplicated pregnancies, it also provides services for selected high-risk obstetrical and neonatal patients. SMC's 16 bassinet Level II nursery has been designed to Level III standards and specifications.

6. SMC's Level II program has a variety of specialty capabilities that can even treat a 670-gram neonate until the point of transfer, and it has the resources necessary to take the next step to Level III NICU services.

7. SMC's Obstetrics ("OB") program consists of 12 labor and delivery rooms ("LDR") and 30 dedicated OB post-partum beds. SMC has two dedicated C-section rooms proximate to the LDRs. SMC also staffs its hospital 24 hours a day, 7 days a week with two laborists, who are in-house OB-GYNs that deal with any OB emergencies or see patients in SMC's dedicated OB emergency department. SMC's current Level II unit, where the Level III NICU bassinets will be located, is housed just seconds away from SMC's labor and delivery unit.

8. SMC has a maternal fetal medicine ("MFM") program staffed with three fellowship-trained MFM physicians⁵ who are dedicated to SMC and who treat high-risk mothers through their pregnancies.

9. Forty-five percent of SMC's deliveries are covered by Medicaid. Patients funded by Medicaid typically have limited socio-economic support and limited financial means, resulting in limited access to healthcare services.

10. Women who are treated at SMC's OB program, one of the busiest by birth volume in the state, have easy access to SMC and can park right next to the hospital.

MUHA

11. MUHA is part of the Medical University of South Carolina ("MUSC"), which is an academic medical center located in Charleston, South Carolina. MUHA and its affiliates offer a wide range of services to a large population base residing primarily in South Carolina. Among the services provided on the MUHA campus is a full range of emergency, maternity, pediatric,

5. A MFM physician is an OB/GYN physician who subspecializes in high-risk obstetrics. SMC's physicians follow the standard of care whereby a mother who undergoes prenatal screening is referred to an MFM if the screening is abnormal or a complication is detected.

medical-surgical, and diagnostic services. MUHA serves as an academic training facility for numerous medical residency programs.

12. MUHA's Shawn Jenkins Children's Hospital & Pearl Tourville Women's Pavilion ("MUHA Children's Hospital") opened in early 2020 and delivers integrated care to women and children in a state-of-the-art facility on MUHA's hospital campus in downtown Charleston, South Carolina.

13. MUHA's Children's Hospital offers comprehensive services to children from birth to age 18. The Children's Hospital is staffed with a multitude of pediatric specialists who provide care in a multidisciplinary team approach. MUHA is the Regional Perinatal Center ("RPC") in PR-V and is licensed as a Level IV NICU. MUHA's NICU is considered a statewide referral center for neonates with complex medical illnesses and neonates who require advanced surgical procedures.⁶ MUSC also offers Extra Corporeal Membrane Oxygenation (ECMO) services for neonates (heart lung bypass). MUHA currently operates an 82-bassinet neonatal unit consisting of 36 Level II special care nursery bassinets and 46 Level III/IV NICU bassinets.

DHEC

14. DHEC administers the CON program and the licensing of healthcare facilities in the State of South Carolina. S.C. Code Ann. § 44-7-140. As part of its obligation to implement the CON program, the Department is required to publish a state health plan to establish the need for medical facilities and services. The South Carolina Health Plan includes an inventory of existing services, the projections of need for additional services and facilities, and the standards for distributing the facilities and services across designated regions referred to as "service areas." S.C. Code Ann. § 44-7-180(B), (C). The Department reviewed both CON applications in the instant case under the 2020 State Health Plan ("State Health Plan").

II. WITNESSES AT TRIAL

SMC'S WITNESSES

15. SMC presented eight witnesses who testified on its behalf: Jeffrey Taylor; Assad Merchak, M.D.; Alexander Soutter, M.D.; Brandi Hardin, M.D.; Brittany Stofko, M.D.; Sanjay Patwardhan, M.D.; Robert Holcomb, M.D.; and Daniel J. Sullivan.

16. Jeffrey Taylor serves as the Chief Executive Officer of SMC.

6. A "neonate" is defined as an infant less than four weeks old. A neonate may or may not be a ELBW or VLBW baby.

17. Assad Merchak, M.D., is a board-certified, fellowship-trained neonatologist and pediatrician with experience in all levels of neonatal care, including Level II, III and IV; he is on the medical staff at SMC; and serves as SMC's Director of Neonatal Services. Dr. Merchak has been practicing pediatric and neonatal medicine for 27 years, and he estimates that he has treated thousands of extremely low birth weight ("ELBW") and VLBW babies, which are neonates weighing 1000 grams and 1500 grams, respectively. Prior to arriving at SMC, Dr. Merchak spent 14 years working in a 90 to 100 bed NICU at Mercy Children's Hospital ("Mercy" or "Mercy Hospital"), in St. Louis, Missouri, as well as a Level II special care nursery at St. Luke's Hospital in St. Louis, Missouri, where he treated a variety of complex NICU neonates at all levels and birthweights. Dr. Merchak spends 95% of his professional time practicing neonatal medicine at the bedside, with the other 5% focused on neonatal administrative duties and quality improvement and assurance. Dr. Merchak was recruited to SMC in 2019 to assist SMC in establishing a Level III NICU. Dr. Merchak was qualified and accepted by the Court as an expert in neonatology.

18. Alexander Soutter, M.D., is a board-certified, fellowship-trained pediatric surgeon at SMC where he has been practicing since 2017 and currently serves as Chair of the Department of Pediatrics. Prior to practicing at SMC, Dr. Soutter practiced in a 1,000-bed hospital that had 200-plus pediatric beds and 108 Level IV NICU beds. Dr. Soutter routinely averaged over 1,000 surgical cases a year, and he worked extensively in the Level IV NICU handling a variety of complex conditions that require surgery. Dr. Soutter undertook employment at SMC in anticipation of its transition from a Level II nursery to a Level III NICU. Dr. Soutter was qualified and accepted by the Court as an expert in pediatric surgery.

19. Brandi Hardin, M.D., an obstetrician-gynecologist ("OB-GYN") who joined the SMC medical staff in January 2022, previously worked for 18 years in a South Carolina RPC with a Level III NICU. Dr. Hardin has delivered thousands of babies and was qualified and accepted by the Court as an expert in obstetrics and gynecology.

20. Brittany Stofko, M.D., is a board-certified, OB-GYN who has been practicing as an attending obstetrician at SMC for four years. From 2011 – 2015, Dr. Stofko was an Associate Professor and attending OB-GYN physician at the University of Pennsylvania's Perelman School of Medicine, and she worked in a hospital facility with a Level III NICU. The University of Pennsylvania hospital had over 600 beds and delivered 5,000-6,000 babies per year. Dr. Stofko

currently serves as core faculty in SMC's OB-GYN residency program. Dr. Stofko was qualified and accepted by the Court as an expert in obstetrics and gynecology.

21. Sanjay Patwardhan, M.D., is a board-certified MFM physician who completed his MFM fellowship at MUSC. Dr. Patwardhan currently practices MFM at SMC, where he is the Director of the MFM Program. Dr. Patwardhan has had academic faculty appointments as an Assistant Professor of Medicine and has been published in peer-reviewed journals. Dr. Patwardhan has consulted thousands of patients as an MFM specialist. Dr. Patwardhan was qualified and accepted as an expert in OB-GYN and MFM.

22. Daniel J. Sullivan is a healthcare management consultant with 32 years of experience who is engaged by clients to consult on healthcare planning and healthcare finance projects. Mr. Sullivan has extensive experience in healthcare consulting and the certificate of need process. Mr. Sullivan has prepared over 1,000 CON applications, has testified in 15 different states as an expert in healthcare planning and finance, and has been involved specifically in NICU services in Florida, Georgia, Alabama, Kentucky, West Virginia, and South Carolina. Mr. Sullivan has made NICU projections in CON applications between 12 and 15 times. He has been qualified as an expert in a court of law approximately 200 times during his career and 30 times in South Carolina. Mr. Sullivan has been involved with at least 25 CON applications related to healthcare projects in the Tri-County Area over the last decade. Mr. Sullivan is extremely familiar with the Charleston healthcare market and its demographics, and over the years he has worked with, in addition to Trident Health, a number of different providers, including MUSC, Roper St. Francis Healthcare, and East Cooper Medical Center. Mr. Sullivan has been working with the South Carolina Health Plan since the early 1980s and has served on a South Carolina Health Plan Task Force. Mr. Sullivan has extensive knowledge of the perinatal system in South Carolina, as well as in other states, and he has knowledge of the South Carolina licensure regulations as they relate to Level I, II, III and IV neonatal units. Mr. Sullivan was qualified and accepted as an expert in the areas of healthcare planning and finance, the South Carolina Health Plan, the South Carolina Perinatal Regional System, and the South Carolina CON program.

23. Robert Holcomb, M.D., is a board-certified pediatrician and neonatologist who received his fellowship training in neonatology at the University of Colorado Health Sciences Center, a level IV neonatal care facility. Dr. Holcomb currently serves as the Director for HCA's Midwest Transport Service for neonatology and high-risk pregnancy. Dr. Holcomb currently

practices in a private neonatology setting that covers the neonatal units at four HCA affiliated hospitals in the Kansas City area that have both Level II and III neonatal units of varying sizes. One of which is Centerpoint Medical Center, a Level III NICU having an average daily census of seven to eight neonates. Dr. Holcomb also works at a Level III NICU at Research Hospital, located in Kansas City, where there are approximately 1,100 births per year, or less than half of SMC's delivery volumes. Dr. Holcomb received training in epidemiology while at Georgetown Medical School and during his medical residency. Prior to working in Kansas, Dr. Holcomb practiced neonatology at military hospitals in Europe and in Biloxi, Mississippi, which had Level III NICUs. Dr. Holcomb spends approximately 95% of a nine-week rotation performing clinical service in a NICU. Dr. Holcomb estimates that he has treated approximately 3,000 – 4,000 ELBW and VLBW babies as a neonatologist. Dr. Holcomb has been involved in teaching most of his career, and he is currently involved in teaching both medical students and residents.

24. Currently, Dr. Holcomb is a senior leader at the American Academy of Pediatrics ("AAP") where he is involved in evaluating neonatal levels of care, the standards associated with those levels, and the relationship between neonatal admissions to determine operational efficiencies and the proper level of care for NICUs. He currently serves as the AAP's Chair for the Section on Transport Medicine. Dr. Holcomb has been working on the AAP's NICU verification program, which is designed to evaluate NICUs based on a checklist to ensure standards are maintained for Level I, II, III and IV NICUs. Dr. Holcomb has worked extensively for the March of Dimes, to include being the President of the Board of Directors for the March of Dimes for the State of Mississippi, and he served on the Board of Directors for the Kansas City March of Dimes as well. While working for the AAP and March of Dimes, Dr. Holcomb would critically review literature and research to ensure that it was evidence-based and reliable in order to form policies and procedures.

25. Dr. Holcomb's research has included perinatal regionalization, access to care, neonatal outcomes, and standards of care. Dr. Holcomb had exposure to the concept of perinatal regionalization during his fellowship training. In preparing for his testimony in this contested case, Dr. Holcomb performed a complete analysis of the neonatal system in South Carolina, to include a review of the providers in the various PRs of South Carolina, and he has reviewed numerous articles looking at the volume and quality components associated with neonatal care. In addition to his personal experience, Dr. Holcomb's work with the AAP has looked beyond volume in terms

of the factors that drive high quality NICU care that will result in excellent outcomes. As part of his practice, Dr. Holcomb regularly reviews peer-reviewed studies and is familiar with the concept of the hierarchy of evidence and the study groupings that are associated with the hierarchy.

26. Dr. Holcomb also has significant experience with the neonatal volume-outcome correlation in terms of being a part of a Level II nursery to Level III NICU transition (similar to SMC's proposal); working with the AAP and preeminent neonatologists; and reviewing the research related to neonatal unit volumes and neonatal outcomes. Dr. Holbrook was qualified and accepted as an expert in neonatology, neonatal transportation, peritoneal regionalization, and levels of care, and in the volume -outcome correlation.

To prepare for his testimony in this case Dr. Holcomb reviewed portions of MUHA's and SMC's CON applications; reviewed numerous studies dealing with neonatal volumes and outcomes; reviewed the depositions of MUSC physicians who provided opposition testimony to SMC's NICU project; reviewed documents published by the Centers for Disease Control (CDC), March of Dimes and the AAP; reviewed the perinatal portion of the Health Plan; visited the MUSC campus, toured the SMC NICU; and met with Dr. Merchak and Jeff Taylor to discuss SMC's neonatal capabilities, ancillary services, staffing and sub-specialists.

MUHA'S WITNESSES

27. MUHA presented ten witnesses who testified on its behalf at the hearing: Mark Scheurer, M.D.; David J. Annibale, M.D.; Ciaran S. Phibbs, PhD; Catherine Twombly, M.D.; Conrad Williams, M.D.; David R. White, M.D.; John B. Cahill, M.D.; John B. Sion, Jr.; David S. Levitt; and Scott Lorch, M.D.⁷

28. Mark Scheurer, M.D., is a board-certified, fellowship-trained pediatric cardiologist who practices medicine at MUHA and holds the title Chief for Children's and Women's Services at MUHA. Dr. Scheurer has authored a multitude of peer-reviewed articles regarding pediatric cardiac intensive care. Dr. Scheurer was qualified and accepted as an expert in pediatric cardiology and pediatric cardiac ICU.

29. David J. Annibale, M.D., is a board-certified, fellowship-trained neonatologist, who teaches and practices at MUHA and serves as its Chief of Neonatology. Dr. Annibale is active in the field of neonatology, writing and reviewing peer-reviewed journals and textbooks, and he

7. Dr. Lorch's testimony for this hearing is contained in a *de bene esse* deposition incorporated as part of the hearing transcript.

receives grants and conducts research in the field of neonatology. Dr. Annibale has reviewed literature related to the NICU volumes and outcomes from the 1980s until the present. He spends about 50% of his time practicing clinical neonatology. Dr. Annibale was qualified and accepted as an expert in neonatology and the NICU volume correlation.

30. Catherine Twombly, M.D., is a board-certified, fellowship-trained, pediatric nephrologist (kidney) who practices and teaches at MUHA, where she serves as its Chief of Pediatric Nephrology. Dr. Twombly has published in the field of Pediatric Nephrology as well, to include publications related to pediatric kidney transplantation. Dr. Twombly was qualified and accepted as an expert in pediatric nephrology.

31. David White, M.D., is a board-certified, fellowship-trained pediatric otolaryngologist (ear and throat) who practices and teaches at MUHA, where he serves as the Surgeon in Chief of the Shawn Jenkins Children's Hospital and the Director of Pediatric Otolaryngology. Dr. White has published extensively in the field of pediatric otolaryngology, particularly in the area of surgical airway management in children. Dr. White was qualified and accepted as an expert in pediatric otolaryngology.

32. John B. Cahill, M.D., is a board-certified, fellowship-trained neonatologist who practices at MUHA and is a Professor of Medicine at MUSC. Dr. Cahill has published in the field of neonatology. Dr. Cahill serves as the Director of the Pediatric Major Care Systems, which provides the medical transport of patients, particularly high-risk critical patients, from other providers to MUHA's Children's Hospital by way of ground, helicopter, and fixed wing transport. Dr. Cahill was qualified and accepted as an expert in neonatology and the method and mode of transporting babies from hospital nurseries in PR-V to MUHA's Children's Hospital

33. Conrad Williams, M.D., is a board-certified, fellowship-trained hospice and palliative care physician who practices and teaches at MUHA, where he serves in the capacity of Medical Director of the Palliative Care Program at MUSC. Dr. Conrad was qualified and accepted as an expert in pediatric palliative care and hospice.

34. John B. Sion is MUSC's former Director of Major Construction Projects who oversaw the construction of MUHA's new Children's Hospital.

35. Ciaran S. Phibbs, Ph.D., is a health economist whose areas of focus have been perinatal care and the regionalization of newborn care. Dr. Phibbs received his Ph.D. in economics in 1987, with a post-doctoral research fellowship in health services research. Dr. Phibbs holds

several professional appointments including Associate Professor (Research), Department of Pediatrics (Neonatal and Developmental Medicine), at Stanford University School of Medicine. Dr. Phibbs has published extensively in the areas of neonatal treatment volumes and outcomes in peer-reviewed journals. Dr. Phibbs serves as an advisor to the AAP Committee on Fetus and Newborn. Dr. Phibbs is not a neonatal clinician, and his time spent in neonatology units has been limited to academic medical centers. Dr. Phibbs has never spent time in a neonatal unit that had less than 25 bassinets. Dr. Phibbs is not aware of the morbidity or mortality neonatal outcomes for any hospitals in South Carolina to include his client, MUHA.; Dr. Phibbs was qualified and accepted as an expert in health economics, NICU regionalization, and the NICU volume outcome correlation.

36. Scott Lorch, M.D., is a board-certified, fellowship-trained neonatologist who practices medicine at the Children's Hospital of Pennsylvania ("CHOP") and is a Professor of Medicine at the University of Pennsylvania School of Medicine. Dr. Lorch also serves as the Associate Chief and the Director of Clinical and Epidemiological Research, Division of Neonatology, at CHOP. Dr. Lorch has published extensively in the area of neonatology, to include the correlation of neonatal treatment volume and outcomes. Dr. Lorch has not conducted any studies concerning Level III NICUs in South Carolina with respect to the specific neonatal outcomes for each hospital's NICU. Dr. Lorch has not done any analysis with respect to the effect that South Carolina's non-RPC NICUs such as Prisma Health Baptist ("Prisma Baptist"), Piedmont Medical Center ("Piedmont") or Self Regional Medical Center ("Self Regional") have had on the perinatal system of South Carolina for infant mortality or morbidity. Dr. Lorch spends about 25% of his professional time in the NICU, while the other 75% is spent on administrative duties, research, writing, and teaching. The last time Dr. Lorch practiced in a small NICU—one that had less than 7 bassinets—was more than 20 years ago while he was in fellowship training. Dr. Lorch was qualified and accepted as an expert in perinatal, neonatal health services research to include NICU regionalization, and the NICU volume outcome correlation.

37. David Levitt is a health care consultant who has drafted over 1200 CON applications, with several hundred being related to South Carolina projects. Mr. Levitt primarily consults in the Southeast area of the country. Mr. Levitt estimates that he has testified approximately 75 times as an expert in healthcare planning and finance with respect to CON matters, with about a third of those appearances being in the SCALC. Mr. Levitt wrote MUHA's

CON application for its NICU beds and submitted a letter in opposition to SMC's NICU project to the Department. Mr. Levitt was qualified and accepted as an expert in healthcare planning and finance.⁸

DHEC'S WITNESSES

38. Margaret Murdock testified on behalf of the Department. At the time the Department rendered its decisions on both MUHA's and SMC's CON applications for NICU bassinets, Ms. Murdock was the Director of the CON program. Prior to becoming the CON Director, Ms. Murdock served as a Senior Consultant in the CON program where she reviewed CON applications, drafted decisions, and updated the Health Plan. In January 2021, Ms. Murdock was appointed the Interim Chief of the Bureau of Healthcare Planning and Construction. She has since left DHEC and become employed at another state agency.

39. Ms. Murdock was the primary reviewer of the SMC and MUHA applications at issue in this consolidated contested case. (Prior to these applications, Ms. Murdock had reviewed at least five other CON applications for perinatal services.) At the hearing, Ms. Murdock demonstrated her knowledge of the concept of perinatal regionalization and the levels of neonatal care in South Carolina.

III. PERINATAL SERVICES IN SOUTH CAROLINA

LEVELS OF CARE

40. The Health Plan states:

Because the cost of high-risk obstetrical and neonatal services is so great, it is not desirable or cost-effective for all hospitals in the State to provide higher levels of care. Over the years, a regionalized approach to perinatal care has been implemented in South Carolina to address the need for high quality, risk-appropriate, cost-effective perinatal health care. Regionalization provides a coordinated system of perinatal care for a well-defined population group.

41. Each hospital providing perinatal services is designated by DHEC's Division of Health Licensing as a Level I, II, III, or IV Perinatal Hospital, or an RPC. Each Level I, II, III and IV hospital maintains a relationship with its designated RPC for consultation, transport, and continuing education. Patients are transferred to the appropriate RPC, when medically appropriate, if beds are available.

8. Mr. Levitt also wrote the CON application for Piedmont Medical Center's Level III NICU.

42. Hospitals with Level I services (Basic Perinatal Center with Well Newborn Nursery) provide services for normal uncomplicated pregnancies. Hospitals with Level II services (Specialty Perinatal Center with Special Care Nursery) provide all the services of a Level I nursery, but also provide services to selected high-risk obstetrical and neonatal patients. A Level II nursery must have on its medical staff, in addition to the staff necessary to deliver normal newborns and provide for normal uncomplicated pregnancies, a general surgeon, pathologist, radiologist, obstetrician, pediatrician and anesthesiologist. A Level II nursery must also have available for consultation an MFM specialist, neonatologist, and pediatric surgeon.

43. Level II providers can manage the care of only those neonates who are at least 32 weeks of gestation with an anticipated birthweight of at least 1500 grams and problems expected to resolve rapidly. Level II hospitals are required to stabilize infants born before 32 weeks of gestation and weighing less than 1500 grams until they can be transferred to a Level III or higher NICU. Neonates in a Level II nursery who require mechanical ventilation support beyond 24 hours of age must be referred to the RPC. Level II hospitals are not permitted to provide care or services which are designated for higher level hospitals unless there are unforeseen, emergent circumstances.

44. Hospitals with Level III services (Subspecialty Perinatal Center with Neonatal Intensive Care Unit) provide all aspects of Level I and Level II care, and all aspects of perinatal care, including intensive care and a range of continuously available, subspecialty consultation services as recommended in the most recent *Guidelines for Perinatal Care* ("GPC") published by the AAP and the American College of Obstetricians and Gynecologists ("ACOG"). Level III hospitals provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age.

45. In addition to the Level II capabilities, Level III hospitals are required to have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Pursuant to the applicable regulation, hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over 24 hours, or require surgery. S.C. Code

Ann. Regs. 61-16 § 1306(C). Level III hospitals that transfer mothers prior to delivery to RPCs or Level IV hospitals may count the transfer in the number of neonatal admissions they are required to manage. Level II hospitals in South Carolina cannot, by regulation, manage very high-risk neonates such as VLBW neonates, ELWB neonates, neonates who require ventilation for more than 24 hours and neonates who require complex surgery.

46. Hospitals designated as RPCs provide all the services found in Level I, II and III hospitals, as well as consultative, outreach, and support services to other hospitals in their region. There is only one RPC per region. RPCs are required to manage no less than 2,000 deliveries annually, and they must participate in residency programs for obstetrics, pediatrics and/or family practice. RPCs are required to provide a perinatal transport system that operates 24 hours a day, seven days a week. RPCs are also required to provide physician-to-physician consultation 24 hours a day for Level I, II, and III hospitals.

47. Level III and RPC hospitals are required to have on their medical staffs, in addition to the Level I and II requirements, an MFM specialist, or effective consultation with an MFM specialist (available 24 hours a day, 7 days a week) via telemedicine; an obstetrician or radiologist with special interest and competence in maternal disease and its complications; a pediatric radiologist; an anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease; and a pediatric surgeon. Additionally, Level III and RPC hospitals must have a roster of pediatric subspecialists available for consultation as set forth in the South Carolina hospital licensing regulations.

48. Level III hospitals must have various pediatric medical subspecialists such as pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists available for consultation at the hospital or at a closely related institution which can be performed using telemedicine, telephone consults, or both from a distant location.

49. Level IV hospitals (Complex Neonatal Intensive Care Unit) provide all of the services as Level I, II and III hospitals but also have additional capabilities and experience to provide care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available on-site twenty-four hours a day. Additionally, Level IV hospitals shall have the capability to perform surgical repair of complex congenital and/or acquired conditions, such as those that require cardiopulmonary bypass with or without ECMO.

PERINATAL REGIONS

50. South Carolina is divided into five Perinatal Regions (PR), and each has a designated RPC.

51. PR-I, which consists of 10 counties in the upstate, has a Level III nursery with 7 NICU bassinets located at Self Regional Medical Center, in Greenwood, South Carolina, in addition to the RPC, which is located at Prisma Health Greenville Memorial Hospital, Greenville, South Carolina. PR-I has a population of 1,165,693 people.

52. PR-II consists of 4 counties with a population of 442,744 people, and Spartanburg Regional Medical Center is the designated RPC.

53. PR-III is a 16-county area with a population of 1.7 million people that has an RPC, Prisma Health Richland Memorial Hospital, located in Columbia, South Carolina, and two Level III NICUs, Prisma Baptist and Piedmont Medical Center. Prisma Health Baptist operates an 8 bassinet NICU located in Columbia, South Carolina, approximately 2 miles from its RPC, and Piedmont has a 5 bassinet NICU unit located in Rock Hill, South Carolina, just across the border from Charlotte, North Carolina, which has two large Level III NICUs about 25 miles from Piedmont.

54. PR-IV consists of 8 counties in the Pee Dee area of the state, with an RPC, McLeod Regional Medical Center, located in Florence, South Carolina. There are no other Level III facilities in PR-IV, which has a population of 731,083 people.

55. PR-V consists of 8 counties in the southeastern part of the state which either border on, or are very proximate to, the coastline. PR-V has a population of 1,165,836 people. MUHA, located in downtown peninsular Charleston, is the RPC for PR-V. There are no additional Level III facilities in PR-V.

56. SMC is a Level II provider that must transfer the care of high-risk neonates who are born less than 32 weeks gestation, require complex surgery or ventilation support for more than 24 hours to its RPC, MUHA. Additionally, SMC will transfer high-risk expectant mothers who are stable to MUHA, but if these mothers are not stable and therefore cannot be transferred prior to delivery, the baby will be transferred to the RPC following delivery.

LEVEL III NICUS AND REGIONALIZATION

57. Despite its regionalized approach to perinatal care, the Department has not prevented the establishment of smaller non-RPC Level III NICUs in the state, especially in PRs with higher populations, such as the 5 bassinet NICU at Piedmont, the 7 bassinet NICU unit at Self

Regional, and the 8 NICU bassinet unit at Prisma Baptist. None of these smaller Level III programs treat over 100 VLBW neonates annually.

IV. SMC'S CON APPLICATION AND MUHA'S OPPOSITION DURING THE CON REVIEW PERIOD

SMC's CON APPLICATION

58. SMC applied on August 6, 2020, to convert 6 of its 16 Level II nursery bassinets to Level III NICU bassinets. SMC's project will not involve major new construction, and SMC listed the total project cost in the CON application at \$287,648, which is primarily made up of equipment costs. Large construction costs associated with SMC's project are not necessary because, when SMC's Level II nursery was built in 2019, it was built to Level III specifications. All 16 of SMC's existing Level II bassinets currently meet Level III standards pursuant to the GPC and can be converted to Level III bassinets. SMC has purchased most of the equipment for the project because an expert review indicated that most of it could be used in its existing Level II nursery.⁹ Therefore, if SMC is approved for the conversion of six of its Level II nursery bassinets to Level III NICU bassinets, the bassinets can be put into service relatively quickly.

59. SMC applied under section 1(e) the Health Plan which permits a CON to be approved for up to 8 NICU bassinets in the absence of a projected need for Level III bassinets provided the Level II applicant can demonstrate, during the 12 month period immediately prior to the month in which the CON application is submitted to the Department, a minimum of 1,500 births and 2,500 intermediate patient days at its facility.

60. SMC represented that it was committed to working with the regionalized system of perinatal care and ensuring that mothers and neonates receive care in the most clinically appropriate setting. SMC acknowledged the importance of having a regionalized system and the importance of having MUHA as the RPC to provide the highest level of care for patients when necessary. SMC's stated goal was to appropriately serve patients who can be served in a Level III unit and identify those neonates who would be better served at MUHA's Level IV unit.

9. An equipment item SMC purchased that drew the concern of MUHA at the hearing was a jet ventilator valued at \$50,250.00. The ventilator was purchased so that SMC's respiratory therapists could train in the event SMC's Level III NICU CON challenge resolved in a favorable manner to SMC. The jet ventilator is not currently in use in the Level II nursery, but it could be used in SMC's pediatric ICU for COVID-19 purposes, if it became necessary.

61. Section B-11 of SMC's CON application was drafted and developed primarily by Mr. Sullivan, with input from HCA personnel. SMC demonstrated in Section B-11 of its CON application that it complied with standard 1(e) of the Health Plan because it satisfied the birth and Level II patient day thresholds during the requisite 12 month period. Moreover, SMC represented that it provided an average of 1,500 deliveries annually for the previous three years, which is a regulation applicable to Level III providers.

62. To demonstrate that it was ready to deliver a higher level of perinatal care, SMC documented in its CON application that it already employed the specialized physicians on its medical staff required to operate a NICU in disciplines such as neonatology; pediatric intensive care; pediatric general surgery; pediatric gastroenterology; pediatric radiology; pediatric otolaryngology; maternal fetal medicine and pediatric emergency care. SMC also had this staff, as well as a pediatric anesthesiologist, in place at the time of the contested case hearing.

63. SMC is part of the HCA healthcare system and informed the Department it could draw from HCA's significant resources because HCA has 53 affiliated hospitals with 1,933 Level III NICU bassinets, and it has developed expertise in the design and operation of NICU units. HCA can also assist SMC in recruiting specialized NICU staff and the development of clinical protocols to ensure high quality care and outcomes for SMC's perinatal patients.

64. SMC informed the Department that all of HCA's affiliated Level III and IV hospitals participate in the Vermont Oxford Network ("VON")¹⁰ so that they can track morbidity and mortality outcomes of VLBW neonates which facilitates facilities intervention to ensure quality improvement, consistency, and outcomes. HCA has key clinical indicators which are reviewed monthly through an enterprise-wide collaborative with NICU Medical Directors and Nursing leadership.

65. SMC partners with Envision Physicians ("Envision"), which staffs HCA affiliated hospitals' Level III NICUs, as well as SMC's Level II nursery. Envision has experience in the provision of neonatal care serving 19 Level III and 22 Level II NICUs nationwide, with more than 350 neonatologists and neonatal nurse practitioners. In addition to VON, SMC participates in eight

10. VON is a quality improvement network that includes all NICUs in the country that has evolved over time and has contributed to the improvement of neonatal care. VON supplies quarterly reports to hospitals that contain performance data set against benchmarks which allows the provider to determine where it stands with respect to other providers and the benchmark. Even though it only has Level II bassinets, SMC participates in VON.

quality improvement initiatives along with Envision to ensure that the neonates and mothers it serves receive the highest standard of care.

66. SMC documented the evolution of perinatal care, to demonstrate that since 1993, there have been many advances in the delivery of perinatal services where a regionalized, rather than a strictly centralized, perinatal system can exist and allow community-based Level III programs to operate.

67. SMC asserted in its application that in South Carolina, high level neonatal care is restricted to just a few hospitals in the state which (a) requires transport that induces physiological stress that can result in poor outcomes; (b) delays the initiation of definitive treatments; (c) removes the expectant mother from the providers she knows and trusts and who are familiar with her medical history; and (d) removes the mother from her family and friends. SMC noted that transport to another hospital can also result in mother-infant separation if the Level III infant is transferred when a mother is not ready for transfer and can cause delays in breast feeding and skin-to-skin care. SMC maintains that the addition of a Level III NICU at SMC can reduce the number of transports and the problems that arise therefrom.

68. SMC asserted that the March of Dimes was careful to distinguish regionalization from centralization, and that future policy modifications to regionalization should consider the diffusion of expertise and technology.

69. In its CON application, SMC discussed the relationship between quality of care and treatment volumes in NICU services with respect to VLBW babies because MUHA maintained in 2017 when SMC first applied for NICU bassinets that SMC would be a low volume program with poor outcomes. SMC referenced and included in its CON application peer-reviewed literature indicating that the rates of neonatal mortality and morbidity among VLBW neonates was more a function of the adoption of evidence-based best practices than a rigid adherence to a VLBW volume treatment threshold.

70. SMC included in its application a 2017 peer-reviewed study published in the journal *JAMA Pediatrics* that concluded that from 2005 to 2014, rates of death prior to discharge and serious morbidities decreased among the NICUs in the study such that within 8 years, 75% of

NICUs achieved rates of performance from the best quartile of the 2005 benchmark for all outcomes except chronic lung disease.¹¹ SMC's application quoted the study:

A possible explanation for the improvements we observed is the development and dissemination of evidence-based perinatal and obstetrical care practices and the application of improvement science to translate that evidence into routine practice. Use of antenatal corticosteroids, widespread adoption of less invasive approaches to respiratory support, standardized care of very low birth weight infants, and improved nutrition management, specifically the recognition of the importance of human milk for feeding infants, are examples of evolving practices that can have a measurable effect on these outcomes. The increased adoption of evidence-based practice and their implementation using quality improvement methods may have contributed to the gains in survival without morbidity that we observed.

71. SMC also included in its CON application a 2004 peer-reviewed study entitled, "Indirect vs. Direct Hospital Quality Indicators for Very Low-Birth-Weight Infants," ("2004 Study") published in the *Journal of the American Medical Association* ("*JAMA*") that reviewed 94,110 VLBW infants who were born in VON hospital NICUs. The study concluded that referral of VLBW infants based on indirect-quality indicators such as patient volume may be minimally effective. Instead, direct measures based on patient outcomes are more useful quality indicators for the purposes of selective referral, as they are better predictors of future mortality rates among providers and could save more lives.

72. One graph in the 2004 study indicates that while there is, on average, an improvement in neonatal outcomes when a NICU treats 50 or more VLBW infants on an annual basis, there are many hospitals that treat less than 50 VLBW infants that perform better than hospitals that treat over 50 VLBW infants, and there are some hospitals that treat less than 50 VLBW babies that perform better than hospitals that treat more than 100 VLBW infants each year.

11. Mr. Sullivan, SMC's health planning expert, opined that he was not surprised by advancements in NICU outcomes over the years given the advancement in treatment techniques and data repositories such as VON. Mr. Sullivan made a comparison to open heart services which were once performed primarily at academic medical centers and large regional hospitals because studies showed that mortality and open-heart surgical volumes were related. He indicated that over time, as research progressed and techniques improved, volume explained less and less of the variation of outcomes at open heart centers, and that quality processes that were in place determined outcomes more so than volumes. As a health planner, Mr. Sullivan opined that there were similarities between open heart services and neonatal services such that if there are well trained practitioners, along with quality measures and best practices in place, a NICU can have good outcomes despite relatively low volume.

The authors explained that “[a]lthough volume and other hospital characteristics are statistically significant, they explain very little of the variation in [VLBW neonatal] mortality across hospitals.” The authors concluded: “The proportion of the hospital level variance in mortality that our estimates attribute to volume (9%) and other hospital-level factors (7%) is fairly small relative to the proportion attributed to the remaining unexplained hospital-level effect (84%).” The authors also stated, “[m]ore importantly, there are large hospital-level differences in mortality for hospitals with similar levels of volume, with mortality at many low-volume hospitals being lower than expected and mortality at many high-volume hospitals being higher than expected.”

73. SMC included these and other studies in an effort to demonstrate that the volume of VLBW babies treated is not determinative of outcomes but a commitment to quality and adoption of best practices by well-trained subspecialists can be determinative.

74. In its CON application, SMC discussed South Carolina’s infant mortality rate (IMR) and its statistical history in the context of perinatal services. SMC referenced the significant racial disparity in neonatal outcomes, and contended that its NICU would enhance, rather than hinder, South Carolina’s perinatal regionalized system because the system in place has not resulted in significant reductions in infant mortality. SMC presented DHEC Vital Statistics which showed that from 2014 to 2018 the IMR in South Carolina went from 6.5/1,000 live births to 7.2/1,000 live births overall. The IMR for “Black & Other” ethnicities went from 9.9/1,000 live births to 11.1/1,000 live births.

75. SMC also set forth the percentage of live births born pre-term, which has been relatively unchanged from 2008 to 2018, and since 2014, the percentage of live births born pre-term has increased. SMC believes that increasing access to Level III providers can benefit patients in the antepartum and postpartum periods and reduce pre-term births because an at-risk expectant mother who is referred to a higher level neonatal provider that is further away from her chosen physician may choose not to go for any number of reasons such as a lack of financial resources or a lack of transportation.

76. SMC noted that in 2018, 89% of all Level III patient days were delivered in a RPC, and yet the IMR in 2018 was 7.2. SMC posited that allowing a portion of the patients transported to an RPC to instead be served in high volume, community hospitals would permit a greater number of high-risk mothers to deliver their babies closer to home and reduce the number of critically ill neonatal transports. SMC also offered that an alternative NICU location in the

Charleston area could increase access to care during times of natural disasters such as hurricanes when travel to MUHA could be limited.

77. SMC highlighted the fact that MUHA's NICU was well utilized at the time it applied for six additional bassinets, especially when compared to other RPC providers. SMC also demonstrated to the Department that other PRs in the state, particularly those with higher population centers, have non-RPC based NICUs and that Charleston, with its large population base, could also support another Level III provider.

78. SMC indicated that it was uniquely positioned to offer Level III NICU services given its volume of births compared to exiting Level III and RPC providers; its location in the greater Charleston area, approximately 24 miles from MUHA; and the rapidly growing population to the north and west of SMC, much of which is younger families taking advantage of the economic development in Berkeley and Dorchester Counties. Seventy percent of the population in PR-V is located in the three-county area primarily serviced by SMC. In its application, SMC indicated that its hospital had a similar birth volume to Prisma Baptist, a Level III provider located less than two miles from its designated RPC which is operating at 149% of its 8-bassinet NICU capacity. At the hearing, SMC demonstrated that it ranked fourth in the state in terms of birth volume when compared to the five RPCs and three non-RPC Level III providers.

79. SMC referenced flooding issues experienced on the Charleston Peninsula where MUHA's NICU is located and noted that access can be difficult due to the street closures on the peninsula. SMC noted that MUHA's NICU, operating at 100% occupancy at times as confirmed by MUHA's Chief of Neonatology, could also create barriers to accessing care.

80. SMC defined its primary and secondary service area in its CON application using SMC's actual 2019 OB discharges by zip code data and projected that it expected to draw most of its Level III NICU patients from the same service area, where it demonstrated significant population growth.¹² SMC's health planner testified that if he were developing the same service area analysis today, he would have shown more patients coming from Orangeburg County given more recent data and the testimony of an SMC obstetrician that even though the volume of births

12. During the hearing, MUHA's health planner criticized SMC's service area as being too broad, but SMC's health planner showed that the service area was based on SMC's *actual* OB discharge patient origin data. It is reasonable to assume that SMC will draw most of its NICU admissions from the same area of origin as that the women who deliver at SMC.

in the service area had remained constant, the projected growth in the female population aged 15 to 44 would result in an increase in the volume of births. SMC proffered, based on 2019 obstetrics market share data, that it was the largest provider of perinatal services in its service area.

81. In its application, SMC projected the utilization of its Level III NICU using three different methodologies. SMC first projected the volume of births and Level II NICU patient days for the years 2021 – 2024 using actual 2020 data (2,708 births and 3,734 Level II patient days) as a baseline with a conservative growth rate of less than 1%.¹³ SMC calculated the number of bassinets needed based on the Health Plan formula, which is a ratio of 3.25 NICU bassinets per every 1,000 live births. This calculation showed that SMC would need 9.2 NICU bassinets.

82. SMC also applied a ratio of Level III NICU days to births across South Carolina, which was .88 patient days per birth. Applying this ratio to SMC's projected births yielded an average daily census at SMC higher than the 6 NICU bassinets for which it was applying. However, because SMC's NICU would be new and would exercise care in patient selection during the start-up period, SMC assumed that its ratio of Level III NICU patient days to births would be .40 in 2022, .60 in 2023, and .65 in 2024, which would yield 79 admissions in 2022, 120 admissions in 2023, and 131 in 2024. Based on a 14-day average length of stay for each neonate, premised on the experience of other HCA Level III NICUs, SMC expected its occupancy of the 6 NICU bassinets to be 50.5% in 2022, 76.4% in 2023, and 83.4% in 2024.

83. Following its utilization projections, SMC demonstrated that it complied with the Health Plan standard 1(e) because it had 2,708 births and 3,734 Level II patient days in the previous 12 months at the time of its CON application.

84. In section B-11 of its CON application, SMC addressed adverse impact and estimated that MUHA would lose 1,832 patient days in 2024, which was SMC's patient day projection for its third year of operations. SMC set forth MUHA's actual 2018 NICU patient days—10,474—applied a .8% growth rate, which is the same assumption SMC applied to its own NICU growth and demonstrated that by 2024 MUHA would experience a loss of 10,987 NICU patient days, which meant SMC would redirect 16.7% patient days from MUHA. SMC explained

13. SMC's Health Planner offered that by virtue of the Level III NICU designation at SMC, births at SMC will increase because less mothers will be transferred to MUHA, and expectant mothers, who are not necessarily high-risk, would choose to deliver at SMC because of the availability of a Level III safety net should a pregnancy complication occur and recent relationships SMC has entered into with In Vitro Fertilization (IVF) physicians.

that its impact on MUHA's NICU would be temporary, especially because the number of preterm births in South Carolina continues to increase; MUHA would continue to receive increased neonatal referrals from other MUHA affiliated hospitals located throughout the state; and the fact that MUHA's Children's Hospital was able to bring all 46 of its NICU bassinets online.

85. SMC's health planner testified that he performed the adverse impact analysis in SMC's CON application before MUHA submitted its CON application for additional NICU bassinets. In its application, MUHA projected 15,653 patient days in 2024, or 4,666 more patient days than SMC's health planner projected. In 2021, MUHA's actual reported NICU utilization was 12,692 patient days, or 1,705 more NICU patient days than SMC projected for MUHA in 2024. SMC's health planner explained that the adverse impact to MUHA was, therefore, overstated in the SMC CON application based on MUHA's actual reported utilization.

86. In the remainder of its CON application, SMC discussed why the status quo (i.e., not converting 6 of its Level II beds) would not benefit the community, the patient, the neonate, or the family, given the problems associated with neonatal transport; mother-infant separation; removal of high-risk mothers, especially those who are indigent, from their care and support networks; and increased travel times for the mother and family, following the birth of a neonate requiring Level III care, especially for those families who live to the north and west of SMC.

87. SMC also set forth its financial pro formas for the financial feasibility of its NICU in all three years. SMC's healthcare financial expert found the pro formas to be reasonable because they were based on SMC's historical experience as a Level II provider, and HCA's input based on the experience of other Level III hospitals. Because the project is projected to generate sufficient excess revenues over expenses, it is also economically feasible.

88. SMC further explained why the project would foster cost containment, included a three-year employee budget, discussed the availability of healthcare employee resources for the NICU, and described the previous experience of the applicant, as required.

89. SMC included in its CON application many physician and community letters of support for its project. One letter, from SMC's Medical Director of its Neonatal Unit, detailed several examples of neonatal transfers to MUHA which would not have occurred if SMC were a Level III provider.

MUHA'S OPPOSITION DURING THE REVIEW PERIOD

90. On December 15, 2020, during the Department's review of SMC's CON application, MUHA submitted a letter in opposition by way of its healthcare consultant, David Levitt, detailing the reasons why SMC should not receive a CON for 6 NICU beds.

91. MUHA informed the Department that because it had recently applied for a CON to add six NICU bassinets, and that its application should be considered competing with SMC's application even though there was no calculated numerical need in the Health Plan. MUHA contended that approval of both projects would exceed the need for Level III NICU bassinets in the service area because both proposed projects would serve PR-V and the Tri-County Area, and that all of SMC's Level III volume would have otherwise been treated at MUHA.

92. MUHA's opposition letter set forth a summary of why MUHA requires 6 more NICU bassinets, stating that despite recently going from 16 NICU bassinets to 46, its NICU continued to experience high demand which would continue to rise with future population growth. MUHA stated that growth in service area utilization for NICU care continues to increase and that there was a need to "increase access to inpatient care."

93. MUHA recognized in its letter that it was the only provider of Level III/IV services in PR-V and that it is well staffed and equipped to deliver evidence-based interdisciplinary care. MUHA also indicated that it already complied with all of the hospital licensure requirements for its NICU.

94. MUHA asserted that because it was an existing NICU with appropriate staff trained to offer NICU care, its project would contain costs. MUHA noted that it was the market provider for NICU services and that patients continue to seek healthcare services at its children's hospital because it is a "premier AMC, RPC, and Level III/IV NICU . . ."

95. In its letter of opposition MUHA claimed that SMC failed to identify the number of hospital-to-hospital transfers to MUHA; SMC overstated the growth of projected births at its facility; the comparison to Prisma Baptist's NICU was improper; the other non-RPC Level III providers in the state were operating at extremely low occupancy, including Piedmont, which reportedly was at 14% occupancy; and that SMC's ratio analysis was improper.

96. MUHA further asserted that if SMC adds Level III bassinets, SMC's Level II patient days will experience constrained capacity.

97. In its opposition letter, MUHA dismissed SMC's concerns regarding peninsular flooding.

98. MUHA noted that because it is the only Level III provider in the PR-V, SMC's NICU patients would have otherwise been treated at MUHA's NICU, which means MUHA would experience adverse impact with the addition of SMC's project.

99. Although MUHA acknowledged that there are small, lower volume Level III NICUs licensed by DHEC that exist alongside RPCs in South Carolina, in its letter of opposition, MUHA focused on the concepts of perinatal regionalization in its effort to convince the Department to deny SMC's project. MUHA suggested that SMC's project undermines perinatal regionalization because SMC is only 30 minutes away from MUHA and area patients have no problem accessing MUHA.

100. MUHA also contended that SMC's project would be an unnecessary duplication of services because the same services are available at MUHA, that quality has never been an issue at MUHA, and that MUHA has always been able to meet the complex needs in PR-V. MUHA referenced DHEC's denial of SMC's 2017 CON application for 6 NICU bassinets where the Department found that "in light of the approval of MUSC's competing application, the Project will result in an unnecessary duplication of services."

V. MUHA'S CON APPLICATION AND SMC'S OPPOSITION DURING THE CON REVIEW PERIOD

MUHA'S CON APPLICATION

101. Approximately three months after SMC submitted its CON application, on November 3, 2020, MUHA submitted a CON application to add 6 NICU bassinets and three intermediate bassinets at its Children's Hospital in downtown Charleston, at a total project cost of \$2,786,450. MUHA described its current capabilities as a Level III/IV NICU and stated that it was a statewide referral center for neonates with complex medical illnesses and neonates who require advanced surgical procedures. MUHA represented that it was experiencing high demand even with 46 NICU (Level III/IV) bassinets, and that the demand would continue to increase given the population growth in the area and further constrain its NICU. MUHA also claimed that the additional NICU bassinets would improve access to inpatient care and relieve capacity constraints.

102. In Section B-11 of its CON application, MUHA stated that "growth in the service area utilization for NICU care continues to increase." MUSC provided the factors that it believed distinguished it from other providers to include references to its various pediatric subspecialties, its research capabilities, and its ability to manage very complex cases.

103. MUHA set forth in its application its NICU discharge patient origin by county of residence, indicating that the population of females ages 15-44 in its service area would increase by 3.9% from 2020 to 2025. MUHA defined its primary service area as the Tri-County area, and its secondary service area as Beaufort, Horry, Georgetown, Colleton, and Orangeburg Counties. MUHA also stated that this service area had a “strong and growing population base,” and that demand for its NICU service would continue to grow, further constraining its NICU. MUHA represented that between 2017 and 2020, utilization of its Level II and III/IV bassinets increased by approximately 11% and 10% respectively.

104. MUHA documented the occupancy percentage of its 46 NICU bassinets at 73.5% in 2020, which was 10% higher than just two years before. MUHA also noted in its application the high utilization of its 36 Level II bassinets at 98.3% in 2020 and indicated that it was adding 3 Level II bassinets to relieve capacity constraints.¹⁴

105. MUHA projected 13,880 patient days in its NICU for 2021, 14,447 for 2022, 15,038 for 2023, and 15,653 for 2024. MUHA reported 11,575 patient days in its 2020 Joint Annual Report (“JAR”), which means MUHA expects a 35.2% increase in NICU patient days from 2020 to 2024.¹⁵

106. At the conclusion of Section B-11 of its CON application, MUHA set forth the applicable Health Plan standards, including standard 1(d), which states that a Level III, IV or RPC neonatal unit may request additional NICU bassinets beyond those indicated as needed by the Health Plan’s methodology, provided it could document the need for additional NICU bassinets based on historical or projected utilization, projected population growth, or other factors demonstrating need. MUHA represented that despite recent additions to the number of NICU bassinets at MUHA, it continued to experience high demand and growth in NICU utilization that would continue with future population growth.

107. In Section B-12 of its CON application, MUHA stated that maintaining the status quo of 36 Level II bassinets and 46 Level III/IV bassinets is not an option. MUHA contends that

14. The Court notes that adding 3 Level II bassinets to MUHA’s complement of 36 would only result in a slight mitigation of its Level II capacity constraints. MUHA’s 36 Level II beds in 2020 were operating at 98.3% capacity, which means 35 were full ($36 \times .983 = 35.4$). Adding 3 Level II bassinets would mean that MUHA’s 39 Level II bassinets would be operating at 91% of capacity.

15. $2024 \text{ MUHA NICU patient days} = 15,653$; $2020 \text{ MUHA JAR reports } 11,575 \text{ NICU patient days}$; $15,653/11,575 = 1.352$ or 35.2% growth.

its project will increase access for patients in need of high level NICU services, and patient families will benefit from the increased convenience of seeking care at a location closer to home.

108. MUHA identified its method of financing, provided three-year pro forma budgets demonstrating the financial feasibility of the project;¹⁶ it provided an average charge per patient day, a three year FTE budget, and described its previous experience as a NICU provider; MUHA provided 20 letters of support; and it provided adequate information for the remaining sections of Part B through D of its CON application.

SMC's OPPOSITION TO MUHA'S APPLICATION DURING THE CON REVIEW PERIOD

109. On January 22, 2021, SMC submitted a letter to the Department indicating that it was an affected person opposed to MUHA's CON application. In its letter of opposition, SMC indicated that it was a provider of similar services located in the same health service area and geographic area to be served by MUHA's proposed project.

110. SMC informed the Department that it had previously applied for a CON to add 6 Level III NICU bassinets in the same health service area and that if the Department considered the two applications to be competing, then SMC's application should be chosen because it would better serve the community. SMC asserted, however, that because both MUHA and SMC applied under separate provisions of the Health Plan to justify the need for their projects, the CON applications were not competing, and the Department could approve both if the projects complied with the applicable regulations.

111. SMC attached to its letter in opposition to MUHA's project a letter signed by Daniel J. Sullivan, SMC's healthcare consultant, who addressed MUHA's CON application. In his letter, Mr. Sullivan contended that the SMC and MUHA CON applications were not competing because there is no limit on the number of bassinets that can be awarded to MUHA under Section 1(d) of the Health Plan, and SMC's request for 6 Level III bassinets is consistent with Section 1(e) of the Health Plan. Mr. Sullivan averred that each project was addressing a separate need based on different considerations set forth in the respective criteria in the Health Plan, and that the approval of each project would increase access to specialized perinatal services in PR-V.

16. MUHA represented in its pro formas that in each of the first three years of its proposed project, it would have a contribution margin of \$1.78 million, \$2.64 million, and \$3.49 million attributable to the additional proposed bassinets. MUHA also represented that by FY 2024, its total operating revenue with the project would eclipse \$2 billion, and its net income would be close to \$100 million.

112. Mr. Sullivan also contended that in the event that the Department found SMC's and MUHA's applications to be competing, it should approve SMC's application because it was comparatively superior, as NICU services at SMC would enhance geographic access to Level III neonatal care for residents of Dorchester and Berkeley Counties as well as portions of Colleton and Charleston Counties. SMC stated that having a Level III NICU closer to families' homes facilitates the ability of mothers to participate in the care of neonates.

113. SMC also referenced the frequent flooding on the Charleston Peninsula, which MUHA had cited in an earlier CON application as one reason its proposed hospital in Berkeley County should have been approved, because flooding can restrict access for critically ill neonates, to include ambulances and helicopters, especially during hurricanes and other significant weather events. SMC's consultant also referenced the other Level III NICU providers that exist alongside their RPCs, indicating that the Department has approved and licensed other non-RPC Level III NICUs in the past.

114. SMC's consultant argued that SMC's project's capital cost at \$287,648 was lower than MUSC's project cost at \$2,786,450 and that patients' families would realize cost savings because neonates could avoid travel to MUHA by ambulance or helicopter.

115. SMC's consultant stated that SMC used a ratio analysis to document need for its project whereas MUHA did not adequately document need for its project, that MUHA inexplicably applied to add 6 NICU bassinets when its need for Level II bassinets was more pressing, and that MUHA's growth projections were inconsistent with historical growth trends. SMC also informed the Department that its project would not result in adverse impact to MUHA given the population growth in the service area, MUHA's high utilization, and the fact that SMC would continue to make high-risk transfers to MUHA.

VI. CON REVIEW PROCESS AND DECISION LETTER

116. The Department received SMC's CON application on August 6, 2020, and the deemed complete notice was published on October 23, 2020. The Department received MUHA's CON application on November 3, 2020, approximately 11 days after SMC's application had been deemed complete. SMC's and MUHA's applications were potentially competing because MUHA's application was received within 15 days of SMC's application being deemed complete, and the applications were for similar services within the same service area.

117. The Department analyzed whether the approval of both CON applications would exceed the need for NICU services in the service area to determine whether that element of the “competing applications” definition was met. In certain instances, such as when there is specified need in the Health Plan and no exceptions, the Department’s conclusion regarding both applications exceeding the need can be quickly determined. The Department found during the review of the two NICU applications that because there were exceptions in the Health Plan that allowed for the establishment of Level III NICUs in the absence of a defined need in the Health Plan, it had to analyze the CON applications to determine if there was a need for both projects. The Department determined the applications were not competing.

118. During the review process, the Department reviewed both applications, the Health Plan, JARs, prior Health Plans, and various scholarly articles filed with the applications.

119. The Department found that both applicants complied with the Health Plan for different reasons. The Department’s witness, Ms. Murdock, testified that an additional Health Plan standard—1(e)—had been added to the 2020 Health Plan which permitted a Level II nursery to apply for a CON for up to 8 Level III NICU bassinets when there was no calculated need for Level III bassinets if the Level II nursery could demonstrate 1,500 births and 2,500 intermediate patient days in the 12 months preceding the application date. SMC applied under Standard 1(e), and the Department found that SMC complied with this standard.

120. The Department also found that MUHA complied with the Health Plan standards in the absence of a bed need because it documented historical utilization and capacity constraints, and it showed that projected utilization and population growth would continue to drive increased utilization for the additional bassinets.

121. The Health Plan identifies the following PRC as the most important in evaluating CON applications for neonatal services: compliance with the need outlined in this section of the Plan; distribution, accessibility, record of the applicant, and adverse effects on other facilities. During the review period, the Department supplemented the “most important” PRC list with PRC 802.2, Community Need, because SMC was the first provider to apply under the new Standard 1(e). Because there was no calculated need in the Health Plan and there was potentially a competing applicant, the Department believed it was important for SMC to set forth a need analysis in its application.

122. The Department deemed the same PRC as most important for both applications. The Department found that both NICU projects complied with all of the most important PRC.

123. The Department found that SMC complied with the requirements of the Community Need PRC because it provided a detailed ZIP code-based population analysis, a market share analysis, and because SMC projected utilization for its NICU using different methodologies, which showed that its 6 bassinet NICU would be well utilized especially because SMC is located in an area of high growth. (The Department considered MUHA's position that SMC improperly used a statewide Level III NICU patient days to births ratio for its utilization projections in the application; however, the Department found that MUHA's methodology of choosing just one hospital for comparison purposes, especially one reporting less than half the number of deliveries as SMC, would be improper.)

124. The Department also considered various articles submitted by the parties regarding the relationship between NICU treatment volume and quality of care. While recognizing that SMC would be a smaller sized NICU program, the Department considered NICU treatment variables other than volume to include SMC's parent company resources and being located in a larger population center.

125. The Department noted that SMC's program would not be dissimilar from other non-RPC Level III NICUs, such as Self Regional, with 7 NICU bassinets, Prisma Baptist with 8 NICU bassinets, and Piedmont with 5 NICU bassinets.

126. The Department also considered the high utilization at MUHA when deciding to approve both projects because it did not want the RPC in PR-V to be without capacity to treat high acuity neonates.

127. The Department found that SMC complied with the PRC 802.3, Distribution (Accessibility), and that duplication was justified given MUHA's coastal location as the RPC and the need for redundancy for Level III NICU services in PR-V in the event of weather emergencies. During the hearing, the Department identified all of the Level II and (single) Level III nurseries in PR-V and their proximity to the coast and bodies of water to demonstrate their vulnerability to weather events. The Department noted that MUHA was in an area known to experience significant flooding and that traffic congestion could make visitation to neonates difficult for families, especially for those neonates who will require longer stays in the hospital. These factors weighed in favor of approving a second Level III provider in PR-V with respect to access.

128. The Department found, through an analysis of MUHA's patient origin, that a Level III NICU at SMC could improve access to families in need of those services who reside in Dorchester and Berkeley Counties and who presently have only one option for high acuity neonatal services which requires travel to the peninsula that can be cumbersome depending on the time of day and the weather.

129. With respect to perinatal regionalization, the Department determined that the relative location of RPC's and Level III NICUs in the state, some just a short drive from each other, has not disrupted the regionalization of perinatal care and that there was no data to support such a position. Prior to the addition of Standard 1(e) in the Health Plan, the Department's CON division asked the Department's licensing division to analyze whether there were any problems at the non-RPC Level III NICUs with patient care in terms of neonatal outcomes, quality, and compliance, and the licensing division concluded that there were no such problems.

130. In 2017, in the context of competing applications filed by SMC and MUHA, the Department did not approve SMC's CON application for 6 Level III NICU bassinets at a time when there were 14 NICU bassinets needed under the Health Plan in effect. In 2017, Standard 1(e) did not exist, and the Department found the applications were competing. Therefore, the Department could approve only one application. The Department found that MUHA's application better complied with the applicable law and State Health Plan and awarded all 14 bassinets shown as needed in the State Health Plan to MUHA.

131. In the current case, the Department weighed equally the benefits of improved accessibility with the adverse effects of duplication when evaluating NICU services. With respect to adverse impact, the Department undertook an analysis and concluded there would be no adverse impact with respect to either project and that the improved accessibility to Level III NICU services afforded by SMC's project outweighed any perceived or projected negative effects of duplication upon MUHA.

132. Regarding PRC 802.13, Record of the Applicant, the Department found that both hospitals demonstrated a record of successful operation with adequate management experience, and both demonstrated the ability to finance the project and compliance with state and federal law.

133. With respect to the consideration of compliance with “other regulations” as referenced in S.C. Code Ann. § 44-7-210(B) ¹⁷ of the CON Act and S.C. Code Ann. Reg. 61-15 § 307.1, the Department explained that the CON program has interpreted the reference to require compliance with CON regulations given the multitude of non-CON related state and federal regulations with which applicants must comply. ¹⁸ The Department also explained that if the CON program were to anticipate an applicant having a problem with regulatory compliance outside of the CON Act and its regulations, it could consult with other Department staff and use the PRC “Ability to Complete the Project” to address a regulatory concern.

134. In its decisions to approve SMC’s and MUHA’s CON applications, the Department addressed each PRC considered most important by the Department and made findings under Regulation 61-15 § 501 of the South Carolina Code of Regulations. The Department addressed the fact that MUHA and SMC challenged each other’s application and found that neither presented sufficient reasons to deny the applications.

135. The Department also informed each applicant in its approval letter that “[t]he issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes,” which acts as a disclaimer that compliance with the CON regulations does not ensure compliance with requirements administered by other regulatory divisions. In its letters approving both CON applications, the Department did not identify any “other regulations,” outside of the CON regulations, with which SMC or MUHA had to comply.

136. The Department’s CON reviewer who approved the applications did not recall MUHA raising the issue of SMC’s compliance with other regulations, such as licensing regulations, and the reviewer therefore did not consider SMC’s compliance with licensure requirements during the review process. Ms. Murdock testified that she did not inquire with the Department’s licensing division, nor did she list the ability to complete the project as a PRC. She further offered that the Department’s CON Division did not make a determination in this case

17. Subsection 44-7-210(B) states that, “[t]he department may not issue a Certificate of Need unless an application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations. Based on project review criteria and other regulations, which must be identified by the department, the department may refuse to issue a Certificate of Need even if an application complies with the South Carolina Health Plan.”

18. Within the Department itself there are several regulatory divisions to include licensing, planning and construction, certification, radiological health, and drug control.

regarding licensing compliance, which is not within the CON program's purview to enforce S.C. Code Ann. Reg. 61-16.

137. In fact, the CON division indicated that it would be premature to analyze the licensing regulations with respect to birth and admission thresholds because it would not be possible to determine the time period at issue. The Department also acknowledged that an applicant for licensing can request an exception to the licensing standards based on patient safety and other factors.¹⁹

138. The Department found that both projects furthered the purposes of the CON program.²⁰ The Department determined that both projects fostered cost containment and the potential costs to patients was reasonable. The Department concluded that SMC's project was not an unreasonable duplication of services because the addition of another Level III NICU had benefits that outweighed any negative effects. The Department recognized that both MUHA and SMC were outstanding hospitals that provided high quality services. Lastly, with respect to guiding the establishment of health facilities and services that best serve the public needs, the Department noted that SMC's project would improve access for families who need NICU services without having to travel to MUHA on the Charleston peninsula, and SMC's project would provide a NICU option and redundancy in a coastal region that is prone to flooding.

VII. ARE THE CON APPLICATIONS COMPETING?

139. As an initial matter, it is necessary for the Court to first make a finding as to whether the CON applications are competing, as MUHA contends, because if the applications are competing, the Court must compare each application and determine which one "most fully complies with the requirements, goals, and purposes of [the CON Act] and the State Health Plan, Project Review Criteria, and the regulations adopted by the Department" In other words, if the applications are competing, the Court may only approve one of the applications. *See* S.C. Code Ann. § 44-7-210(B). If the applications are not competing, then the approval of one application

19. In the Order Denying Motion to Lift Stay, the Court expressed concern with the Department's ability to grant exceptions to licensing requirement because it was not readily apparent that an affected party is afforded an opportunity to contest such a decision. As will be explained, this issue has been resolved.

20. The South Carolina CON Act states that "[t]he purpose of this article is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." S.C. Code Ann. § 44-7-120.

does not preclude the approval of the other, and the Court must determine whether each application on its own merits complies with the Health Plan, PRC, and other applicable regulations.

140. It is undisputed that both applicants intend to provide similar services in the same service area and that MUHA's CON application was received by the Department within 15 days after Notice of Affected Persons for SMC's application was published in the *State Register*. See S.C. Code Ann. Regs. 61-15 § 103.6. Thus, the question becomes whether the approval of both would exceed the need for NICU services in the service area as outlined in the State Health Plan.

MUHA'S POSITION ON COMPETING APPLICATIONS

141. MUHA claims that the Department erred in concluding that the CON applications were not competing. MUHA contends that because there is no stated need for NICU bassinets in the Health Plan, the approval of both projects would exceed the demonstrated need, or lack thereof, identified in the State Health Plan. As such, MUHA believes each applicant must demonstrate the need for additional NICU bassinets. MUHA avers that the need for services would be exceeded because birth rates in the area are declining, and SMC has admitted that the NICU patients it will serve are those who would have otherwise gone to MUHA. MUHA further contends that because there is a finite number of patients and a limited number of sick babies, the babies should be treated in a central location, which is the concept behind regionalization.

142. MUHA also alleges that SMC's project would exceed the need for services in the service area because SMC transfers a limited number of babies and mothers to MUHA, and therefore, the SMC project will be a "low volume" NICU provider. MUHA further asserts that because SMC's patient population is able to ultimately access care at MUSC, through a transfer or otherwise, there is no "barrier" to care.

143. In 2017, when the Department considered CON applications for NICU bassinets submitted by SMC and MUHA, it deemed the applications to be competing. The Department did not approve SMC's CON application for 6 Level III NICU bassinets at a time when the Health Plan projected a need for 14 NICU bassinets. However, at that time MUHA had applied for all 14 NICU bassinets and there was not a Health Plan exception such as standard 1(e), as there is now, that permitted a high-volume Level II provider to apply for Level III bassinets absent a projected bed need. Therefore, in 2017 the Department had to consider the two applications competing, and in that situation found that MUHA's application most complied with the CON Act, the Health

Plan, and the applicable regulations. By contrast, here, the Department found the applications were not competing and therefore evaluated each independently.

SMC'S POSITION ON COMPETING APPLICATIONS

144. SMC agrees with the Department that the current CON applications are not competing and therefore both can be approved because SMC and MUHA are seeking approval of their respective NICU bassinet projects using different Health Plan standards and the need for services in the area would not be exceeded if both applications were approved. SMC contends that MUHA was approved as a high-volume provider that could justify additional bassinets under Section 1(d) of the Health Plan, whereas SMC satisfied the volume thresholds in Health Plan NICU Standard 1(e). SMC's expert health planner opined that because the Health Plan clearly recognizes two separate exceptions for approval of CON applications even where there is not a projected need for Level III bassinets in the Health Plan, the exceptions are independent of each other, and both CON applications can be approved.

145. SMC also contends that the applications should not be considered competing because MUHA can justify adding Level III capacity due to very high utilization of its existing bassinets—at times 100% occupancy—even though it has expanded the number of bassinets significantly over the past few years. MUHA's need for additional six bassinet capacity, however, does not obviate the need for SMC's project because SMC is a high-volume Level II provider that meets the thresholds to become a Level III provider.

146. SMC disagrees with MUHA's contention that because there are a finite number of patients who need neonatal services, the need for NICU services would be exceeded by approving SMC's application. While SMC believes that there is a finite number of patients for most health services, the question whether CON applications for NICU services are competing depends on how many patients there are who need the particular service and what reasonable levels of utilization can be predicted for the two projects.

147. SMC contends that the need for NICU services will not be exceeded if both applicants are approved because SMC has documented that it can grow its NICU program and that MUHA has the opportunity to increase its Level IV utilization given MUHA's statewide referral network of hospitals, to include facilities in Lancaster County, Columbia, and Florence. Moreover, MUHA's CON application projections indicate that after adding 6 Level III bassinets, it would grow to 15,653 NICU patient days in 2024 after reporting 11,575 patient days in 2020.

Thus, if SMC's 6 Level III bassinets were to redirect 1,832 patient days from MUHA, MUHA would still have 13,821 NICU patient days, which is 2,246 more patient days than it had in 2020, the year it applied for six more bassinets.

148. The Court finds that the two CON applications are not competing (1) because there are two independent Health Plan exceptions that permit the Department to approve, in the absence of a projected bed need, CON applications for additional NICU bassinets to include a high volume Level III or IV provider exception, and a high volume Level II provider exception; and (2) because, as set forth in more detail *infra* in the PRC Compliance section, the approval of both applications will not exceed the need for NICU services in the service area. As such, the Court will review each application independently and determine if each satisfies the CON Act, its regulations, and the Health Plan.

VIII. COMPLIANCE WITH THE 2020 HEALTH PLAN NEONATAL STANDARDS

SMC'S COMPLIANCE WITH STANDARD 1(e)

149. As stated above, SMC applied under Health Plan Standard 1(e) because it is a Level II nursery seeking to become a Level III NICU and there was no projected need for Level III bassinets in the Health Plan. In its CON application, SMC reported that as of June 30, 2020, it had 2,708 births and 3,734 Level II patient days in the previous 12 months. In 2021, there were 2,424 births at SMC, and 2,988 Level II patient days, which is well above the birth and patient day thresholds in NICU Health Plan standard 1(e). At the time of the hearing, SMC's annualized birth volume was 2,610 babies in 2022, and 3,100 Level II patient days. MUHA did not provide any credible evidence challenging these numbers. Therefore, the Court finds that SMC complied with, and continues to comply with, Health Plan Neonatal Services Standard 1(e).

MUHA'S COMPLIANCE with State Health Plan Standard 1(d),

150. In its CON application, MUHA set forth the usage rate of its existing 46 Level III/IV bassinets, as of February 2020, when its new Children's Hospital opened, based on 16,790 bassinet days available. The capacity increased over 10% from two years earlier based on the 46 NICU bassinet count. MUHA projected 2024 utilization of 15,653 intensive care patient days in its CON application. At 16,790 bassinet days available with 46 bassinets, MUHA's projected 2024 capacity is 93.2%. ²¹

21. 15,653 patient days / 16,790 bassinet days available = 93.2%.

151. MUHA also documented in its CON application significant population growth in both its primary and secondary service areas, which revealed a service area with a strong and growing population. MUHA demonstrated that the 6 NICU bassinets would relieve capacity constraints, which would allow MUHA to better meet the needs of the growing service area population.

152. Additionally, MUHA's Chief of Neonatology testified that at times MUHA's 46 NICU bassinets are 100% utilized, which is significant because just three years earlier, in 2019, MUHA was operating only 16 NICU bassinets. MUHA, therefore, has increased the number of NICU bassinets by 287% in just a couple of years and believes an additional 6 NICU bassinets are still needed. MUHA witness Dr. Cahill confirmed that there is a need for the additional 6 NICU bassinets because there are times when MUHA operates at capacity. MUHA needs to meet the needs of the PR-V population, as well as the changing needs of ELBW babies who have longer length of stays, which means they are occupying MUHA's bassinets for longer periods of time.

153. Based on the data set forth in MUHA's CON application and the respective testimony of MUHA's neonatologists regarding the capacity and utilization of MUHA's NICU bassinets, the Court finds that MUHA's application complies with Neonatal Services Standard 1(d).

IX. COMPLIANCE WITH APPLICABLE PRC

SMC'S APPLICATION

i. Compliance with the Need Outlined in the Health Plan

154. The Department determined that SMC complied with the need outlined in the Health Plan, PRC § 802.1, and, as discussed previously, the Court concurs.

ii. Community Need Documentation- Utilization

155. The Department determined that SMC complied with PRC § 802.2, Community Need Documentation. To meet the Community Need Documentation PRC, an applicant must satisfy the elements set forth in S.C. Code Ann. Regs. 61-15 § 802.2 (a) – (e). Based on the following findings, the Court concludes that the Department correctly determined that SMC complied with this PRC.

156. SMC's CON application identified the target population as the same service area from which its 2019 OB discharges originated, and it expects that most of its Level III patients will be drawn from the same service area, which is comprised of Dorchester, Berkeley, Colleton,

and portions of Charleston County—primarily the North Charleston area. The Court finds this assumption to be reasonable. The Court also finds that given the volume of deliveries at SMC from patients who originate from Colleton and Orangeburg Counties and the testimony of SMC's obstetricians who treat expectant mothers from these counties, it is reasonable to include these counties in SMC's target population for Level III services. SMC also referenced in its CON application that underserved populations were more susceptible to higher IMRs, and it provided information at the hearing that its Medicaid population, which has limited access to healthcare services, comprises nearly half of SMC's deliveries. The Medicaid patient population has limited access to health care, experiences poverty, and at times struggles with transportation, even to see SMC's obstetricians. Many Medicaid patients are single without a solid support system. An SMC obstetrician testified that if she has to transfer Medicaid patients to MUHA, it can create difficulty for the mother, especially if the neonate has an extended length of stay.

157. SMC set forth in detail its population growth expectations and the methods appear to be reasonable. SMC's CEO testified that many new families are moving into his service area daily, and that major corporations as well as companies supporting the Port of Charleston are establishing a presence in SMC's service area as well. This expected growth in population in the Tri-County Area was a theme repeatedly echoed by MUHA in its CON application to support its request for additional NICU bassinets, as referenced *supra*, which underscores the reasonableness of SMC's methods.

158. Although SMC is reducing its Level II NICU bassinets from 16 to 10 to accommodate the conversion to 6 Level III bassinets, to the extent it requires additional Level II NICU bassinets, which do not require a CON, SMC can build out additional Level II bassinets in space adjacent to the existing unit.

159. SMC's health planning expert testified that SMC's NICU would enhance the regionalized system of perinatal care in PR-V given that presently PR-V has only one Level III NICU provider to serve a population of 1.2 million people, which is the highest ratio of population to NICU program in any PR in South Carolina. In other words, similarly populated PRs in the State are served by more than one Level III provider.

160. When comparing South Carolina to other states in the Southeast, South Carolina has the lowest number of Level III/IV NICUs per 100,000 females in the 15-44 age category. If

SMC were added to the inventory of NICUs in South Carolina, the state would still have the lowest number of NICUs per 100,000 females ages 15-44.

161. At the hearing, SMC presented updated utilization projections to account for a 2023 start date; to account for the COVID-19 year; and to account for an increased 2022 volume of 2,610 deliveries at SMC, per its CEO's testimony. SMC's health planner used a 1% growth rate to reflect the likely increase in births at SMC due to its Level III status, and he applied a revised ratio of Level III days to births across the state to reflect a realistic assessment coming out of the pandemic.

162. SMC's updated projection of 132 Level III NICU patients by the year 2025 was very close to the third-year projection of 131 NICU patients set forth in its CON application. Moreover, using the Health Plan formula of 3.25 Level III bassinets per 1,000 births, SMC would show a need for nearly 9 Level III NICU bassinets from 2023 to 2026. I find these assumptions and projections to be reasonable given the reasons SMC's health planning expert provided.

163. SMC is very likely to see a faster than 1% increase in births annually because Berkeley and Dorchester Counties have seen the fastest growth in births in recent years (2015 to 2020), because some of the patients who are transferred to MUHA physicians prior to admission will be served at SMC, and because the presence of a Level III NICU will attract some expectant mothers who want to deliver in a hospital with more specialized neonatal services. The Court finds that these factors could lead to a greater volume of deliveries at SMC and more utilization of SMC's NICU than it projected.

164. SMC presented evidence that in 2021 it had approximately 85 inpatient expectant mothers and neonates transferred to MUHA for perinatal services. Data maintained by MUHA indicates that there were 30 neonatal transfers from SMC in 2021, and 14 were considered VLBW neonates. Of the 59 expectant mother inpatient transfers to MUHA, 29 gave birth to neonates, and 17 were considered to be VLBW neonates.²² Therefore, a total of 31 VLBW neonates were either

22. In an effort to discredit SMC's NICU projections, MUHA's health planner presented an analysis that compared only the inpatient neonatal transfers from SMC to MUHA with SMC's three-year projections in the application, even though the data in MUHA's possession clearly indicate that significant Level III deliveries at MUHA result from SMC's inpatient maternal transfers to MUHA. For example, in 2021, MUHA's own data indicate that 29 neonates delivered at MUHA following an inpatient maternal transport from SMC. Of these neonates, 24 were delivered at less than 32 weeks, and 17 were considered VLBW babies. In South Carolina, only a Level III NICU can manage babies delivered at less than 32 weeks. S.C. Code Ann. Regs. 61-16 § 1306(B) and (C). Even though MUHA's own documents indicate that it received 30 neonatal transfers from SMC in 2021, MUHA used *only* the 24 neonatal transfers to make its comparison

neonatal transports from SMC to MUHA or delivered from women who were inpatient transfers from SMC. SMC's MFM Director testified that 50 of the inpatient expectant mothers who were transferred could have avoided a transfer and remained at SMC if SMC had a Level III NICU.

165. SMC also offers that another source of potential Level III NICU neonates at SMC will be women who could have remained and delivered at SMC if it had a Level III NICU but who instead had their OB care transferred to MUHA on an outpatient basis before they ever presented to the hospital in labor. The evidence established that obstetricians who deliver at SMC often identify high-risk pregnancies in their office practices and refer them to MUHA before delivery, and therefore, before these mothers are admitted to SMC. Because of these outpatient mother transfers, SMC asserts that simply observing the neonatal transfers would not be indicative of the expected number of neonates who could be served at the SMC NICU. MUHA acknowledged that one reason an SMC obstetrician or MFM physician might transfer the outpatient care of an expectant mother to MUHA is because the neonate may require a Level III delivery.²³

166. SMC's health planner interviewed three SMC MFM physicians and a small sample of 6 of the 30 OB physicians on SMC's medical staff about the volume of high-risk expectant mother outpatient transfers they made to MUHA annually, and the volume estimate ranged from 84 to 107 annual outpatient transfers.²⁴ He then offered that, in addition to SMC's 59 neonatal and inpatient maternal transfers to MUHA that were recorded in 2021, SMC demonstrated that there was a range of another 168 to 215 high-risk expectant mother outpatient transfers to MUHA on an annual basis, thus meeting Reg. 61-16 § 1306(C)'s requirement that a Level III NICU transfer at least 100 neonates prior to delivery to a higher level perinatal hospital. The Court disagrees with this assertion. The plain reading of Reg. 61-16 § 1306(C) does not support counting outpatient

to SMC's three-year neonatal projections. Had MUHA used the correct 2021 neonatal transfer volumes from SMC as well as inpatient maternal transfers from SMC that resulted in birth, when comparing SMC's three-year projections to the transfers, it would have been comparing 59 actual neonates to SMC's first year NICU utilization projection of 79 neonates, instead of 24 neonates to 79 neonates. Comparing only neonatal transfers to SMC's projections mischaracterizes the volume of patients who would benefit from SMC's Level III unit.

23. As will be explained, the Court does not believe the transfer of outpatient mothers directly to MUHA can be used by SMC to satisfy the maternal transfer provision under Reg. 61-16 § 1306. Nevertheless, SMC's evidence of outpatient transfers supports its position regarding the need for NICU services.

24. MUHA's Chief of Neonatology was not aware if MUHA tracked pre-delivery outpatient transfers from SMC physicians to MUHA physicians.

transfers by OBs to MUHA for purposes of the maternal transfer requirement.²⁵ Nevertheless, although it did not clearly quantify these numbers, SMC demonstrated that there were additional sources of admissions to SMC's Level III NICU to include expectant mothers who choose not to deliver at a hospital unless it has a Level III NICU and mothers who are undergoing *in-vitro* fertilization.

167. SMC also projected the volume of VLBW babies it expects to serve based on a reasonable assumption that 1.7% of births in PR-V were VLBW babies. When applied to SMC's birth volumes, SMC expects that 42 to 43 births at its NICU each year will be VLBW, based on birth volumes less than what its CEO estimated for 2022. Given that SMC is already transferring 31 VLBW babies each year to MUHA, the Court finds the VLBW projection, and the methodology used to be reasonable.

168. To further support its position that there is additional need for NICU services in the service area, SMC demonstrated that MUHA's NICU volumes have increased significantly from 2005, when it had 16 NICU bassinets and reported 5,197 NICU patient days, to 2020, when it had 34 NICU bassinets and reported 11,575 patient days, which is a 123% increase. MUHA projects in its CON application that by 2024, its NICU will be utilized at 15,653 patient days, which is 4,078 more patient days than it reported in 2020. From 2020 to 2021, MUHA experienced over 1,000 NICU patient days of growth alone and, according to its neonatologists, MUHA's NICU bassinets are at times 100% utilized.

169. MUHA acknowledged that it expects its neonatal population to grow more so than what MUHA receives directly from PR-V based on the NICU referrals that it receives from all over the state due to the specialized services it offers. Additionally, MUHA is currently recruiting three more neonatologists and replacing one that is retiring.

170. In 2020 and 2021, when compared to the RPC and non-RPC NICU providers, SMC was the fourth busiest hospital in terms of birth volume. SMC currently has a very busy MFM practice with three board-certified MFM physicians who experience 900 to 1,200 patient

25. Although Ms. Murdock testified that interpretation of Reg. 61-16 § 1306(C) should be left to the DHEC Licensing Division and that interpretation of this regulation was outside the scope of her responsibility, when pressed during cross examination, she offered her personal opinion that Reg. 61-16 § 1306(C) only encompasses facility to facility transfers: "My understanding of transfer involves a hospital to hospital or faci --- some facility to a hospital movement of a patient."

encounters per month, which are typically routine or emergency consultation requests from OB/GYN physicians at SMC.

171. The Court finds that SMC has adequately demonstrated the need for additional NICU services at SMC based on the overall growth in utilization in the service area.

iii. Community Need Documentation – Medical Considerations of the Population

172. SMC introduced testimony from its Director of the MFM Program and two obstetricians on its medical staff who identified a defined healthcare need of the target population that would be met by SMC's Project.

173. Per the March of Dimes 2021 Report Card, South Carolina scored an "F" in terms of preterm birth rate, and its IMR is well above the national average and has remained relatively unchanged from 2009 to 2019. South Carolina's IMR compares unfavorably to the rest of the United States even though South Carolina is considered more regionalized in terms of perinatal care when compared to the rest of the United States.

174. Patient choice is an important concept because patients become comfortable with their physician or "medical home," and continuity of care is central to quality prenatal care for the patient. Bonding between the patient and obstetrician is critical to ensure trust because the physician takes care of two patients when the mother is expecting. When complications during pregnancy arise, the trust and bonding between the physician and the patient becomes overly critical to prevent the patient from focusing on the worst-case scenario.

175. Expectant mothers who are so high-risk that their original obstetrician can no longer be involved in their care are transferred to a place they may have never been, and when transferred to MUHA, will be cared for by physicians with whom they are unfamiliar. If the care becomes a long-term admission, the patient is separated geographically from her home, work, and at times, family. This separation can be especially trying when the expectant mother has multiple children who are cared for by a spouse, grandparent, or friend, and the expectant mother is severed from her support system in an unfamiliar hospital where she does not know anyone, all of which can lead to anxiety and stress that could be avoided.

176. Moreover, the referral of the patient to a new facility with new providers greatly undermines the continuity of care and the benefits that stem therefrom. This break in the continuity of care from a patient's usual provider to a new provider could lead to the new provider missing

important information, especially with a patient who is under stress and is unable to provide a comprehensive history of her care and complications.

177. The delivery of a VLWB baby at SMC who then requires transport and transfer to MUHA, may result in separation between mother and baby, which disrupts fetal bonding that can lead to full-blown, postpartum depression, breast feeding issues, and problems caring for the newborn. Because of the length of time a newborn may need to be in the NICU, the mother may have to go back to work before her baby has left the NICU, which may mean the mother cannot be as involved in day-to-day care. This can be devastating to the mother and result in a higher rate of postpartum mental illness.

178. SMC treats a significant volume of patients who rely on Medicaid for healthcare reimbursement. These patients have higher risk pregnancies, a higher pre-term birth rate, and higher rates of not availing themselves of all the prenatal visits to which they are entitled. Medicaid patients may have issues with transportation or referrals to other physicians, even those 15 minutes away, and Medicaid mothers may not be able to see their critically ill newborns as often because they lack the necessary resources.

179. A Level III NICU at SMC will foster the continuity of care through the entire pregnancy, allowing mothers to stay in a healthcare system closer to home, which will allow them to spend more time with their newborns. This increased access will also foster higher breast-feeding rates and lower post-partum depression because there will be less separation between mother and baby and more access to the family support team. Increased bonding fosters well-being for both the mother and child. In terms of the patients who already have to travel long distances to SMC, adding an additional period for travel to MUHA to access Level III care could be an insurmountable obstacle. Some patients who deliver at SMC travel long distances from Orangeburg, Cottageville, Ridgeville, Bowman, Santee, St. George, which are towns in the geographical area between Summerville and Columbia. One SMC obstetrician testified that 50% to 60% of her patient population is high-risk, which consists of mothers with chronic hypertension, pre-gestational diabetes and pre-rapid BMI, which can add to patients developing other comorbidities throughout their pregnancy.

180. A Level III NICU at SMC will enhance the quality of care because there will be limited separation between mother and baby which fosters skin to skin care between mother and baby; bonding will be easier, and lactation care will be more accessible. When a neonate requires

transfer from SMC to MUHA for higher level care, another issue that SMC's obstetricians encounter at MUHA is there may not be an available bed for the mother, which is an access impediment.

181. Piedmont's CON application referenced a number of mothers and infants from the York County area, which borders the Charlotte area, who were being served by providers in Charlotte, and traveling was causing a financial and emotional burden for families related to travel expense, housing, separation anxiety, and decreased bonding. In the Piedmont CON application, MUHA's health planner references the fact that, like SMC, physicians sent expectant mothers, who were high-risk, to higher level providers in Mecklenburg County, which took volume from Piedmont. SMC may also experience lost volume through transfers that could be avoided. It is reasonable to believe that mothers at SMC, whose infants are transferred to MUHA, will experience issues similar to those experienced by mothers at Piedmont.

182. Furthermore, a MUHA witness admitted that EMS transfers can cause destabilization in neonates and changes in physiological status to the extent that 35% have a decompensation. Dr. Phibbs admitted that transferring neonates from one hospital to another can be physiologically disruptive to the neonate.

183. The Court finds that testimony of SMC's MFM/OB witnesses compelling and it demonstrates that a NICU at SMC will fulfill an important medical need of the target population.

MUHA's Opposition

184. At the hearing, MUHA asserted that the Department erred in finding that SMC complied with the Community Need PRC, based primarily on the following reasons: obstetric admissions in the service area have been in decline; the birth rate in the service area is in decline; SMC has experienced decreasing obstetric admissions; SMC does not transfer enough neonates to justify the addition of 6 NICU bassinets; SMC's methodology and assumptions with respect to projecting Level III utilization were deficient; SMC's admissions, if all were VLBW neonates, would constitute a large portion of service area VLBW neonates and SMC's Level II patient days would exceed the capacity of its available Level II bassinets.

185. Regarding MUHA's contention that the birth rate has been in decline, MUHA's health planner relied upon birth trends for the Tri-County Area from 2016-2018, meaning the data is now five to seven years old. SMC's health planner testified that because the overall population that SMC serves is located within high-growth areas, he expects to see a larger number of births.

In fact, from 2015 to 2020, the number of births in Berkeley and Dorchester Counties, which is SMC's primary service area, increased 2.0% and 4.1% respectively.

186. Regarding the volume of obstetric admissions in the service area, MUHA's exhibit detailing the decline in such admissions from 2017 to 2021 actually shows growth in obstetric admissions from 2017 to 2020, and 2021 included just one-half year of annualized admissions. Also, while SMC did experience a decline in year over year births from 2020 to 2021, SMC's CEO testified that the expected annualized birth volumes at SMC would exceed 2,600 for 2022, which undercuts MUHA's testimony that birth volumes would continue to decline at SMC from 2020, an anomalous year impacted by Covid.

187. MUHA's health planner testified that SMC does not transfer enough neonates to demonstrate a need for the project. However, MUHA misstated the number of neonatal transfers from SMC to MUHA in 2021 as 24, when MUHA's own documentation indicates there were 30 neonatal transports and another 29 infants who were delivered at MUHA following an inpatient maternal transport from SMC, which totals 59 neonates. Moreover, MUHA discounts other factors which will undoubtedly result in higher usage of SMC's NICU.

188. MUHA asserts that SMC's methodology and assumptions regarding projecting Level III utilization are deficient. To argue this point, MUHA presented a slide that included a utilization analysis prepared by Mr. Sullivan that had been revised and adjusted by MUHA's health planner. The modified slide applied an adjusted ratio of Level III NICU days to births to show that SMC's utilization was overstated. Mr. Sullivan disagreed with the adjustment because he projected need at SMC in three different ways: he used a statewide ratio of Level III days to births, a ratio of non-RPC Level III days to births, and a state-wide projected number of bassinets to births. Each method produced a consistent result that by year three of operations SMC's NICU bassinets would be over 79% utilized. Mr. Levitt, however, took a baseline ratio number developed from two low delivery non-RPC's from the COVID-19 year, 2020, which is a low point in Level III days in recent times, and assumed that would be the experience going forward, which is not as reasonable.

²⁶ SMC's CEO testified that the expected number of births at SMC for 2022 was going to be 2,610, or 271 more than Mr. Levitt predicted for 2022, which means there is no trending decline from

26. The rate of Level III days to births was significantly lower in 2020 (the COVID-19 year) than it was in 2018 and 2019.

2020 and no reason for Mr. Levitt to include a decline in his adjustments to SMC's Level III admission projections.

189. Mr. Levitt, in challenging SMC's NICU projections during MUHA's case in chief, adjusted the ratios of NICU days to births, and projected that SMC would have 71, 69, and 66 NICU admissions during the first three years of operation, and therefore concluded that SMC would be a "low volume" NICU provider. Assuming, *arguendo*, that Mr. Levitt is correct, SMC would still have higher birth volumes than two of the non-RPC Level III programs operating in the state that reported NICU data separately in 2020 and 2021. Mr. Sullivan also noted that Mr. Levitt projected only 73 NICU admissions for the third year in the Piedmont NICU application Mr. Levitt drafted, and there was no indication in the CON application that Piedmont was a low volume NICU or would operate anything but a high quality NICU.

190. During MUHA's rebuttal testimony, Mr. Levitt presented yet another utilization analysis whereby he ratcheted down SMC's Level III NICU admissions even lower to 49 admissions and 683 NICU patient days by year three of operations. In other words, MUHA's health planner contended that SMC overstated its third-year projection of 1,832 NICU patient days by 1,149 patient days. The Court does not find this analysis to be convincing for three reasons: (1) because SMC had a 2021 documented combined 59 neonatal and maternal inpatient transfers to MUHA, which resulted in NICU births, it seems improbable that the number of admissions at SMC would not eclipse 50; (2) Mr. Sullivan set forth more than one methodology to project the number of bassinets required in its NICU, one of which showed that SMC could require as many as 8 NICU bassinets based on its delivery volumes;²⁷ and, as will be demonstrated *infra*, (3) MUHA disavowed all of its revised patient day projections for SMC when it chose to use SMC's third year NICU patient day projection of 1,832 in its adverse impact analysis. If MUHA firmly believed that SMC would be so underutilized, it should have used its health planner's revised NICU projections in its adverse impact analysis.

27. Dr. Holcomb testified that the CDC and the March of Dimes have concluded that using a percentage of between 6% and 8% of live births will derive a NICU admissions volume. Thus, if SMC delivers 2,610 babies, which is the annualized volume its CEO reported, SMC's NICU admissions would range between 156 and 209, making Mr. Sullivan's third year projection of 131 NICU admissions for SMC conservative. It is also important to note that a Level III NICU treats much more than neonates weighing less than 1500 grams or requiring a ventilator for more than 24 hours, or surgery, as referenced in the regulations, such as babies who have a variety of conditions that would not be appropriate for a Level II.

191. MUHA also challenged SMC's 14-day average length of stay ("ALOS") assumption claiming that SMC understated the ALOS in its utilization projection calculation and that, if Mr. Levitt's assumption were applied, SMC would show fewer projected NICU admissions. Mr. Sullivan testified that ALOS varies dramatically from NICU program to NICU program and that MUHA's most recent data indicated an ALOS of 19.5 days combined for Level III/IV patients.²⁸ Mr. Sullivan did not believe it was reasonable to assume an ALOS of 22.3, as Mr. Levitt did in his challenge to SMC's projections, because SMC is going to serve a less acute population than MUHA. Mr. Sullivan indicated that he also consulted HCA on the ALOS number and it felt that a 14-day ALOS was consistent with its experience in the southeast.

192. Mr. Sullivan does not believe it is reasonable to use discharges, rather than admissions, to calculate ALOS, as Mr. Levitt suggested, because Level III neonates are often "stepped-down" to Level II care after their conditions improve, which can be seen in MUHA's reported Level III numbers, where there are many more patients admitted to its Level III than are discharged. Mr. Sullivan further did not believe it reasonable to utilize an ALOS of a lower volume program with very few admissions.

193. On cross examination, Mr. Levitt admitted that the ALOS for Piedmont's 5 bassinet NICU was 14 days based on 73 Level III NICU admissions and 993 patient days, which is exactly the same ALOS assumption Mr. Sullivan used for SMC's utilization projections.

194. Mr. Sullivan opined that it is not reasonable to simply identify in isolation, as Mr. Levitt did, a neonate who had a 24 day length of stay from an SMC transfer document when challenging SMC's ALOS because the 24 day stay included the neonate's entire stay and did not indicate whether the neonate had been stepped down from a Level III bassinet to a Level II bassinet and, because there are also many Level III neonates who only spend a few days in the unit, the length of stay averages out.

28. SMC presented data showing 2020 utilization of RPCs and non-RPC NICUs. Two of the non-RPC NICUs that reported Level III admissions *had under 40 Level III NICU admissions*. The ALOS of all the NICUs varied significantly, and at the lower volume non-RPC NICUs, the ALOS was higher than at the RPCs. SMC reviewed 2021 ALOS for the Level III NICUs, and they ranged broadly from a low of 7.7 at McLeod Regional to a high of 28.7 at Self Regional, which had only 22 Level III NICU admissions in 2021. SMC projects 132 NICU admissions, or six times as many as Self Regional.

195. The Court finds SMC's ALOS assumption to be reasonable because SMC will be a higher volume provider than some of the other non-RPC Level III units, and the complexity of care of its Level III neonates will be less than MUHA's.

196. MUHA presented a slide that indicated that if all of SMC's projected NICU volume in the CON application were all VLBW babies, it would constitute 87.9% of all VLBW babies delivered in the Tri-County Area in 2018. When questioned about the slide, Mr. Levitt admitted that he was giving SMC the benefit of the doubt and that it would equate to a large percentage of the service area VLBW babies and SMC would need to achieve 75% to be above the 100 VLBW threshold. However, SMC has not indicated that it would treat 131 VLBW babies annually in its CON application and, in fact, the 131 year three volume projection includes all NICU admissions for 2024.²⁹ Moreover, Mr. Levitt admitted that there was not a requirement that SMC or any other Level III perinatal center in South Carolina achieve a threshold of 100 VLBW babies, and he recognized under the state licensing standard that references managing 100 neonatal admissions, which includes maternal transfers, a provider could be in compliance if it did not treat a single VLBW baby. The Court does not find MUHA's analysis to be persuasive.

197. With respect to MUHA's allegations that SMC's Level II NICU bassinets would be operating over 100% if SMC gets Level III NICU bassinets, Mr. Sullivan testified that the Level II patient days had leveled off to approximately 3,000 patient days in 2021, but even if the capacity of the Level II bassinets became an issue, he noted that SMC could nearly double the number of Level II bassinets without significant construction and without a CON. The Court finds that SMC can accommodate additional Level II bassinets easily if required.

198. Mr. Levitt also testified that babies above the age of 32 weeks are not the type of babies who receive Level III care to which Mr. Sullivan responded that just because a baby is above 32 weeks does not mean he or she will not have other conditions, such as respiratory problems, which require Level III care. A Level III NICU treats all babies who have a variety of conditions who would not be appropriate for a Level II. Mr. Sullivan identified an example whereby a 40-week baby weighing 4,730 grams (roughly ten pounds) was on a ventilator for 11 days, which meant the baby had to be transferred to a Level III NICU per the South Carolina regulations. The Court finds that SMC will treat some neonates in its Level III unit who are above the age of 32 weeks.

29. In fact, SMC projected that it would treat 43 VLBW babies by the third year of operations.

199. With respect to Community Need Documentation, based on the foregoing, the Court finds that SMC complies with PRC 802.2 because it adequately identified the target population, including the Medicaid and underserved populations served by SMC; it adequately addressed the population elements with respect to its service area; it satisfactorily documented the needs of the target population to include the assumptions and methods used to determine the level of need, as well as the clinical needs of the patient population that is currently being transferred from SMC to MUHA; and it can expand if necessary in the event more Level II bassinets are required. The Court also finds the projected utilization of SMC's NICU bassinets at 80% by year three of operations to be reasonable, if not understated for the reasons set forth above.

iv. Distribution (Accessibility)

200. The Department concluded that SMC complied with PRC § 802.3, Distribution (Accessibility). To comply with this PRC, the applicant must demonstrate that it satisfies the elements of S.C. Code Ann. Regs. 61-15 § 802.3. In its application, SMC indicated that its site would be appropriate for a Level III NICU given its location 24 miles inland from MUHA, and it referenced the issues its service area patients have with respect to the distance they must travel to MUHA for Level III services and the peninsular flooding that makes travel and access to MUHA even more difficult. At the hearing SMC indicated that the issue is not solely the time it takes to transport a neonate from SMC to MUHA by ambulance. The need for reduced travel time is magnified for some families of neonates requiring a NICU because they may lack a vehicle or be unable to afford the cost associated with daily travel and there is limited public transportation options in the Charleston area.

201. To support its position that flooding can impede access to the peninsula, SMC presented MUHA's CON application for its Berkeley County Hospital ("Berkeley Hospital") which is planned for the Summerville area. The application is dated December 27, 2017, approximately three years prior to MUHA's and SMC's applications in the instant case. In its Berkeley Hospital CON application, MUHA represented to the Department that:

Patients travelling to MUHA's downtown campus for care encounter many unforeseen challenges when it floods. MUHA's campus is located in a major flood zone and when it rains at high tide, this portion of the peninsula shuts down, delaying patient care and inhibiting access points. . . . The new Community Hospital will allow for MUHA to decant cases from the peninsula during severe flooding and prevent the delays in patient care that occur today.

202. MUHA also included in its CON application for its Berkeley Hospital several images of the MUHA campus depicting severe flooding, including a photo of its Children's Hospital under construction, and surrounded by water. The images of flooding shown in the MUHA Berkeley Hospital application were related to rainfall from tropical storm Irma.³⁰ Although MUHA witnesses indicated that flooding was rare,³¹ and biking to work was routine, MUHA clearly believed that flooding on its campus was significant enough to justify construction of Berkeley Hospital and to ensure that its Children's Hospital was heavily fortified from flooding and high storm winds so that it could "defend in place" during significant weather events.

203. SMC introduced a map into evidence which was posted in the elevators at MUHA to give visitors and employees an indication of where flooding may occur around the MUHA campus and to warn of the dangers of flooding. The map included several images of MUHA campus streets including Jonathan Lucas Street, Ashley Avenue, Doughty Street, Courtenay Drive, Calhoun Street, and Ehrhardt Street. The map includes an inset with the title: "TURN AROUND, DON'T DROWN" and then provides the following warnings: "Six inches of moving water can make you fall;" "Do not drive in flooded waters;" "Six inches of water will reach the bottom of most passenger cars causing loss of control and possible stalling;" "a foot of water will float many vehicles;" "Two feet of rushing water can carry away most vehicles."

204. While MUHA's former Director of Major Construction Projects testified that during his ten and a half year tenure at MUHA, there were only six major flooding events —similar to the flooding caused by tropical storm Irma. SMC also referenced data from the City of Charleston which reported 89 flooding events in 2019 alone, which SMC's health planner indicated was not unusual, and which referenced the "medical district" that serves 75,000 patients

30. MUHA's Director of Major Construction Projects referred to the storm as Hurricane Irma. However, SMC demonstrated that by the time Hurricane Irma's path was able to affect the Charleston area, it had been downgraded to a tropical storm.

31. SMC's health planner testified that he lives on the Charleston peninsula and has personally experienced recurring flooding issues, to include two occasions around the time of this contested case hearing, in which a rainstorm, not related to a hurricane or tropical storm, caused significant flooding that impeded access to MUHA. Likewise, when Dr. Holcomb visited Charleston two weeks before his testimony to tour SMC's neonatology unit, and meet with its CEO and Director of Neonatology, he had the opportunity to drive around MUHA's campus. Dr. Holcomb recounted that it rained the day he visited for about an hour, and that streets were flooded out, the area was restricted and that he got caught in traffic that could not be negotiated because other streets were completely flooded and the traffic in and out of the hospital came to complete standstill.

annually. The medical district is the area on the peninsula where Roper, MUHA and the VA hospital are located.

205. MUSC introduced evidence indicating that the City of Charleston had undertaken significant measures to mitigate the flooding in the Charleston area through drainage projects to include the construction of tunnels and pump stations.³² MUHA was forced to acknowledge, however, that not only did the pump stations have limits such as caps, MUHA's Children's Hospital was not in the catch basin for the mitigation system MUHA referenced. SMC also showed that the goal in the mitigation efforts for flooding was a 20% reduction in the duration, frequency, and severity caused by moderate to heavy rainstorms along the access points to the medical district. While MUHA noted that another pumping system was being installed at some point in the future, flooding would continue to be a problem. MUHA also admitted that it spent significant monies to create its Children's Hospital on an island and that the City of Charleston is going to continue to fight water intrusion with a \$1.5 billion seawall project around the peninsula that will help mitigate flooding due to sea level increases.

206. During significant weather events, MUHA's Children's Hospital has the ability to lock down and the staff can shelter in place and take care of the patients who are in the building; however, during those events, no one can come in and out of the hospital. MUHA admitted that ingress and egress to its Children's Hospital would be limited during events like tropical storm Irma and that drainage of storm water determined overall access to the building.

207. With respect to neonatology transportation, Dr. Holcomb has had significant experience training for and dealing with severe weather events, such as Hurricanes Ivan and Katrina. During Hurricane Katrina, Dr. Holcomb was stationed in Biloxi, Mississippi, at Keesler Medical Center ("KMC"), which is as close to the water as MUHA's Children's Hospital. During this weather event, Biloxi, Mississippi experienced storm surges of 25-26 feet which flooded out the basement and generators at KMC and affected the electrical system for the entire hospital. In preparations for Katrina, KMC had to evacuate the NICU. Dr. Holcomb was concerned about the

32. Much of MUHA's testimony with respect to flooding focused on the effect that the flood waters would have on patient care areas at the MUHA Children's Hospital. SMC's exhibits and testimony regarding flood waters focused more on the ability of new mothers and family members to access downtown Charleston to visit the MUHA Children's Hospital more so than how the flood waters affected the patient care delivery within the Children's Hospital.

MUHA Children's Hospital because its witness testified that the generators and barrier walls were only fifteen feet above sea level.

208. With respect to EMS transport, community member transport and access for mothers and families to MUHA from Berkeley and Dorchester Counties, it can be very difficult to leave an area when a hurricane is approaching because traffic makes patient transportation more difficult. During the hurricane itself, there is absolutely no transportation via helicopter or ambulance because of significant winds. Moreover, storm surges prevent ambulance transport during the surge and afterwards because of the time it takes the surge to withdraw and the remaining debris field. Dr. Holcomb opined that if a major hurricane were to hit Charleston, it would incapacitate MUHA and there would be no access to MUHA for mothers or families seeking to visit their babies who remained at the hospital.

209. MUHA challenged SMC's assertions that traffic posed an access problem for patients who reside around SMC and beyond by presenting a travel time analysis comparing travel times from 20 SMC service area zip codes to SMC and MUHA, which purported to show that SMC's location only resulted in a short travel time savings. The travel time analysis was conducted on March 30, 2022, at 11:00 a.m. The analysis shows that SMC was quicker to access than MUHA from 15 of 20 zip codes. However, as Mr. Sullivan testified, 11:00 a.m. is the "sweet spot" in terms of travel time because it is before lunch and after rush hour. Mr. Sullivan, who is from the Charleston area and maintains a residence there, testified that based on his personal experience, the travel times can vary dramatically, and the times listed by MUHA are inconsistent with his experience and not reflective of actual road conditions that can materialize.

210. Dr. Annibale acknowledged that perhaps outside of certain areas in North Charleston, mothers and families of Level III babies who can be treated at Summerville would enjoy reduced travel times, as compared to MUHA, when visiting those neonates if they lived in Summerville, Moncks Corner, and other outlying areas in Dorchester and Berkeley County.

211. MUHA presented a travel time range between MUHA and SMC, sourced from Google Maps, which showed it could take anywhere from 28 to 50 minutes to get to MUHA from SMC, depending on the time of day. Mr. Sullivan testified that based on personal experience, he found it improbable that at 9:00 a.m. one could get from SMC to MUHA in 28 minutes, as the

Google Maps travel time indicated for a low range.³³ If patients have to travel an additional 30, 35, 40 minutes each day, one way, then it would make a material difference in travel time especially for patients who live in the northern part of the Tri-County Area.

212. As it did with flooding in its Berkeley Hospital CON application, MUHA indicated that its patients residing in the North Charleston and the Summerville areas could save up to 30 minutes travel time, one-way, by using MUHA's proposed hospital in Berkeley County over its downtown campus on the "congested" peninsula. MUHA explained in its Berkeley Hospital CON application that patients would also be able to avoid the estimated 10 to 20 minutes associated with "parking and wayfinding" when traveling to the downtown campus. The application represented that the location of MUHA's proposed hospital in Berkeley County "significantly reduces the drive time for the targeted populations of North Charleston, Summerville, and Moncks Corner with an average savings of 30 minutes and that its patients will "experience overall increased convenience and access through the project."

213. SMC noted that MUHA did not include parking and wayfinding in downtown Charleston in its travel analysis regarding the SMC NICU application. SMC's health planning expert believed that MUHA should have included time for parking and wayfinding in its analysis concerning SMC's NICU if MUHA believed it was a factor in supporting the Berkeley County hospital application.³⁴ While MUHA's planning expert testified that there was a parking garage attached to the Children's Hospital, which mitigated parking and wayfinding, SMC presented an aerial view of MUHA showing that MUHA had other parking garages connected to its hospital buildings when it applied for the Berkeley County hospital.

214. MUHA introduced evidence indicating that many people travel from all over the state for NICU services at MUHA. However, they were likely referred by a physician to MUHA rather than independently choosing to receive their care at MUHA, and it is likely a hardship for them to travel to Charleston. Mr. Sullivan provided the example that if an Orangeburg patient could exit I-26 at Summerville rather than having to travel to downtown Charleston, that patient would experience a significant reduction in travel time because the traffic in the Charleston area starts to become difficult after mile-marker 203, and this does not consider the other issues on the Charleston peninsula like flooding.

33. Mr. Taylor stated it took 47 minutes via I-26 to get from SMC to MUHA along a 22.3-mile route.

34. Parking has not been an issue at SMC as OB patients park right next to the hospital.

215. SMC stated in its CON application that its patients will be admitted to its hospital without regard to race, sex, creed, national origin or ability to pay, and it set forth in its CON application its Uninsured Discount Policy for Patients and a Charity Write-off Policy for Patients, which are attached to the CON application and provide for discounted or free care for patients who are uninsured or under-insured.

216. Mr. Sullivan opined that the project will not be an unnecessary duplication of services because the Level III services SMC is proposing are needed by patients born at SMC and mothers who could deliver at SMC, and it will foster continuity of care, mother-baby bonding, and avoid the risk of neonatal transport.

217. Based on the foregoing, the Court finds that SMC demonstrated there are significant patient access impediments to MUHA's campus on the Charleston peninsula including flooding and traffic, as well as socioeconomic factors referenced *supra*. While the Court appreciates that MUHA has significant air and ground transportation capabilities for neonates, these modes of transportation may not be readily available for expectant mothers and mothers who have delivered Level III neonates who reside in Berkeley and Dorchester Counties, and counties west of SMC generally, and those who lack resources to easily access MUHA on the peninsula, especially during times of high traffic or heavy rain. While the SMC project duplicates NICU services located on the Charleston peninsula, it is not an unnecessary duplication given the access issues identified by SMC, which are similar to those identified by Piedmont when it applied for Level III services. There was no evidence offered that by adding these beds, MUHA would be unable to continue to serve the medically underserved groups it currently serves, and there was no evidence presented that SMC restricts admissions.

218. The Court does not find MUHA's testimony concerning the access issues raised by SMC to be convincing, especially when MUHA relied heavily on these same access issues when applying for its Berkeley Hospital in the Summerville area.

v. Record of the Applicant

219. The Department determined that SMC's application complied with PRC § 802.13, Record of the Applicant.

220. When compared against other Level III NICUs, SMC is one of the highest volume delivery hospitals in the state. SMC currently has significant neonatal capabilities, has access to its parent company's resources to support the NICU program, and has the experience of the

Envision-employed physicians with respect to NICU care and treatment. Further, SMC's current Director of Neonatal Services has significant experience practicing in Level III and IV NICUs.

221. In addition to the board-certified neonatologists and MFM specialists on its medical staff, SMC, as a Level II provider, already has all the specialty physicians required of a Level III provider. Additionally, SMC has 26 full-time and 8 part-time neonatal nurses staffing its Level II nursery, and each has training for neonatal resuscitation. SMC also has nutritionists; pediatric pharmacists; a social worker dedicated to the women's and children's program; pastoral care; physical, occupational and speech therapists; and neonatal nurse practitioners.

222. SMC is one of the few Level II nursery programs that reports to VON, and it performs very well. SMC is affiliated with HCA, which has significant Level III and IV neonatal resources, as set forth above. The HCA network provides infrastructure and resources to SMC in terms of sharing knowledge and best practices. Moreover, in addition to participating in VON, HCA and Envision provide quality data to SMC. HCA's network, which is organized by service lines such as Women's and Children's services, provides programmatic development, and has a team devoted to quality processes. SMC's staff is already visiting an HCA affiliate hospital that operates a large Level III NICU in Savannah, Georgia, for training purposes, and the affiliate hospital's Level III staff members are coming from Savannah to SMC to assist in training.

223. MUHA argues that SMC cannot satisfy the Record of the Applicant PRC because SMC purchased a jet ventilator; because Envision is dealing with a legal matter in California; because its neonatology director refers to SMC's Level II nursery as a NICU; and SMC's pediatric surgeon conducts certain surgical procedures on neonates. None of these arguments are supported by the evidence.

224. There was no testimony that indicated there were any DHEC violations arising out of any of MUHA's allegations against SMC, and Mr. Sullivan indicated that the Envision legal matter, as referenced by MUHA's counsel, was related to insurance issues concerning emergency services in California and was unrelated to neonatal care.

225. Regarding the jet ventilator, the evidence establishes that this piece of equipment is not in use in SMC's Level II nursery, nor has it been used.³⁵ SMC's CEO explained that the jet

35. Dr. Merchak explained that the jet ventilator could be used for rescue purposes for very small neonates who are "crashing" and other babies for whom the conventional ventilators did not work who are waiting for transfer. While the Level II neonatal regulations indicate that "neonates shall not require high-frequency ventilation support," there does not appear to be a prohibition for Level II providers using a high frequency

ventilator was purchased for training purposes and for normal use on pediatric ICU patients for COVID-19 purposes.³⁶

226. SMC's health planner was not aware of any DHEC reported violations related to complex surgical procedures being performed on neonates at SMC. The Level III neonatal regulations indicate that Level III hospitals shall provide care to neonates who have actual or anticipated complex medical or surgical conditions. MUHA did not introduce any evidence indicating that the type of procedures performed by SMC's pediatric surgeon were complex.

227. Dr. Merchak testified that he sometimes refers to SMC's Level II nursery as a NICU because that is how it is commonly identified amongst neonatologists when they communicate with one another. Neonatologists often refer to a unit where babies need more care than is required for a healthy baby as a NICU. In fact, one of MUHA's own experts, Dr. Phibbs, in an article he authored referred to a Level II neonatal care unit that provides care for a "mildly ill infant" as a "NICU." MUHA did not question Dr. Phibbs on his use of the term NICU when referring to a Level II nursery.

228. The Court finds that SMC complies with the PRC, Record of the Applicant, because it is currently running a successful Level II program, it has the staffing and equipment in place to begin operating a NICU, and its management is more than adequate to establish a Level III NICU. SMC also has the vast resources of HCA, to include a NICU in Savannah that is assisting SMC in training personnel. As referenced earlier, the project costs for SMC's Level III NICU are relatively minor; therefore, capital financing is not necessary. The Court finds that MUHA's assertions that SMC is not in regulatory compliance with applicable state law to be wholly unsupported and unconvincing.

vi. Adverse Impact

ventilation in the event there is an emergency, and it becomes necessary to keep a neonate alive until other arrangements can be made. In fact, the Level II hospital regulations state that in no uncertain terms, "hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours." S.C. Code Ann. Regs. 61-16 § 1306(B).

36. There is no law that prevents a hospital in South Carolina from purchasing a jet ventilator for use on pediatric patients or for training purposes. The jet ventilator in this case cost SMC \$50,250. The CON regulations indicate that a CON is required for medical equipment that is used for diagnosis or treatment if the total project cost is more than \$600,000. S.C. Code Ann. Regs. 61-15 § 102(f).

229. The Department determined SMC satisfied the PRC § 802.23, Adverse Effects on Other Facilities.

230. In its case in chief, MUHA presented a slide indicating that SMC's adverse impact on MUHA would be a \$1.3 million contribution margin loss in 2021 in the NICU department, which had otherwise projected an \$18 million contribution margin gain.³⁷ Thus, according to MUHA, its NICU department will still have a positive \$16.7 million contribution margin. In its adverse impact analysis, MUHA used SMC's Year 3 NICU projection of 1,832 patient days from its CON application—not the much lower 931 patient day projection for 2024 that Mr. Levitt calculated to challenge SMC's utilization projection—and applied it to MUHA's 2021 MUHA 13,880 patient day projection instead of MUHA's 2024 projected 15,653 NICU patient days.³⁸ Had MUHA used its revised, and much lower SMC NICU patient day projection, the projected impact on MUHA would have been much lower.

231. MUHA represented in its CON application pro forma budgets, which included its 6 NICU bed project, that it would have total operating revenue of \$2 billion and positive net income of \$98.4 million in FY 2024. MUHA also projected that its NICU project alone would have a \$3.5 million positive contribution margin in year 3 of operations. Therefore, if SMC's project were to impact MUHA's project by a \$1.3 million contribution margin, MUHA would still have \$2.2 million in positive contribution margin with respect to the expansion of its NICU.

232. Mr. Sullivan disagreed with MUHA's adverse impact analysis that showed a negative 7.3% contribution margin impact on MUHA's NICU program resulting from the SMC project. Mr. Sullivan indicated that using a contribution margin impact on the NICU department alone, rather than the hospital as a whole, was improper, and he testified that in past CON applications, Mr. Levitt typically showed the impact on overall net income of the organization; thus, assuming the numbers are even correct, MUHA's adverse impact is greatly overstated. Mr.

37. "Contribution margin" may be loosely defined as a hospital's revenue minus variable costs. Variable costs are those that increase with each successive patient. *See* "Calculating a Potential Increase in Hospital Margin for Elective Surgery by Changing Operating Room Time Allocations or Increasing Nursing Staffing to Permit Completion of More Cases: A Case Study." In the context of NICU services, contribution margin is a measure of how much each additional patient contributes to a hospital's profitability.

38. During MUHA's rebuttal case, Mr. Levitt used an even lower NICU patient day volume for SMC of 683, after making further revisions to Mr. Sullivan's assumptions. Mr. Levitt did not use the lower 683 NICU patient days volume in his adverse impact analysis, which would have resulted in an even lower impact on MUHA.

Sullivan also testified that rather than using the alleged corrected version of neonatal patient days that Mr. Levitt developed using revised utilization assumptions, Mr. Levitt used Mr. Sullivan's third year projection of 1,832 patient days from the CON application to assess adverse impact. MUHA cannot have it both ways. Mr. Levitt wants to use a revised lower patient day NICU volume to claim that SMC will be less utilized than what it projected, but he also wants to use SMC's stated utilization in the CON application to show an increased impact on MUHA.

233. Mr. Sullivan testified that MUHA's financial reports, which are available in the public domain, indicated that MUHA's Charleston market had a total operating margin on May 20, 2022, of \$102.6 million. Mr. Levitt corrected Mr. Sullivan and reported that MUHA's operating margin in the Charleston market was \$51.5 million favorable to budget, and that MUHA had budgeted a loss, although Mr. Levitt did not offer the amount of that loss.³⁹ Mr. Levitt testified that MUHA does not make \$100 million and probably never will, and while he indicated that MUHA received COVID funds which MUHA has to repay, he did not testify that MUHA could not afford to repay the funds, nor did he indicate what MUHA's net income was for 2021 or what it was expected to be going forward.

234. Although Mr. Levitt testified that MUHA had a negative financial margin from operations in 2021, he admitted that it was positive with the Covid funding MUHA received, but he did not know what the amount of the positive operating margin. Mr. Levitt claimed that MUHA had negative margins in previous years, but he did not report the amounts of those margins. This is important because MUHA's CON application was submitted in November 2020, well after the pandemic had been declared, and MUHA projected positive operating margins ranging from \$73.5 million to \$81.6 million, and net income at \$90.3 million to \$98.4 from FY 2022 through FY 2024. Thus, if MUHA had been operating at negative margins, it is peculiar that it would represent to DHEC that it would have positive margins year over year to FY 2024.

235. Mr. Levitt admitted that MUHA has \$2 billion in debt capacity; MUHA currently has plans to build a new hospital in Lancaster County at a cost of \$200 million; MUHA recently purchased a 30% share in Tideland's Health; MUHA recently purchased the Providence Hospitals in Columbia, South Carolina; MUHA recently purchased four other hospitals in the last five years after spending \$450 million on its Children's Hospital; and, MUHA is spending another \$200

39. If the budgeted loss was a \$5 million operating loss and MUHA's Charleston market was \$51.5 million favorable to the budget, then MUHA's operating margin would still be \$46.5 million.

million to build two additional hospitals. The Court finds it to be improbable that MUHA would be expanding at such a rate and cost, but that it would be unable to withstand a \$1.3 million contribution margin loss in a department that is projected to have \$18 million in positive contribution margin.

236. MUHA also alleged that SMC's NICU would result in a dilution of team-based expertise and experience caring for the high-risk neonatal population, and that SMC's NICU would have an adverse effect on staffing with the possible loss of respiratory therapists or nurses to SMC. Dr. Merchak testified that MUHA had just hired away one of his neonatal nurses and that such employee movement happens from time to time.

237. MUHA's Chief of Neonatology testified that MUHA has had a high-quality Level III NICU program with good outcomes since he began working at MUHA in 1989. Dr. Annibale admitted that in 2005, when MUHA reported 5,107 NICU patient days, or approximately 44% of the patient days MUHA reported to the state in 2020, MUHA had good outcomes, just as it did in 2020. In 2020, MUHA's NICU patient days decreased from 12,257 in 2019 to 11,575, and Dr. Annibale reported that MUHA's outcomes for 2020 were good.

238. At the hearing, Mr. Sullivan opined that MUHA is going to experience more growth going forward than SMC's project will offset in terms of patient days, and he showed that if SMC took 1,832 patient days from MUHA's 15,653 patient days projected for 2024, MUHA would still experience 2,246 patient days of growth from 2020 to 2024. In rebuttal testimony, MUHA's health planner took exception to Mr. Sullivan's analysis that MUHA would still experience 2,246 NICU patient days of growth from 2020 to 2024. Mr. Levitt testified that MUHA had not experienced significant growth since 2015, and based on this, indicated "we're not going to have substantially more patient days in the future" and that MUHA's projections were probably optimistic. Mr. Levitt then showed that MUHA experienced growth of 900 NICU patient days from 2016 to 2021; such that SMC's impact would result in a MUHA loss, rather than a gain, of 929 NICU patient days.

239. The Court finds Mr. Levitt's analysis flawed for three reasons: (1) Mr. Levitt used SMC's 2024 NICU projection of 1,832 patients days and offset it against MUHA's growth in NICU patient day volume from 2016 to 2021 to arrive at a NICU patient day loss of 929, when he should have offset SMC's 2024 patient day projection against MUHA's 2024 patient days projection; and (2) Mr. Levitt, while stating that MUHA's projections, presumably from the CON

application, were probably optimistic, failed to offer any revised projections going forward to 2024 that would allow SMC or the Court to determine what the impact on MUHA's growth would be in that year; and (3) Mr. Levitt's statements are not consistent with the statements MUHA set forth in its CON application regarding the growth in service area and continued high demand of its NICU program, nor are they consistent with the testimony of MUHA's Chief of Neonatology who stated that the 46 bassinets are often times 100% full.

240. The NICU volume projection MUHA has presented to the Court for 2024 is 15,653 NICU patient days which, when offset by SMC's 1,832 patient days, leaves 13,821 patient days, or 2,246 more patient days than MUHA treated in 2020.

241. Even assuming that Mr. Levitt's analysis was valid, the Court does not find that a MUHA loss of 929 days would materially adversely impact MUHA financially given that its NICU has a significant contribution margin, and MUHA has patient revenues of nearly \$2 billion. Furthermore, the Court does not find that the loss of 929 days would dilute care at MUHA in any respect, given that it operated at 682 less patient days in 2020 than it did in 2019, and Dr. Annibale testified that neonatal outcomes were good in 2020. Moreover, if MUHA's NICU patient day volume is higher in 2024 than it was in 2020 and neonatal outcomes were good in 2020, it stands to reason that outcomes will not suffer if its volume is even higher in 2024.

242. The Court finds that MUHA will not lose staff due to SMC's Project, as SMC has represented that it is fully staffed to begin Level III operations. Therefore, the Court finds that SMC's project will not adversely impact MUHA's NICU program to such an extent that it necessitates the denial of SMC's NICU CON application.

vii. Findings Under Regulation 61-15 § 501 of the South Carolina Code of Regulations

243. As referenced above, the Department found that SMC complied with Regulation 61-15 § 501 of the South Carolina Code of Regulations. The Court agrees with the Department because there are minimal project costs associated with SMC's project, and there have been no allegations that SMC's project would have an impact on patient charges. There are no superior alternatives to SMC's project given the volume of neonatal and maternal transfers from SMC to MUHA and the access issues presented and proven by SMC; there are minimal construction costs associated with SMC's project; and SMC's identified patient population will continue to

experience serious problems in terms of cost, availability and accessibility in obtaining Level III care if SMC cannot establish Level III NICU services.

244. The findings related to S.C. Code Ann. Regs. 61-15 § 501 are not applicable to MUHA.

viii. Other PRC

245. MUHA challenged SMC's financial feasibility by identifying a discrepancy in the charges listed in the application as compared to the pro forma budgets, but MUHA did not provide any information as to what it believed would be the effect on SMC's overall bottom line. The CFO of SMC certified the review of the assumptions contained in the pro forma budgets, and she found them to be reasonable. The Court has no reason to doubt the CFO's certification. SMC's expert in healthcare finance also testified that he found the pro forma budgets to be reasonable. The Court also finds that the \$90 million budgeted pre-tax income for Trident Health, of which SMC is affiliated, would be more than enough to offset any income loss in the event SMC's figures are overstated in its pro forma. Lastly, MUHA's projected net revenue per patient day in its NICU is \$2,326, while SMC's is \$1,684, which indicates that SMC may have understated the amount it might collect per patient day for Level III neonates. Based on the pro forma budgets set forth in the CON application, the Court finds SMC's project to be financially feasible.

MUHA's APPLICATION

246. As stated above, SMC represented that it did not believe the applications were competing and therefore both could be approved. During the hearing, SMC did not specifically challenge MUHA's community need documentation, MUHA's Record as an Applicant, or whether MUHA's project would adversely affect other facilities. While SMC challenged the accessibility of MUHA's services, it did so to demonstrate the separate need for SMC's NICU and the improvement in accessibility that would be realized for hundreds of patients who are transferred from SMC to MUHA if SMC's Project were approved.

247. As such, the Court finds that MUHA, for the reasons identified by the Department, satisfies the most important PRC identified by the Department.

X. FINDINGS CONCERNING THE PURPOSES OF THE CON ACT

248. The CON Act states that its purpose is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health

facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. S.C. Code Ann. § 44-7-120.

(i) Promote Cost Containment

249. SMC has demonstrated that it can implement its project immediately at minimal cost, whereas MUHA's project costs \$2.7 million and has a ten-month construction time frame. In addition to being a low capital cost project, SMC has shown that its project meets the needs of the community, that it would result in decreased transportation costs associated with neonatal transfers, and that it would mitigate costs for families who currently must travel longer distances to MUHA.

250. SMC also presented testimony that when there is only one provider of Level III NICU services, there is no competition. Mr. Sullivan opined that SMC's project will enhance competition in PR-V, which will allow managed care companies to negotiate better rates that could have a beneficial impact on healthcare insurance premiums. Mr. Sullivan also opined that competition can also enhance healthcare quality and patient experience.

251. MUHA asserted that because it has all the necessary resources and expertise, it does not have to do any recruiting. MUHA further contends that because it spent \$400 million on its Children's Hospital and another \$1 million on new ambulances, it makes more sense to expand services at its existing location rather than develop a NICU at a different location in PR-V. In its letter of opposition to SMC's project, MUHA also stated that unnecessary costs would result from the development of such a specialized, costly program for only 6 Level III bassinets. First, MUHA has not indicated the positions it believes SMC will need to recruit, and SMC has presented evidence that it currently has all the physician, non-physician staff, and equipment in place to transition from a Level II nursery to a Level III NICU. Moreover, the state of South Carolina recently approved and licensed Piedmont for 5 NICU bassinets; therefore, the state must have believed that there was value in establishing a Level III NICU even though there were Level III NICUs proximate to Piedmont in the Charlotte area.

252. The Court finds that SMC's project promotes cost containment given that the costs to implement the project are relatively small, the patients will realize savings in terms of travel, and the promotion of competition may serve to reduce insurance rates associated with neonatal care.

253. The Court also finds that MUHA's project promotes cost containment given its established position as the Level IV provider in PR-V and the fact that it can implement the project in 10 months for what appears to be a reasonable project cost.

(ii) Prevent the Unnecessary Duplication of Services

254. SMC's project does not unnecessarily duplicate services because, as referenced *supra*, SMC's Level III NICU would provide a critical access point to NICU services for hundreds of expectant high-risk mothers and their neonates who are presently transferred on an annual basis out of their communities to MUHA and who may consequently experience decreased mother-baby bonding, a break in the continuity of care, postpartum depression, neonatal physiological deterioration and other adverse effects. Moreover, expectant mothers, new mothers and family members currently experience, and will continue to experience, problems accessing the Charleston peninsula during weather events and traffic congestion. These access impediments are especially difficult for the medically underserved, indigent population.

255. MUHA satisfies this CON Act purpose because its project is needed, as referenced above, and it will not unnecessarily duplicate other NICUs in the service area.

(iii) Guide the establishment of health facilities and services which will best serve public needs and ensure that high quality services are provided in health facilities in this State.

256. SMC has demonstrated that establishing 6 NICU beds at its facility in Summerville will improve access to neonates and high-risk mothers who must be transferred annually because SMC cannot, by law, treat certain neonates, and that it will provide high quality services just as it does today. SMC further asserts, based on the testimony referenced below, that it will offer high quality services to critically ill neonates in its NICU with superior neonatal outcomes.

257. MUHA argues that because SMC will not treat 100 VLBW babies annually, its neonatal morbidity and mortality outcomes will be worse than higher volume NICUs like MUHA that achieve such volumes. MUHA further argues that the introduction of SMC's NICU will undermine perinatal regionalization in South Carolina resulting in more VLBW baby morbidity and mortality statewide.

(iv) Quality Factors, NICU Outcomes, and Perinatal Regionalization.

258. Dr. Annibale, a MUHA witness, agreed that a host of quality efforts have improved outcomes in VLBW babies over the last 20 to 30 years to include the introduction of surfactant; improvements in mechanical neonatal ventilation; the widespread adoption and the emphasis on

treatment using antenatal corticosteroids; the development of evidence-based medicine and standard protocols for treating VLBW babies; access to sub-specialists, which can be accomplished through tele-medicine; the development of large databases like the VON; and various collaborations devoted to improving the care of not just VLBW babies, but intensive care babies as a whole. Dr. Merchak agreed with Dr. Annibale's conclusions concerning outcome improvements in the last two to three decades. Another MUHA witness, Dr. Phibbs, also acknowledged that neonatal outcomes have improved in the last 20 to 25 years partly due to the improvements in the practice of neonatal care and that the improvements have taken place even though not a single state requires a NICU to show that it can treat 100 VLBW babies at the time of licensing.

259. Dr. Annibale acknowledged that the ability to provide rapid emergency C-sections is important in terms of preventing fetal deaths and to avoid morbidity.⁴⁰ Dr. Annibale did not know if the hospitals in the California and New Jersey neonatal studies he reviewed for his volume/outcome opinions had that ability.

260. Dr. Annibale also acknowledged that the factors in neonatal care raised by Dr. Lorch in his 2012 study, such as increased patient-nurse ratios and fewer sinks that were associated with higher infection rates, were quality of care factors which could be mitigated through the use of standardized guidelines.

261. While he continues to believe that volume is more important than quality factors, Dr. Annibale admitted quality factors, such as quality assurance, quality improvement, protocols, training and benchmarking, all have a role to play in improving outcomes within any size nursery, and that VON has shown that at various levels of volume there are a range of outcomes, and there is both a volume and quality effect on outcomes.

262. Dr. Lorch, another MUHA witness, admitted that states with at least one large metropolitan area, which also had CON legislation, had significantly lower IMR compared with states without CON legislation. South Carolina is considered a state with a large metropolitan area and CON program. Dr. Lorch also admitted that policy decisions make a difference in neonatal outcomes.

40. Dr. Holcomb, a SMC witness, indicated that as a Level II, SMC currently performs 800 C-sections deliveries a year, and that SMC is available 24/7 for immediate deliveries.

263. Dr. Phibbs acknowledged that there are smaller, low volume NICUs with good statistical neonatal outcomes in terms of morbidity and mortality. He testified that there are lower volume NICUs that continuously perform well, and there are high volume NICUs that perform poorly, despite treating more than 100 VLBW babies annually. Dr. Phibbs admitted that his volume-outcome relationship is an average and there are dispersions around the average. Likewise, Dr. Lorch testified that there are times when hospitals that treat less than 50 VLBW babies will have better outcomes than those that treat more than 50 VLBW babies annually.

264. Dr. Phibbs admitted that a leadership team committed to the delivery of quality is important because there is variability in terms of the effectiveness of quality improvement across hospitals. He also admitted that quality measures, such as having enough nursing staff, could affect neonatal outcomes. Dr. Phibbs acknowledged that certain larger hospitals lack money and nurses and therefore have worse risk adjusted neonatal outcomes.

265. Dr. Phibbs acknowledged that transferring neonates from one hospital to another can be physiologically disruptive to the neonate, and that babies who were transferred and thus did not have NICU care from birth, sometimes have significantly worse outcomes.

266. Even though there are three so called "low volume" NICU providers in South Carolina, Dr. Phibbs testified that South Carolina has done "very well" in terms of regionalization because it has one of the highest shares in the country of having very pre-term babies delivered at Level III hospitals.

267. Dr. Annibale testified with respect to regionalization in general, that SMC's project could increase the risk of harm to patients in the region if the process goes the way it has gone in other states. However, Dr. Annibale acknowledged that when there is no need for neonatal bassinets in the Health Plan, a Level II nursery must satisfy a standard that requires the hospital to perform a minimum 1,500 births per year and 2,500 Level II nursery days to move to a Level III NICU, a requirement which necessarily limits the number of Level II providers that can become a Level III NICU. Dr. Annibale also acknowledged that a Level III NICU is required to have certain medical staff, clinical support staff, consultation arrangements and the proper equipment, which come at a certain financial cost.

268. Dr. Phibbs admitted that if California had volume thresholds like South Carolina's CON program, where the applicant must show 1,500 deliveries and 2,500 Level II patient days, California would not have a problem with de-regionalization.⁴¹

269. South Carolina's IMR has dropped over the last 15 years, as have other states such as Pennsylvania and California. Compared with Pennsylvania and California, however, South Carolina has the highest degree of regionalization, but it also has the highest infant mortality, which indicates that perhaps regionalization is not strictly linked to improvements in infant mortality.

270. Dr. Merchak believes that while treatment volume matters, there are other factors that should be considered in the care of neonates such as keeping families together, patient choice, and access to care. Based on his 20 years working in Level II, III, and IV NICUs, Dr. Merchak believes the better the quality of care that is delivered, the better outcome the neonate will have.

271. Based on the foregoing testimony, the Court finds that quality factors play an important role in neonatal outcomes. The Court also finds that policy decisions such as whether a state has a CON program and Health Plan thresholds for Level II programs to become Level III programs foster prudent regionalization. The Court also finds that regionalization is not necessarily determinative of outcomes for individual lower volume providers, as there is evidence that lower volume providers can perform as well as or better than higher volume providers. The Court does not find that the establishment of a NICU at SMC will result in a domino effect that threatens South Carolina's current system of regionalization as there has been no evidence presented that South Carolina's other lower volume programs have caused deleterious effects on South Carolina's system of perinatal regionalization.

(v) Quality at SMC and Similarly Sized NICUs

272. As referenced above, Dr. Merchak, SMC's Director of Neonatology, practiced at Mercy Hospital for 14 years. Mercy operated a Level III NICU with approximately 90 to 100 bassinets, which is many times the size of MUHA's proposed NICU. The only NICU services not offered at Mercy were ECMO, cardiothoracic surgery, complex heart disease treatments and neurosurgery. Otherwise, Mercy took care of all babies at all levels and weights, and Dr. Merchak

41. Dr. Phibbs' opinion on this point is consistent with Dr. Lorch's testimony, that policy considerations make a difference in neonatal outcomes and that states with CON programs and large metropolitan areas have significantly lower infant mortality rates compared with states without CON legislation.

treated the neonates at Mercy for all the conditions except those listed above. After his tenure at Mercy, Dr. Merchak arrived at SMC in 2019 and became the Medical Director of the Level II nursery.⁴²

273. Currently, SMC holds interdisciplinary meetings every other week where the nursing director and Director of Neonatology address any problems and operations. The neonatologists and nurse practitioners meet once a month to discuss standardizing care utilizing the latest literature and medical applications. Once a month, there is a multi-disciplinary meeting that includes neonatal services, MFM services and other subspecialties to discuss high-risk mothers who will have high-risk deliveries that are identified prior to birth. During these meetings, the team goes through the patients individually, identifying what the needs will be for the baby being delivered, and whether a transfer will be necessary for higher level care.

274. SMC currently has the staff necessary to operate as a Level III hospital as per the regulations on staffing requirements and the GPC. SMC does not anticipate any changes in terms of the subspecialty consulting relationships and its relationship with its RPC — MUHA. Currently, SMC's neonatologists consult with pediatric specialists such as pediatric surgeons, pediatric ophthalmologists, pediatric gastroenterology physicians, and MUHA physicians via telephone when SMC does not have a particular specialist on staff.

275. When a neonatal cardiac issue arises, SMC consults with a pediatric cardiology group remotely. SMC's physicians order an echocardiogram for the neonate, and it is electronically submitted to the cardiologists. The pediatric cardiology group will respond based on the urgency assigned by the SMC's physicians.

276. SMC anticipates that as a Level III NICU it will treat babies in the 1000 gram and above range, and as it grows and its staff becomes more comfortable, it will begin taking care of more complex neonatal cases.⁴³ As a Level III provider, SMC will be able to perform complex

42. Dr. Merchak does not believe his lack of time in a Level III NICU since 2019 will impair his ability to treat Level III neonates because he continues to care for them at SMC until neonatal transfers can be accomplished, and he has transitioned from a non-Level III practice to a Level III practice in the past without a problem. Moreover, Dr. Merchak testified that he would soon start working in a Level III NICU in Georgia in addition to his Level II work at SMC.

43. MUHA referred to SMC as "NICU Lite" and alleged that SMC will avoid treating difficult NICU cases. SMC explained that it intended to ramp up its NICU program over time, as one would expect, avoiding unnecessary risks by making appropriate transfers to its RPC. SMC indicated that the breadth of patients it would serve will grow as SMC gains volume and experience. While the majority of neonatal patients who would qualify for Level III services would be appropriate for treatment at SMC, there are going to be

surgeries that it cannot now perform per the regulations.⁴⁴ SMC will not have set transfer protocols as a Level III NICU provider because neonatologists will have to make case by case decisions based on the assessment, available services, and needs of the baby. At SMC, care in the Level III NICU will be delivered by neonatology physicians directly rather than neonatologists in training.

277. SMC is positioned to manage a 10 bassinet Level II and a 6 bassinet Level III program because it will be staffed 24 hours each day by physicians and neonatal nurse practitioners through a team approach. This staffing will additionally include respiratory therapists and neonatal nurses. SMC's neonatologists have taken care of many more neonates who were more acutely ill in training and in past neonatology medical staff positions. Furthermore, SMC will ensure the application of evidence-based medicine and will monitor clinical performance against published benchmarks, which all leads to better outcomes.

278. SMC is an affiliate of HCA which collects and monitors data from a multitude of NICUs, benchmarks that data, and shares it with SMC. Additionally, HCA holds leadership meetings monthly where neonatologists and the neonatology directors address various areas the Level II and III units need to address based on their performance and benchmarks.

279. SMC is already a member of VON as a Level II nursery. As discussed in detail above, SMC will have three separate quality improvement/quality assurance programs in place while operating its Level III NICU.

280. Dr. Holcomb reported that SMC's volumes justify a Level III NICU, and that he visited SMC's Level II nursery and spoke to its providers and was impressed with the experience of the senior staff neonatologists and nurses. Dr. Holcomb opined that, with the exception of not having the sign on the door, SMC is essentially functioning as a Level III NICU today, and it has all the necessary elements to become an outstanding Level III NICU. SMC also has a fetal board, multi-disciplinary teams and the subspecialists that are necessary for a Level III NICU.

281. Based on Dr. Holcomb's experience working in smaller NICUs, the babies of expectant mothers who present to and deliver at SMC will be at less risk and will be better cared for at SMC if it is a Level III NICU because the delivering mother and the neonate will have better access to care. Based on Dr. Holcomb's evaluation of SMC's Project, he does not believe its

patients who, nevertheless, must be transferred to the RPC because of its special capabilities. The Court believes that SMC's "ramp up" approach is reasonable.

addition to the South Carolina perinatal regionalization system will result in increased morbidity or mortality. If anything, more, not fewer, babies will be delivered in a Level III setting, especially as the population grows, which will enhance South Carolina's reputation of having a high share of premature babies delivered in a Level III NICU.

282. SMC estimates that it will treat 40 VLBW babies in its initial years as a Level III NICU. Dr. Holcomb believes that SMC's staff will be able to develop proficiencies because treatment and therapies overlap for VLBW babies and non-VLBW babies with critical needs, and the providers' skill sets are shared. Dr. Holcomb recounted that one of the lower-volume NICUs that he covers does not have the same robust staffing complement that SMC has today; and yet, that NICU, which treated 20 VLBW babies out of 120 to 150 neonatal admissions a year from 1,100 deliveries, is meeting or exceeding the VON thresholds in all areas.

283. Dr. Annibale, who has no evidence that SMC will not comply with the Level III staffing regulations, admitted that MUHA, as the RPC, is required to provide physician consultative services to Level I, II and III nurseries 24 hours a day. In terms of analyzing SMC's Level II nursery for this matter, Dr. Annibale looked at the number of expectant mothers who were transferred from SMC to MUHA and delivered VLBW babies, and the number of live VLBW babies who were transferred to MUHA from SMC. Dr. Annibale admitted he was not familiar with SMC's OB or MFM programs, he did not know how many obstetricians or MFM physicians SMC had on its medical staff, he had no knowledge about how SMC's Level II nursery is staffed today, and he did not have any knowledge about the number of Level II patient days that SMC manages annually.

284. Dr. Annibale opined that based on the maternal and neonatal transfer volumes he has reviewed, he believes SMC will treat, at best, less than 40 VLBW infants annually, but he admits that he did not consider any other factors that might increase the volume of VLBW infants treated at SMC, such as volume of inpatient and outpatient referrals to MUHA, or women who want to deliver at a Level III regardless of their situation.

285. Despite being aware that SMC is affiliated with HCA, which operates over 50 Level III NICUs nationwide, Dr. Phibbs was not familiar with HCA's neonatal outcomes and had not done any research on HCA affiliated NICUs. Dr. Phibbs testified that there are structural factors that a small NICU cannot avoid such as experience or proficiency, particularly with the nurses who have not handled enough VLBW cases. Dr. Phibbs had no knowledge of how SMC

was currently staffed in terms of neonatologists or MFM physicians. Dr. Phibbs acknowledged that SMC would need to staff according to South Carolina's neonatal regulations in the event SMC's Level III NICU is approved.

286. Even though he testified that SMC needs to continue to transfer VLBW neonates to MUHA, Dr. Phibbs had no knowledge of MUHA's actual neonatal outcomes in terms of morbidity and mortality, and he had no knowledge of how MUHA compares to other Level III providers in the state.

287. Based on the foregoing, the Court finds that SMC has the necessary elements in place in terms of clinical staffing, experience, leadership, organization, and equipment to deliver high quality care. The Court finds Dr. Holcomb's testimony regarding the outcomes of the smaller volume NICU he covers to be instructive and reflective of the fact that a high quality, but lower volume NICU, can have good outcomes. The Court also finds that the weight of the opinions of MUHA's witnesses is less convincing given the lack of knowledge displayed about SMC's neonatal program, and the contradictory testimony provided concerning smaller volume programs' ability to provide good outcomes.

(vi) Medical Literature Regarding the Treatment of VLBW Babies and Outcomes

288. In South Carolina, the care of a VLBW baby, defined as one weighing 1,500 grams or less, must be managed by a Level III or Level IV NICU. *See* S.C. Code Ann. Regs. 61-16 § 1306(C), (D). MUHA introduced witnesses who offered that the morbidity and mortality outcomes of VLBW babies is determined primarily by the volume of VLBW babies a Level III NICU treats, while SMC's witnesses asserted that the quality of the NICU program, more than the volume of NICU care provided, is more determinative of VLBW baby outcomes. Based on the previous findings made by the Court concerning SMC's current and expected quality initiatives in its Level III NICU and those of a similar size, the quality improvements in NICU care that have been realized in the last two to three decades, the forthcoming findings relative to the quality of the evidence presented, the VLBW baby treatment standards recognized by states and professional organizations, and MUHA's witnesses' lack of knowledge concerning VLBW outcomes in South Carolina NICUs, the Court declines to impose a VLBW baby volume standard on SMC, nor does it find that SMC's VLBW neonatal treatment outcomes will be in any respect substandard or

otherwise inferior to those of other Level III NICUs that may operate above SMC's VLBW baby projections.⁴⁵

(vii) The Evidence Pyramid

289. Both parties presented testimony about the evidence pyramid to demonstrate the strength of the studies they introduced demonstratively during the hearing. Dr. Lorch referenced and explained the evidence pyramid but limited his discussion to only three levels of evidence—case series, cohort studies, and randomized controlled trials. (“RCT”).

290. Dr. Holcomb expanded on the evidence pyramid by presenting a demonstrative exhibit indicating there are *seven* levels of the evidence pyramid, which included the three levels referenced by Dr. Lorch, and four additional levels of the pyramid, one of which was lower than the levels discussed by Dr. Lorch—the background information/expert opinion level—and three of which set forth levels considered higher in terms of the quality of evidence than the levels discussed by Dr. Lorch: article synopsis, or Tier 3 evidence, which would be a seminal article that brings together a significant amount of research on a topic and is considered evidenced-based medicine; critically appraised topics or Tier 2 evidence; and Tier 1 evidence—systematic review—which might include a database where all of the proven studies that have been accepted, peer-reviewed and are ready for publishing at the clinical level, are compiled into a format and overseen by an organization like VON or incorporated into a textbook. .

291. Dr. Holcomb explained that the pyramid is important because reliance on a study that will change clinical practice before it is ready can have disastrous results at the bedside.

292. Dr. Holcomb testified that RCTs, or Tier 4 evidence, would be the best study evidence. However, RCTs, where the therapy is randomized and the provider and patient are blinded to remove the placebo effect, are difficult to conduct in the neonatal setting because an expectant mother, regardless of her baby's condition, cannot be directed to a NICU of a certain level or volume over another, given the ethical implications. MUHA and SMC both put forth Tier 5 studies—cohort studies—just two levels up from the weakest evidence, to support their positions on the neonatal volume/outcome correlation. Dr. Holcomb testified that it would not be appropriate for the Court to rely on Tier 5 studies when it comes to MUHA's position on the volume-outcome correlation and the conclusions MUHA's witnesses reached regarding potential outcomes for

45. The Court is well aware of its opinions expressed at the Motion to Lift Stay stage. After weighing all of the evidence, however, its concerns at that stage of the proceedings have largely been mollified.

SMC's Level III NICU because, while volume plays a factor in outcomes, even more important, is ensuring a program has process improvements in place, monitors outcomes, and makes adjustments.

293. The Court finds that while the testimonies of both SMC's and MUHA's expert witnesses concerning the evidence pyramid are instructive, it further finds Dr. Holcomb's testimony to be more helpful in analyzing the medical literature presented by the parties.

(viii) SMC's Studies

294. Dr. Holcomb introduced a 2004 medical article by Rogowski, referenced above and published in *JAMA*, which studied indirect versus direct hospital quality indicators for VLBW babies. The study collected data from 1995 to 2000 on 94,000 NICU babies who were in the VON database, which means the data was acquired at the bedside, and therefore, the basis for the outcomes was known. The NICU data for the study came out of 49 states and 22 foreign countries, rather than from one state like the Phibbs 2007 New England Journal of Medicine ("NEJM") article, discussed *infra*, which was solely focused on California neonates.

295. Dr. Holcomb noted that Rogowski looked at direct measures of quality such as outcomes, evidence-based medicine, and collaborative quality improvement, and that the key variables that were analyzed were mortality, the mother's demographics, annual VLBW admissions, and NICU levels of care. Rogowski found that volume only accounted for 9% of the outcomes, which is where quality became a factor. While Rogowski found that in hospitals with less than 50 annual admissions of VLBW infants, an additional 10 admissions were associated with an 11% reduction in mortality, using a graph in the study that plotted NICU units by VLBW volume and outcomes, Dr. Holcomb demonstrated that a number of the NICUs Rogowski studied were treating less than 50 VLBW babies, but they, nonetheless, had very good outcomes, while some number of NICUs treating more than 50 VLBW babies—some of which treated more than 150 VLBW babies—had poor outcomes. Dr. Holcomb explained that the Rogowski study shows that caution should be taken before setting an arbitrary VLBW baby treatment threshold because there is a risk that smaller volume NICUs with excellent outcomes could be closed. Rogowski's conclusion was that volume cannot prospectively identify high quality providers.

296. Dr. Phibbs testified that Rogowski's study was of limited value because VON, where the data for the study originated, did not include large county hospital NICUs that lacked money and nurses, which tend to have the worst outcomes. Dr. Holcomb agreed with Dr. Phibbs

and opined that staffing is a quality indicator that affects outcomes. Dr. Phibbs acknowledged, however, that the study was risk adjusted and the methods of estimating volume function were solid. Dr. Phibbs, who is also a peer reviewer ⁴⁶ for JAMA, offered that JAMA would not knowingly publish a fatally flawed study.

297. Dr. Holcomb noted that the hospitals that made the investment in VON, a quality improvement organization, saw a difference in quality outcomes. Dr. Holcomb cited a study by Horbar, which suggested that healthcare providers participating in the VON Network tend to have higher health outcomes for its patients. Dr. Holcomb believes that this research demonstrates how the implementation of quality control measures and techniques gained from this network serves to improve healthcare outcomes, independent of a provider's service volume. Dr. Holcomb testified that if the large county hospitals Dr. Phibbs alluded to had been included in the data, it would have further emphasized Rogowski's conclusion that quality makes a difference in outcomes.

298. Dr. Holcomb discussed two German studies by Bartels and Jochum that reviewed smaller data sets. The Bartels study, which is referenced in the AAP 2012 Policy Statement, found that if the hospitals treated more than 36 VLBWs babies annually, they had the best results, regardless of whether the babies were treated in a Level II or Level III NICU. Dr. Holcomb noted that rural hospitals in Germany, where he was stationed while in the military, often have smaller neonatal units due to their locations. Dr. Holcomb stated that as a result, the hospitals and providers in these areas are more likely to be equipped and trained to provide care at all stages of neonatal delivery irrespective of delivery volume.

299. Dr. Holcomb discussed the Jochum article, another German study, which reviewed two years of data from 2003-2004 that was collected at the bedside, which meant the researchers understood what was driving the outcomes. Thus, while it was a small volume study, the quality of the data was very good, and it showed that there was no difference in outcomes between the small NICUs (VLBW < 20) and the larger NICUs (VLBW > 20). The Jochum study noted that quality programs were put in place to support all NICU levels. On the other hand, Dr. Phibbs offered that the two German papers cited by SMC are flawed because they are underpowered, i.e., one looked at outcomes data related to 7,000 neonates and the other looked at only 700 neonates.

46. A peer reviewer reviews papers that are submitted to journals after an editor initially screens them to determine if the article is worthy of review. If so, the article is sent to experts in the same field study to determine if the research methods used were reasonable and appropriate, if the citations were correct, and whether the conclusions were supported by the results.

300. Dr. Holcomb responded to MUHA's criticism regarding the smaller studies by pointing out that there is not a lot of literature regarding VLBW babies that goes beyond the cohort studies. Dr. Holcomb differentiated the smaller studies from the larger cohort studies with tens of thousands of VLBW babies, and stated that as a practicing physician, the smaller studies, where the data is collected at the bedside, serve a purpose for him because he practices at the bedside, while many of the researchers do not spend as much time at the bedside.

301. Dr. Holcomb discussed the Horbar article, which was referenced in SMC's application and in this Order, *supra*, for the proposition that quality can drive outcomes. Dr. Holcomb explained that this study tested the concept of VON, which is charged with improving the quality of NICU units enrolled in its the program through evidence-based research, plans of care, and educational and medical protocols, among other factors. Horbar found that 75% percent of the 695 NICUs studied had improved their outcomes, especially with respect to death and late onset infection, which is primarily related to nursing care. The quality factors that drove this improvement were evidence-based practice, antenatal steroids, less invasive respiratory support, standardization of VLBW baby care, improved nutrition, and the use of expressed breast milk.

302. Dr. Lorch criticized the Horbar study because it does not discuss volumes and outcomes specifically, and it does not show a narrowing of the variation of outcomes over time. While Dr. Lorch is correct that volume is not specially discussed in the Hobar study as a factor in the outcomes improvement experienced by 75% of the NICUs, Dr. Lorch provides no explanation for the improvement over the eight-year period studied. The authors of the Hobar article stated that "The increased adoption of evidence-based practices and their implementation using quality improvement methods may have contributed to the gains in survival without morbidity that we observed." Notably, the one factor that the authors do not attribute to the neonatal improvements found over the eight-year period is increased NICU volumes.

303. In response to Dr. Lorch's testimony regarding the Horbar study, Dr. Holcomb opined that if volume made such a difference, then there should be a narrowing or more defined linear association between volume and outcomes in terms of the larger volume hospitals showing better outcomes. Dr. Holcomb further asserted that if volume was the primary driver of outcomes, then there should not be a cut-off of neonatal outcome benefits at 50 VLBW babies like there is in the Rogowski scatter plot; rather, there should be more of a defined linear negative correlation whereby as volume increases in the NICU units observed, mortality should continue to decrease.

(ix) MUHA's Studies

304. Dr. Phibbs discussed a 2007 NEJM article he authored, which was based solely on California data from the 1990s. He alleged that VLBW babies had better mortality outcomes as the volume of VLBW infants treated increased at certain cut-off points up to 100. Dr. Phibbs admitted, however, that any hospital in California can open a NICU because the state is not subject to CON or health department regulations, and there are no thresholds in place like there are in South Carolina.

305. Dr. Phibbs also relied on a study published in 2011 that examined the effect of hospital level factors on the mortality of VLBW infants based on data collected in California from 1997 to 2002. The data indicated that volume drove outcomes and, more specifically, treating 100 VLBW babies ensured the best outcomes. To the contrary, Dr. Holcomb pointed out that of the 177 hospitals studied in the 2011 study, only three of them actually treated over 100 VLBW babies, and one-third delivered less than 10 VLBW babies; thus, Dr. Holcomb stated that while the statistical analysis resulted in a finding that 100 VLBW babies was a treatment threshold, the real numbers in the study did not; accordingly, while there was an association found, Dr. Holcomb would not use the 2011 study offered by Dr. Phibbs to make a clinical decision.

306. Dr. Phibbs referenced a 2006 study out of Portugal by Neto to support MUHA's argument that SMC's NICU will have poor outcomes – the study showed the neonatal mortality rate going down in Portugal from 8.1/1,000 births to 2.7/1,000 following the closure of small NICUs which led to expectant mothers delivering at larger volume centers. Dr. Phibbs characterized the Neto Study as a “real world example” because it reviewed mortality outcomes after Portugal shut-down smaller NICUs in birthing centers that, he claimed, had less than 1,500 deliveries. Dr. Phibbs was presented with evidence that the Neto study involved the closure of all NICUs that did not have a delivery service of 3,500 deliveries—not 1,500—which he disputed even though the study did not support his contention. This is important because SMC's delivery service is expected to be over 2,600 deliveries in 2022, which means this study would not be comparable because SMC's NICU would not have been subject to closure in Portugal. Dr. Holcomb challenged the utility of the Neto study spanning from 1989 to 2003, because the authors admitted that social and economic changes had improved greatly in Portugal over the previous 15 years and that advancements in neonatal treatment had a big impact. Dr. Holcomb opined that the Neto study was not applicable to SMC's project.

307. Most of the papers Dr. Phibbs referenced to support MUHA's contention that SMC should not be approved for a Level III NICU because it will not have sufficient VLBW volumes assign the morbidity and mortality of the transferred neonate to the transferring hospital. VLBW neonates who are transferred, stable, and doing well, will sometimes suffer infections, bleeds, necrotizing enterocolitis, and other deleterious outcomes while at the receiving facilities, to include nosocomial infections caused by the receiving hospitals' NICU nursing care. However, for purposes of studying and comparing neonatal outcomes, the transferring hospital will be credited with the poor outcome even if the neonatal death or morbidity occurred as a result of the care provided at the receiving hospital.

308. Dr. Lorch introduced data from several studies to counter SMC's arguments regarding the utility of MUHA's studies in assessing care at SMC: the 2012 Lorch study; the 2014 Watson study; and the 2022 Phibbs/Lorch Abstract ("Abstract study"). Dr. Lorch testified that the 2012 Lorch study "approximately randomize[d]" the population through a distance variable. Dr. Lorch explained that he found that women who delivered their babies at a high-level, high-volume hospital with a VLBW baby threshold over fifty, and a Level III NICU or greater, experienced improvements in mortality and morbidity. The 2012 Lorch study reviewed data collected from 1995 to 2005.

309. The 2014 Watson Study, which was a replication of the 2012 Lorch study, reviewed data from England ranging from 2009 to 2011. Watson found the volume threshold for VLBW babies to be 100 deliveries; in other words, this quota serves as the reference point for good versus bad outcomes in VLBW infants. Lorch admitted, however, he was not aware of the requirements in England to become a Level III NICU. Dr. Lorch further alleged that the 2014 Watson and 2012 Lorch papers are higher on the pyramid for proof that there is a strong association between higher volume and lower risk of mortality.

310. Despite Dr. Lorch's emphatic testimony regarding the outcomes of the studies he referenced, in a 2017 article that he authored, Dr. Lorch stated that with respect to the 2012 AAP recommended guidelines for NICUs "there is uncertainty about the role of unit volume on neonatal outcomes, and what outcome thresholds to use in future policies."⁴⁷ Dr. Holcomb opined that Dr. Lorch essentially admitted there were additional components to the volume outcome equation

47. The article, entitled "Perinatal Legislative Policies and Health Outcomes," was published in the journal *Seminars of Perinatology*.

because studies reference varying treatment thresholds of 36 VLBWs, 50 VLBWs and 100 VLBWs. Dr. Lorch's 2017 article post-dated the 2012 Lorch study and the 2014 Watson study by several years. Only the Abstract study, discussed *infra*, which has not been published or peer-reviewed, came after Lorch's 2017 statement.

311. Currently, Dr. Phibbs and Dr. Lorch are attempting to convince the AAP to add volume thresholds to the AAP's Guidelines for newborn care. In fact, Dr. Phibbs was a consultant to the AAP, and he knew that the AAP believed that volume mattered, but he admitted that the AAP did not have enough information to include a volume standard in the 2012 guidelines.⁴⁸ According to Dr. Phibbs, he and Dr. Lorch were motivated to conduct the Abstract study because they felt the AAP needed stronger evidence regarding the proper NICU volume threshold. The research is complete for the Abstract study, but the paper itself is not, and therefore, it has not been published in a peer-reviewed journal.

312. In the Abstract study, Dr. Phibbs and Dr. Lorch analyzed data of VLBW babies born between 1995 and 2005 from four states, including South Carolina. Dr. Phibbs testified that the major take away from the research is that volume matters and, depending on whether one is concerned about mortality or major morbidities, the volume threshold for beneficial effects would be either 50 or 100 very pre-term infants a year, respectively. The Abstract study shows that some hospitals are consistently operating at less than 100 VLBW infants year over year with very good outcomes, just as there are hospitals consistently operating above 100 VLBW neonates with bad outcomes. Dr. Lorch presented the Abstract study at a conference and discovered the study contained an error in that it excluded certain neonatal cases that were supposed to be included, and the error had an effect on the mortality volume threshold. Dr. Phibbs admitted that the Abstract was a "work in progress." Dr. Holcomb testified that the Abstract had not undergone peer review to be used in the instant proceeding, and, while it showed some trends that needed to be explored, until the completed study can be seen, it should not be relied upon. The Abstract study had also not been published in a journal at the time of trial. Even if the study is subsequently published and peer-reviewed, Dr. Holcomb asserted that it would still only be a Tier 5 study with the appropriate

48. Dr. Phibbs testified that the 100 VLBW standard has not been imposed because the body of research over the last 30 years hasn't been sufficient to inform the various neonatal organizations where to draw the line in terms of VLBW volumes. This 30-year period would include all the studies referenced herein.

evidentiary value. Dr. Holcomb declined further comment on the study because he did not have it in its entirety and had only seen a part of it.

313. According to Dr. Holcomb, all the studies that MUHA offered for the proposition that treatment volume is the primary determinant of VLBW baby outcomes are cohort, or Tier 5, studies. However, the AAP 2012 Policy Statement that addresses the NICU Levels of Care is a higher tier study than MUHA's studies because it is a review of the medical literature, which includes studies referenced *supra*, such as the Phibbs 2007 NEJM article, the Chung study, the Rogowski study, and a German study. While the AAP respected the fact that volume plays a factor in outcomes, the 2012 AAP Policy Statement did not include a volume threshold because the science was not sufficient. Dr. Holcomb indicated that the 2012 AAP Guidelines publication was not quite at the top tier—Tier 1—of the evidence pyramid, which is a systematic review, therefore it would be categorized either as a critically appraised article or critically appraised topic, which is Tier 2 or 3 evidence, or two levels up from MUHA's Tier 5 evidence.⁴⁹

314. Dr. Holcomb, who is one of the editors of the AAP Policy Guidelines, testified that the 2012 policy statement is still supported by the AAP. Dr. Holcomb agreed that stronger evidence was needed to draw a volume line regarding neonatal outcomes. Neither the AAP nor any states have accepted MUHA's witnesses' VLBW threshold recommendations referenced in the studies MUHA cited because they are not the "gold standard," and there is not enough evidence to support a threshold, as Dr. Phibbs had to admit. In fact, the AAP specifically omits volume criteria in its defined levels of NICU care, and it emphasizes the importance of quality.

(x) State and Professional Standards and the VLBW Baby Treatment Threshold

315. South Carolina policy makers have not adopted a 100 VLBW baby treatment threshold that a hospital must satisfy to become a Level III NICU. The Level III regulations indicate that a Level III NICU needs to be able to manage any combination of 100 VLBW babies, vented babies, and babies who require surgery, plus maternal transfers. Under the neonate management provisions set forth by the State, a NICU could conceivably treat 10 VLBW neonates, 20 vented neonates, 20 surgical neonates and have 50 maternal transfers and satisfy the provision.

49. While Dr. Lorch indicated that two of the studies he relied upon for his opinions "approximately randomize" the population studied, the Court is unsure whether the studies would fall into Tier 4 evidence – RCTs — or Tier 5 cohort studies as Dr. Holcomb has testified. Either way, the Court finds that the 2012 AAP Guidelines publication is higher on the evidence pyramid than Tier 4 studies, and therefore it need not decide the tier level into which the 2012 Lorch and 2014 Watson studies would fall.

316. Dr. Holcomb, Dr. Merchak, and Dr. Phibbs testified that the March of Dimes does not use a VLBW baby volume threshold recommendation for a Level II hospital to become a Level III NICU or maintain Level III licensure, nor does ACOG, or any of the fifty states. Dr. Phibbs also acknowledged that the AAP has not adopted the standard that a Level III NICU must treat 100 VLBW babies annually. Dr. Lorch testified that the GPC, which is published by the AAP and ACOG, does not set forth any specific volume recommendations for a Level II program to become a Level III program or for a Level III program to maintain its status.

317. Despite all the neonatal outcome research that Dr. Phibbs and Dr. Lorch can identify, including their own, no state in the country has adopted VLBW threshold in their regulations to become a NICU or to maintain NICU status. Dr. Annibale testified that MUHA and his colleagues are still affiliated with the South Carolina Neonatal Consortium, an organization of South Carolina NICUs dedicated to improving the quality of care in South Carolina. Dr. Annibale is not aware of the Consortium advocating for the closure of any of the non-RCP Level III NICU programs in South Carolina.

318. The Department's witness, Ms. Murdock, testified that when DHEC was considering the new neonatal standard 1(e) in the Health Plan, the CON division requested that DHEC's Health Licensing Division review its records to determine whether there were any issues at the non-RPC Level III NICUs with respect to quality, patient care, and outcomes. Ms. Murdock testified that the Licensing division found nothing to indicate that there were problems with quality, patient care, and compliance at the non-RPC Level III NICUs. Given the conflicting research addressing the quality of care factors and treatment volumes related to VLBW baby outcomes; the limitations of the studies; the quality of the evidence presented; the fact that no state or professional organization has adopted a VLBW baby volume treatment threshold; the Department's testimony concerning DHEC's Licensing Division's review of the non-RPC Level III NICUs, and the testimony indicating that lower VLBW volume programs can achieve similar or better VLBW baby outcomes as higher volume programs, the Court is not inclined to impose a VLBW baby threshold standard on SMC or find that its neonatal outcomes for VLBW babies will be determined by its treatment volumes.

(xi) MUHA's Subspecialists' Testimony

319. Several MUHA subspecialty physicians testified and expressed concern that SMC would lack certain in-house subspecialty care with respect to nephrology, ENT, cardiology,

and physician specialty palliative care and that quality will be lacking as a result. More specifically, MUHA's witnesses expressed concerns that SMC would not be able to manage intubation (airway issues, neonatal tracheotomies), kidney issues, and palliative care issues.

320. As an initial observation, while SMC will not have in-house access to certain subspecialty pediatric physicians, MUHA's subspecialists are required to provide physician consultative services to SMC's Level III unit 24 hours a day as needed. SMC's physicians currently consult with MUHA physicians over the telephone, and they have not had any problems with this method of communication.

321. MUHA's expert in pediatric cardiology, Dr. Scheurer, admitted that the neonatologist is the quarterback of the neonatal care team who identifies the complex cases.⁵⁰ Dr. Holcomb testified that because the neonatologist treats the neonate at the bedside every day and is responsible for maintaining the child's state, neonatologists are specialists in the premature infant, which includes specialization in neonatal organs such as the lung, kidney, and brain. While Dr. Holcomb consults NICU patients with specialists who are not onsite, it is not often. The most common consultation is with cardiology, which involves performing echocardiograms that are then sent remotely to the cardiologist, who reads them and then calls the neonatologist. With respect to airway issues, Dr. Holcomb indicated that neonatologists intubate and extubate babies more than anyone else in the hospital. Dr. Merchak testified that while working at Mercy's Level III NICU, he could recall perhaps three times over a fourteen-year period being unable to intubate a VLBW. SMC has a pediatric anesthesiologist on staff who intubates and extubates neonates in the operating room. With respect to ventilation, Dr. Merchak is experienced in all forms of ventilation to include jet ventilation.

322. Dr. Holcomb also explained that many difficult airway cases can be identified *in utero*, and those cases will likely be transferred to the highest level of NICU care where a procedure is performed by an ENT that will allow the neonate to avoid a tracheotomy in the future. If there is a delivery and the airway issue has not been identified *in utero*, and the neonate requires a procedure to open up a difficult airway, the delivery should take place in a Level III that already has a pediatric anesthesiologist and a pediatric surgeon on staff, like SMC. SMC's pediatric

50. Dr. Scheurer admitted that he did not believe there would be an impact on his pediatric cardiology practice if SMC becomes a Level III NICU, and he expected to continue to receive the same kind of referrals he currently receives from SMC.

surgeon performed tracheotomies on many occasions while working in the NICU in his previous medical staff appointment; in fact, he performed virtually all of them at the previous hospital NICU where he worked. (While ENT physicians can perform tracheotomies, a pediatric general surgeon commonly performs them as well.)

323. Dr. Merchak explained that premature babies rarely required tracheotomies and while he practiced at Mercy Hospital, which delivered 10,000 to 12,000 babies per year, they would do tracheostomies about three to four times per year, or about 1 per 250 NICU admissions. Given SMC's projections on its number of NICU admissions, the Court believes that tracheotomies will rarely be necessary.

324. It is extremely rare that a tracheotomy procedure is emergent because a neonate with a lung injury is typically on a ventilator until the baby goes home. At that time, the ventilator is replaced with a tracheostomy. This is not a sudden event, and in the rare event that a baby at SMC requires a tracheostomy for discharge from the Level III NICU, that baby would likely be transferred to the RPC – MUHA – for the highly specialized procedure. Dr. Holcomb has been practicing neonatology for 30 years and has never experienced an emergency tracheostomy at any level of NICU.

325. Dr. Merchak testified that during the 14 years he was at Mercy Hospital, there was no pediatric nephrologist on the medical staff, but on the very rare occasion that he needed a nephrology consult, he engaged in a telephone consultation with a pediatric nephrologist to develop a plan of care.⁵¹ It was not Dr. Merchak's experience at the Mercy Hospital Level III NICU that a pediatric nephrologist had to perform a physical examination on most of the VLBW babies.

326. At Overland Park, which has a similar volume of neonatal admissions as MUHA, there were very few ENT consults and even fewer referrals annually for a tracheotomy. Dr. Holcomb further testified that when he is at Overland Park, he consults with a pediatric nephrologist on his NICU babies less than once a year and that includes his VLBW babies. Neonatologists manage babies with nephropathy of prematurity often and almost all neonates recover by the time they are discharged. It has not been Dr. Holcomb's experience that a pediatric nephrologist has to "lay hands" on VLBW neonates to physically examine them. Dr. Holcomb

51. Dr. Twombly, the Chief of Pediatric Nephrology at MUHA, admitted that at least two of South Carolina's RPCs did not have a pediatric nephrologist on their medical staffs.

disputed Dr. Twombly's assertion that all VLBW babies develop chronic kidney disease by referencing a study that found while premature babies have twice the risk of developing chronic kidney disease, it is by no means 100% of them.

327. Dr. Holcomb disputed Dr. Twombly's assertion that only a pediatric nephrologist can recognize critical kidney issues in a neonate and stated that being able to do so is within a neonatologist's expertise.

328. Centerpoint Medical Center, which is one of the smaller NICUs that Dr. Holcomb covers, has full-time onsite neonatologists; an MFM physician onsite once a week; and an offsite pediatric cardiologist like SMC. However, Centerpoint lacks onsite pediatric subspecialists unlike SMC, such as pediatric radiologist, pediatric ophthalmologist, and a pediatric surgeon. (Both the smaller NICUs that Dr. Holcomb covers perform cardiology consultations in the same manner that SMC's Level II nursery does today).

329. For most of Dr. Merchak's 14-year tenure at Mercy Hospital, there was no pediatric palliative care physician ("PPCP") on the medical staff. At the tail end of his tenure, a PPCP was recruited, and her time was spent primarily dealing with pediatric cancer patients.⁵² Mercy Hospital had a palliative care team that rarely included the PPCP. Dr. Holcomb echoed Dr. Merchak and explained that the Overland Park and Centerpoint NICU programs do not have PPCPs, but instead use a multidisciplinary team consisting of neonatologists, nurses, social workers, and pastoral care, which is very similar to what SMC is doing now for palliative care in its Level II program.

330. While the Court appreciates the testimony of MUHA's subspecialists, based on the testimony of the neonatologists presented by SMC who have extensive experience providing complex neonatal care in Level III NICUs of varying sizes, the Court finds that the NICU care provided at SMC will not be negatively impacted due to the lack of in-house subspecialists such as the types presented by MUHA. Moreover, because the Court finds that SMC will have access to the very subspecialists who testified on behalf of MUHA in this hearing, as well as MUHA's full roster of pediatric subspecialists, the quality of care at SMC's NICU will not be in jeopardy.

52. Although MUHA's neonatologist described palliative care medicine as a very important subspecialty, South Carolina does not yet require a PPCP to be on the hospital medical staff or even available for urgent consultations for Level III or Level IV care.

331. Based on its status as the only Level IV provider in the state, the Court finds that MUHA's project satisfies the remaining two purposes of the CON Act that address serving the public's needs and providing high quality care.

XI. DISTINCTION BETWEEN THE DEPARTMENT'S DENIAL OF SMC'S NICU APPLICATION IN 2017 VERSUS THE APPROVAL IN 2020.

332. SMC applied for 6 NICU bassinets in 2017, and the Department denied the CON application because it found that MUHA's application, which was considered competing, better complied with the applicable law and Health Plan; therefore, the Department awarded all 14 NICU bassinets shown as needed in the Health Plan to MUHA.

333. A comparison between the two decisions indicates that the Department found in 2017 that SMC minimally complied with the Health Plan and that MUHA more fully complied with the Health Plan, at a time when the two applications were considered competing, which is not the instant case. Here, the Department determined that the applications were not competing because SMC complied with an exception in the Health Plan, which was not available in 2017, that set forth standards to allow a Level II nursery to be approved as a Level III even when there was no need for bassinets in the Health Plan. Moreover, MUHA met a different Health Plan exception applicable to Level III and IV NICUs, which is a major distinction from the CON decisions made in 2017.

334. With respect to Community Need Documentation, the 2017 and 2020 Department decisions were the same. With respect to Distribution (Accessibility), the Department determined that SMC did not comply with the Distribution PRC § 802.3 primarily because SMC did not comply with the Health Plan to the same degree as MUHA, which means the Department believed there was an unnecessary duplication of services. In the instant case, there is not an unnecessary duplication of services because there is an exception to "bed need" and thus, an independent need, for SMC's project under the 2020 that was not present in 2017.

335. The Department did not make a finding regarding the Record of the Applicant in 2017 but found that SMC complied in 2020. The Department found that SMC complied with the Acceptability PRC in 2017 and did not make a finding in 2020 as that was not a PRC considered most important in the Health Plan. The Department also found in 2017, as it did in 2020, that there would be no adverse impact from SMC's project on MUHA, and it reasoned that in the 2020 decision there would be improved accessibility to Level III NICU services that outweighed any

negative effects of duplication. Lastly, the Department made findings in 2017 that SMC's project failed to demonstrate superior alternatives to its project and that patients would experience serious problems in terms of cost, availability, or accessibility in obtaining care of the type proposed, but found in 2020 that SMC complied with the requirements of S.C. Code Ann. Regs. 61-15 § 501.

336. The Court finds that although the Department denied SMC's 2017 CON project, the denial was premised on the fact that SMC's project was considered competing with MUHA's project, and there was no independent need for its project based on attaining certain birth volumes and Level II patient days, which is now set forth in a separate Health Plan exception. SMC has demonstrated by substantial evidence that residents who live in SMC's service area have significant impediments to accessing MUHA's campus for neonatal services, especially during times of heavy traffic and inclement weather, which was also recognized by MUHA in its Berkeley Hospital CON application that the Department approved.

XII. SMC's COMPLIANCE WITH SECTION 1306(C) OF THE LICENSING REGULATIONS

337. In its pretrial Motion for Summary Judgment, which was denied by the Court because of the presence of disputed facts, and further, at trial, MUHA contended that the Department erred in approving SMC's CON application because ultimately the SMC Project will not be able to qualify as a Level III NICU under the licensing requirements for inpatient perinatal care services set forth in S.C. Code Ann. Regs. 61-16 § 1306(C). MUHA argues that the Department erred in not considering section 1306(C) as an "other regulation" under S.C. Code Ann. § 44-7-210(B), which provides that the Department may not issue a CON unless an application complies with the Health Plan, the PRC, and other regulations identified in advance by the Department.⁵³

338. Specifically, MUHA alleges that the SMC Project does not meet the second neonatal management admissions threshold ("100 Neonate Management Provision") set forth in Section 1306(C), which provides:

Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include

53. In its CON application, SMC touts its current compliance with the 1500 deliveries threshold and its ability to prospectively comply with the neonate management requirement set forth in Section 1306(C).

the number of maternal transfers made prior to delivery to higher level perinatal hospitals. (Emphasis added.)

Id.

339. To support its contention that SMC does not meet the 100 Neonate Management Provision, MUHA asserts that the provision is more than a threshold to be maintained by licensed Level III providers. MUSC contends that the provision also must be interpreted and applied as a retroactive threshold that must be met by a Level II provider seeking to establish a Level III NICU. Under MUHA's interpretation, a Level II facility applying for Level III NICU CON approval meets the 100 Neonate Management Provision if it demonstrates that, on average over the prior three years, it has transferred to a higher level perinatal hospital at least 100 neonates who each weigh less than 1500 grams, who need ventilatory care for longer than 24 hours, or who need surgery. MUHA further asserts that the maternal transfer language in Section 1306(C) must be interpreted as retroactive and available to Level II providers calculating neonate admissions but only when an expectant mother is admitted to the Level II hospital and then transferred to a higher level facility prior to the delivery of a neonate that falls into the categories of risk described in the 100 Neonate Management Provision. .

340. By letter dated March 9, 2022, MUHA presented its interpretation of the 100 Neonate Management Provision to the Department in the form of suggested revisions to section 1306(C) that MUHA characterized as "clarifying" the licensing requirements for Level III providers by adding all of the following new language to the current section 1306(C):

To receive a Level III designation, a hospital must have no less than an average of 1500 deliveries annually, calculated over the previous three years, and must have not less than an average of 100 neonate admissions annually, calculated over the previous three years, who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. To be included in a hospital's calculation of average annual neonate admissions as a maternal transfer, the mother must be admitted to the hospital, transferred to a higher level perinatal hospital, and give birth to a neonate who weighs less than 1500 grams each, requires ventilatory support for over twenty-four (24) hours, or requires surgery based on individual hospital statistics.

341. Although MUHA's neonatologists testified that the proposed revisions set forth in the March 9, 2022, letter would clarify the Department's longstanding interpretation of section

1306(C), they admitted that they were unaware of any case in which the Department has actually applied section 1306 as interpreted by MUHA.

342. Mr. Levitt, MUHA's expert health planning consultant, testified that, in his opinion, the current section 1306(C) provision that a Level III provider shall manage "at least an average of 100 neonate admissions" is a retrospective standard that must be met by a Level II provider applying for Level III NICU status because the requirement uses the term "average." In Mr. Levitt's view, the reference to an "average" number of neonate admissions indicates that the number of neonate admissions must be calculated over the same prior three-year period that applies to the 1,500 deliveries threshold. Similarly, Mr. Levitt opined that the maternal transfer provision of section 1306(C) refers to expectant mothers who present at a Level II hospital and get transferred to a Level III perinatal center to deliver or to be evaluated for delivery of a baby. In Mr. Levitt's opinion the reference to maternal "transfers" does not encompass the transfer or referral of outpatient expectant mothers who present with high-risk pregnancies earlier in the treatment process. Using MUHA data and applying his interpretation of the 100 Neonate Management Provision, Mr. Levitt calculated that SMC transferred a combined three-year average of 66 direct transfers of inpatient newborns and mothers during the 2018 to 2020 period and 61 such direct transfers for the 2019-2021 time period, neither of which, in his opinion, satisfy MUHA's retroactive 100 Neonate Management Provision.⁵⁴

343. SMC disputes MUHA's contention that Section 1306(C) of the perinatal licensing regulation is applicable to the SMC Project during the CON review phase. SMC also contends that, even if the requirements of section 1306(C) can be considered at this stage of the process, MUHA's interpretation of the 100 Neonate Management Provision as a retroactive transfer standard is incorrect and ignores the plain language and purpose of the licensing regulation.

54. MUHA claims that SMC admits the retrospective interpretation of the 100 Neonate Management Provision in the form of former Trident Medical Center Chief Executive Officer Todd Gallati's comments to the draft 2020 State Health Plan. Mr. Gallati's comments, as summarized by the Department, were "Related to [Very Low Birth Weight Babies], change the 100-volume requirement prospective versus 3-year average." The Department's response to this request was that any change in the volume requirement would require a regulatory change that was outside the scope of State Health Plan revisions. As Mr. Sullivan testified, Mr. Galati's reference to a 100 VLBW standard is not accurate as no such standard exists – this regulatory provision can be met if the hospital manages "an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery." The Court finds that Mr. Gallati's comments do not equate to an admission by SMC that MUHA's retroactive interpretation of Section 1306 is correct.

344. In support of SMC position, SMC's expert health planning consultant, Daniel Sullivan, testified that, in his opinion, Section 1306(C) is not a standard that must be met by a Level II CON applicant such as SMC. Mr. Sullivan points to the plain language of the 100 Neonate Management Provision "Hospitals with Level III designation shall manage ... at least an average of 100 neonate admissions" as establishing a prospective compliance threshold that must be met by a licensed Level III provider, rather than a retrospective standard requiring an historical lookback at what a Level II provider has done. As Mr. Sullivan notes, Level II providers such as SMC, by law, cannot "manage" newborns who weigh less than 1,500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery and, thus, "it does not make sense for there to be a historical requirement or a three-year lookback...of providing 100 patients that fall into these categories if you, by regulation, have to be a Level III provider to serve those patients."⁵⁵ Level II providers, such as SMC, are prohibited from managing neonates that weigh less than 1,500 grams, require more than 24 hours of ventilatory support or require surgery.

345. The Department's witness, Ms. Murdock, was questioned extensively by the parties on the issue of the applicability of section 1306(C) of the licensing regulation to SMC's CON application. First, and most importantly, Ms. Murdock indicated that the Department's CON program interprets S.C. Code Ann. § 44-7-210(B)'s reference to "other regulations" that the Department may consider in evaluating CON applications to mean the CON regulations found at S.C. Code Ann. Regs. 61-15. According to Ms. Murdock:

The CON program's interpretation of that is that other regulations refers to other CON regulations....[T]hat makes sense because if we extended that inquiry to include some other non-CON regulation, then where would we stop....Number one, we would have to be aware of that regulation and CON staff is not particularly well versed in all the other DHEC regulations, let alone federal, you know, CMS and everything else...I don't read the statute or the regulation as requiring the CON program to anticipate whether or not a project will be able to comply with all other future regulations, even future DHEC regulations....[I]t would be an unrealistic undertaking and most of

55. Mr. Sullivan testified with regard to the Department's enforcement of the 100 Neonate Management Provision that there are three non-RPC Level III providers currently operating in South Carolina – Piedmont Medical Center, Self Regional, and Prisma Baptist, none of which meet the 100 Neonate Management Provision as interpreted by MUHA. According to Mr. Sullivan, each of Self and Baptist's total Level III admissions are below 100 and, even though Piedmont Medical Center reports a combined Level II/Level III admissions number, it is unlikely that the Level III total admissions are over 100. Ms. Murdock testified that as part of the Health Plan drafting process the Department reviewed its records to determine whether these non-RPC Level III programs had any quality-of-care issues or licensing issues and determined that they did not.

the CON analysis [is] prospective—is prediction. And compliance with other regulations a lot of the time [is] real time and based on inspection of existing facts.

Ms. Murdock further testified that, if the Department were faced with a realistic inquiry concerning an applicant's compliance with a non-CON regulation, the Department could potentially address the issue under the CON regulation's PRC 14 concerning an applicant's ability to complete its project.⁵⁶

346. Ms. Murdock indicated with regard to SMC's application that:

"[I]f I believed or had found that SMC might not ever be able to comply with a licensing regulation, of which I was aware, then I would've continued inquiring about that. . . .but I didn't have any of those concerns with this project.... It wasn't really an issue that was raised...I don't recall MUSC really inviting any opposition on that concern while I was reviewing the applications."

Ms. Murdock testified that, because she was not concerned that SMC would never be able to comply with licensing requirements, she did not discuss this issue with SMC or consult the Department's licensing division about the issue, and she did not identify PRC 14 "Ability to Complete the Project" as an important PRC. Further, as emphasized by Ms. Murdock, the Department's CON division, as a matter of policy, does not make determinations of compliance with licensing requirements.⁵⁷

347. Despite her testimony that the CON program does not consider or make decisions on compliance with licensing regulations, Ms. Murdock was repeatedly asked her opinion of whether the Department considers the 100 Neonate Management Provision to be retroactive or prospective. Her response each time was to indicate that the Department's licensing division would need to make that decision when presented with the issue⁵⁸ but, for CON purposes, she accepted

56. S.C. Code Ann. Regs. 61-15 § 802(14), entitled "Ability to Complete the Project" provides in relevant part, "[t]he applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application."

57. In this case, each CON decision letter issued by the Department contained the standard disclaimer "[t]he issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes."

58. Ms. Murdock indicated that "I don't know how [licensing] has or would interpret whether or not they would make those threshold requirements looking back three years prior to the initial licensure application or whether or not that is something that they look at as a once you're designated as a Level 3 NICU, then [this] is what you need to maintain [over the course of] the entire existence of the Level 3 NICU...I know the regulation doesn't specify that it is a requirement prior to establishing Level 3 services."

SMC's assertion that it could comply with section 1306(C) when the time for applying for licensure arrived, which could be long after the filing of the CON application. As explained by Ms. Murdock, once awarded, a CON is valid for a period of up to a year, with the opportunity for two additional extensions of up to nine months and even further extensions as granted by the Department's Board.

348. Finally, Ms. Murdock recognized that, regardless of whether the Neonate Management Provision is interpreted to be retrospective or prospective, once SMC actually applies for licensure, it can request and receive, in the discretion of the Department, an exception to the licensing standards based on patient safety and other factors.⁵⁹ Further, as Mr. Sullivan observed in his testimony, Piedmont Medical Center's Level III program is licensed under the current version of section 1306(C), and neither it nor the other existing non-RPC Level III programs are currently managing the volume of high-risk patients required by the 100 Neonate Management Provision. Because those programs are not being closed for failure to comply with the Level III licensing standard, in Mr. Sullivan's opinion, there is a reasonable expectation that SMC can be licensed fully or with an exception if it does not meet exactly all of the section 1306(C) thresholds.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Court makes the following Conclusions of Law:

As stated previously, MUHA bears the burden of proof in challenging the Department's decision to approve SMC's project. S.C. Code Ann. § 44-7-210(E) (2018); S.C. Code Ann. Regs. 61-15, § 403(1) (Supp. 2005); *see also Leventis v. S.C. Dep't of Health & Envtl. Control*, 340 S.C. 118, 132-33, 530 S.E.2d 643, 651 (Ct. App. 2000) (holding that the burden of proof in administrative proceedings generally rests upon the party asserting the affirmative of an issue). As the moving party, MUHA must prove its case by a preponderance of the evidence. *Nat'l Health Corp. v. S.C. Dep't of Health & Envtl. Control*, 298 S.C. 373, 379, 380 S.E.2d 841, 844 (Ct. App. 1989) (indicating the preponderance of the evidence standard applies in CON disputes). Preponderance of the evidence means "evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole show that

59. S.C. Code Ann. Regs. 61-16, § 202 states that "[t]he Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility." According to Ms. Murdock, the Department has a specific team of persons assigned to review and determine licensing exception requests.

the fact sought to be proved is more probable than not.” *Black's Law Dictionary* 1182 (6th ed. 1990). In the same fashion, SMC bears the burden of proof in establishing its case against the approval of MUHA’s CON application.

As a threshold issue, MUHA raised the ability of SMC to comply with the Neonate Admissions Requirement set forth in Reg. 61-16 § 1306(C). For the reasons set forth below, the Court concludes that Reg. 61-16 § 1306(C) is not applicable to the instant matter.

A. The Neonate Admissions Requirement under Regulation 61-16 § 1306(C) Must Be Read Independently of Section 44-7-210(B).

Subsection 44-7-210(B) of the South Carolina Code of the CON Act establishes the prerequisites for issuance of a CON as follows:

The department may not issue a Certificate of Need unless an application complies with the South Carolina Health Plan, Project Review Criteria, and other regulations. Based on project review criteria and other regulations, which must be identified by the department, the department may refuse to issue a Certificate of Need even if an application complies with the South Carolina Health Plan. (Emphasis added.)

Id.

The Department’s discretion to refuse issuance of a CON on the above basis is reiterated in Regulation 61-15 § 307.1:

The Department may refuse to issue a Certificate of Need even if an application is in compliance with the South Carolina Health Plan but is inconsistent with project review criteria or department regulations. The Department must identify any regulation that is used as a basis for denying an application that is in compliance with the South Carolina Health Plan.”⁶⁰

MUHA contends that Reg. 61-16 § 1306(C) constitutes an “other regulation” applicable to SMC’s CON application, and that the Department should have denied the SMC Project for failure to meet the requirements stated therein. Specifically, the regulation states as follows:

“Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals.” (Emphasis added.)

60. The Department found that the SMC Project complied with the State Health Plan and relevant PRC. It did not identify any regulations outside the CON regulations as being applicable to its review.

Reg. 61-16 § 1306(C) contains two minimum average volume requirements for Level III hospitals pertaining to (1) deliveries; and (2) neonate admissions and maternal transfers. MUHA contends SMC cannot demonstrate compliance with the latter requirement because SMC did not transfer an annual average of 100 neonates and maternal transfers meeting the stated criteria, calculated over the previous three years.

SMC contends Reg. 61-16 § 1306(C) is a licensing regulation independent of section 44-7-210(B) of the CON Act, and is thus subject to a different application, review, and decision-making process than that administered by the CON program. Thus, SMC argues, subsection 1306(C) cannot be used for deciding whether a CON to establish a Level III NICU should be granted. SMC asserts that this Court should confine its evaluation of SMC's CON application pursuant to the State Health Plan and applicable project review criteria identified by the Department.

SMC makes several arguments in support of its position. First, SMC contends subsection 1306(C) only applies to hospitals possessing Level III NICU licensure, rather than Level II hospitals seeking Level III licensure. Since SMC has not yet applied for Level III NICU licensure, it maintains that this Court lacks the authority to determine its compliance under this provision. In other words, SMC asserts that such a ruling would be premature as DHEC has neither received a licensing application nor rendered a final licensure decision for the ALC to review under section 44-1-60, which governs appeals of Department decisions to the ALC.

While SMC's position that the Court lacks jurisdiction over this issue has some appeal, the Court does not agree. SMC represented in its CON application that it would, in the future, comply with the 100 Neonate Management Provision of the licensing regulation such that in the Court's opinion, SMC raised this matter as an issue for the *de novo* hearing.⁶¹ Secondly, the applicability of Reg. 61-16 § 1306 in the instant case centers on its relation to the "other regulation" language used in section 44-7-210(B) of the CON Act. Based on the plain wording of Reg. 61-16 § 1306(C), i.e., "Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually and at least an average of 100 neonate admissions who weigh less than 1500 grams each,

61. In its Order on Motion to Lift Stay, the Court pointed out that SMC's CON application, "on its face, suggests that Summerville does not currently comply with the Reg. 61-16 § 1306(C), "inasmuch as the application contained charts indicating that SMC will meet the requirement in 2023." Upon further reflection, as stated, the Court does not believe that compliance with Reg. 61-16 § 1306(C) is required at the CON stage.

require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics (emphasis added),” because SMC is a Level II hospital, coupled with the Department’s testimony on the issue, the Court agrees that the CON requirements found in the CON Act, the Health Plan, the PRC and other CON regulations found in Reg. 61-15 are structured by law to be evaluated independently from the requirements for licensure set forth in Reg. 61-16.

In the case of a provider seeking to establish a facility or service for which a CON is required, a provider must (i) submit a CON application in accordance with the provisions of S.C. Code Ann. §§ 44-7-160 and -200, (ii) be reviewed, approved and receive a CON in accordance with S.C. Code Ann. §§ 44-7-200 and -210, and (iii) implement and complete the proposed project in accordance with the terms and conditions of the CON. *See* S.C. Code Ann. § 44-7-230. If a project is not implemented within one year from issuance of the CON, the CON becomes void unless extensions are requested and granted by the Department CON staff and by the Board of the Department in accordance with S.C. Code Ann. § 44-7-230. Once a provider has implemented its project and filed a final completion report accepted as satisfactory by the Department, the CON is considered fulfilled. *See* S.C. Code Ann. Regs. 61-15 §§ 601 and 604.

Only after an applicant has received a CON to begin establishing the project can a provider apply for a license to operate its facility or service. S.C. Code Ann. § 44-7-260. The application process for licensing, which must be undertaken annually, is set forth in S.C. Code Ann. § 44-7-270. Under section 44-7-270, the Department may require such additional information as it needs, including “affirmative evidence of ability to comply with standards and regulations adopted by the department.” In addition, under § 44-7-290, the Department may not issue a license for operation of a facility or service unless the facility and all persons named in the application are found to comply with the law and the Department’s regulations. Reg. 61-16 provides for an inspection prior to initial licensing and provides that no license can be issued until the licensee demonstrates compliance with the applicable licensing standards. S.C. Code Ann. Regs. 61-16 §§ 302(A) and 303. In the case of a CON, either the CON applicant or an affected person can request further review of a staff decision involving a CON. *See* §§ 44-1-60(E), (G); § 44-7-320(B).

MUHA asks the Court to apply the 100 Neonate Management Provision to the SMC Project in this case and to find that SMC will not qualify for licensure to operate a Level III NICU when it applies at some time in the future. MUHA urges the Court to use this finding of future

noncompliance as a basis for denying SMC's currently pending CON application to establish a Level III NICU. The Court finds that it cannot do as MUHA asks.

B. Regulation 61-16 is Not an "other regulation" under § 44-7-210(B) of the CON Act.

To the extent that MUHA argues that S.C. Code Ann. § 44-7-210(B) of the CON Act contemplates the consideration of "other regulations," such as the Level III NICU licensing requirements set forth in Reg. 61-16 § 1306(C), as relevant to the review of SMC's application, SMC urges the Court to defer to the Department's longstanding interpretation of section 44-7-210(B) to the contrary.

It is well-settled under South Carolina law that "the deference doctrine properly stated provides that where an agency charged with administering a statute or regulation has interpreted the statute or regulation, courts, including the ALC, will defer to the agency's interpretation absent compelling reasons. We defer to an agency interpretation unless it is 'arbitrary, capricious, or manifestly contrary to the statute.'" *Kiawah Dev. Partners, II v. S.C. Dep't of Health & Envtl. Control*, 411 S.C. 16, 34-35, 766 S.E.2d 707, 718 (2014), quoting *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844, 104 S.Ct. 2778 (1984).

The Department's witness, Ms. Murdock, testified at the hearing that the Department's interpretation of the term "other regulations" refers to other CON regulations and not the numerous regulations that govern other activities related to healthcare facilities, such as zoning laws, construction codes and requirements, licensing requirements to include rules governing staffing and all other facets of operation of a facility, Medicare/Medicaid reimbursement rules, and environmental requirements. According to Ms. Murdock, as a policy, the Department's CON division specifically does not make determinations of compliance with licensing requirements. In furtherance of this policy, the Department's decision letters on CON applications, including those issued to SMC and MUHA in this case, state that "[t]he issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes." (Emphasis added).

Ms. Murdock indicated that the reason for Department's longstanding interpretation of "other regulations" to mean only CON regulations, and not licensing or other non-CON regulations, is that CON staff would have the impossible task of being aware of, and familiar with, countless rules and requirements in order to determine compliance with regulations that are not administered, interpreted, or enforced by the Department's CON program. Ms. Murdock also

specifically noted that compliance with many regulations must be determined in real time and after inspection, which would place an additional unreasonable burden on CON staff.

The Court finds that the Department's interpretation of "other regulations" in § 44-7-210(B) as referring only to CON regulations is reasonable and not arbitrary, capricious, or manifestly contrary to the statute or to the Department's authority as the sole administrator of the CON program. *See* S.C. Code Ann. § 44-7-140 ("The department is designated the sole state agency for control and administration of the granting of Certificates of Need and licensure of health facilities and other activities necessary to be carried out under this article.") Therefore, the Court concludes that the licensing requirements of Reg. 61-16 § 1306(C) are not "other regulations" that should have been identified and considered by the Department in approving SMC's CON application.⁶²

C. Consideration of Reg. 61-16 under PRC 14 Ability to Complete the Project

As an alternative means of requiring consideration of Reg. 61-16 § 1306(C)'s licensing requirements, MUHA argues that the Department should have considered SMC's failure to meet the 100 Neonate Management Provision as a factor that would prevent the SMC Project from complying with PRC 14 "Ability to Complete the Project." PRC 14 is a criterion contained in the CON regulations that is used in evaluating CON applications. *See* S.C. Code Ann. Regs. 61-15 § 802(14). PRC 14 provides in relevant part:

"[t]he [CON] applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application." In its CON application, SMC indicates that its anticipated date for submission of the Final Completion Report will be approximately 60-90 days after project licensing.

At the hearing, Ms. Murdock indicated that the Department could potentially address a serious issue of noncompliance with a non-CON regulation in the context of an applicant's ability to complete the project under PRC 14. Murdock stated, however, that, in this case, as the CON reviewer and primary decision-maker, she did not believe that SMC would never be able to meet Level III NICU licensing requirements. Therefore, she was not concerned about SMC's ability to complete its project to establish a Level III NICU.

Although PRC 14 was not identified by the Department as an important criterion for the review of SMC's CON application, it is clear that Ms. Murdock, as the Department's reviewer,

62. The Court realizes that it reached an opposite conclusion at the Motion to Lift Stay stage of this proceeding.

considered it and determined that SMC had demonstrated that it could complete its project, to include licensing, within the time frame anticipated in its CON application. Because SMC's compliance with PRC 14 was considered by the Department below, that issue is properly before the Court in the context of the Court's *de novo* review of the Department's CON decision to approve the SMC Project.

MUHA's argues that SMC will not be able to meet the 100 Neonate Management Provision in Reg. 61-16 § 1306(C) and, therefore, will not qualify to be licensed as a Level III NICU. Hence, MUHA contends, SMC should be denied a CON because, in essence, it is a futile first step in establishing a Level III NICU that ultimately will never be approved or completed, at least within the time frame specified in the CON application.⁶³

MUHA's assertion of SMC's inability to comply with the 100 Neonate Management Provision depends, in the first instance, on the acceptance by the Court of MUHA's interpretation of the licensing requirement as a retroactive "transfer standard" for Level II providers applying for Level III status. SMC contends that the plain language of § 1306(C) does not support MUHA's interpretation of the requirement as being either retroactive or a transfer standard, and that SMC has adequately demonstrated in this CON proceeding that the SMC Project will be able to receive a Level III license when the time for licensure occurs.

"The cardinal rule of statutory construction is to determine and give effect to the intent of the legislature." *Estate of Nicholson ex rel Nicholson v. S.C. Dep't of Health & Human Servs.*, 377 S.C. 590, 595, 660 S.E.2d 303, 305 (Ct. App. 2008) (quoting *Charleston Cty. Sch. Dist. v. State Budget & Control Bd.*, 313 S.C. 1, 5, 437 S.E.2d 6, 8 (1993)). The best evidence of legislative intent is the text of the statute. *Jones v. State Farm Mut. Auto. Ins. Co.*, 364 S.C. 222, 231, 612 S.E.2d 719, 724 (Ct. App. 2005). In *State v. Hudson*, the South Carolina Court of Appeals observed the following regarding the construction of statutes:

The legislature's intent should be ascertained primarily from the plain language of the statute. . . . Words must be given their plain and ordinary meaning without resorting to subtle or forced construction which limits or expands the statute's operation. . . . When faced with an undefined statutory term, the court must interpret the term in accord with its usual and customary meaning. . . . The terms must be construed in context and their meaning determined by looking at the other terms used in the statute. . . . Courts should consider not merely the language of the

63. The Court found some favor with MUHA's argument in its Order on Motion to Lift Stay. After further reflection, given the finding that Reg. 61-16 § 1306 is not applicable at this stage in the proceedings to SMC, a Level II hospital, this contention is rejected.

particular clause being construed, but the word and its meaning in conjunction with the purpose of the whole statute and the policy of the law. (Emphasis added.)

State v. Hudson, 336 S.C. 237, 246, 519 S.E.2d 577, 581 (Ct. App. 1999) (internal citations omitted).

These same construction principles apply to the interpretation of regulations. *Murphy v. S.C. Dep't of Health & Envtl. Control*, 396 S.C. 633, 723 S.E.2d 191 (2012) (noting regulations are interpreted using the same rules of construction as statutes).

Briefly described, the perinatal organizations' licensing scheme requires that a hospital providing perinatal services must be designated as either a Level I, Level II, Level III, or Level IV perinatal center or an RPC. Reg. 61-16 § 1305(A). Each designated level provides a progressively higher level of care, with Level I perinatal centers providing basic services for normal uncomplicated pregnancies, and Level IV perinatal centers and RPCs providing care for the most critically ill newborns. *Id.* at §§ 1305(D) – (E). As the level of care increases, the requirements that must be met for designation likewise increase. *See generally id.* at § 1306(A) – (E). Each level must meet all the requirements of the levels below it, as well as the additional requirements specific to it, and a lower-level center may not provide care above that for which it is approved.

Thus, a Level III provider, which SMC seeks to become, must meet all the requirements of Level I and Level II perinatal centers in addition to the more comprehensive requirements set forth in § 1306(C). The 100 Neonate Management Provision appears in the following part of § 1306(C):

Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals.

Id. (Emphasis added).

In order to characterize the 100 Neonate Management Provision as a retroactive requirement that must be met by SMC as a prerequisite to being licensed as a Level III NICU, MUHA offers an interpretation of the requirement that essentially rewrites the regulation. First, MUHA disregards the plain meaning of the initial phrase “Hospitals with Level III designation shall” and construes it to mean “in order to receive a Level III designation, Hospitals shall.” This interpretation is necessary if the requirement is to be made applicable to SMC, a hospital with a

Level II designation. The word “with” means “in possession of.” See “*with*,” Merriam-Webster.com (2023), *available at* <https://www.merriam-webster.com/dictionary/with>. The plain meaning of the word “with” suggests the requirement applies to hospitals that have already received a Level III designation.

Second, MUHA disregards the plain meaning of the unambiguous phrase “shall manage” in the requirement and instead construes that phrase to mean “shall have transferred.” Thus, under MUHA’s interpretation, a Level II provider such as SMC must demonstrate *at the time of* its Level III licensure application that it has transferred at least 100 critical neonates to higher level perinatal facilities. The plain meaning of the word “manage” is “to handle or direct with a degree of skill; to exercise executive, administrative, and supervisory direction of.” See “*manage*,” Merriam-Webster.com, (2023) *available at* <https://www.merriam-webster.com/dictionary/manage>. Additionally, the word “transfer” means “to convey from one person, place, or situation to another.” See “*transfer*,” Merriam-Webster.com (2023), *available at* <https://www.merriam-webster.com/dictionary/transfer>. Thus, the literal requirement to “manage” neonate admissions indicates that the requirement applies to existing Level III providers, who can legally manage critical neonates, and not to Level II providers seeking Level III status, who cannot. It would work an absurdity to require SMC to comply with a standard that it cannot lawfully do.

MUHA also seeks to move the phrase “calculated over the previous three years” to the end of the sentence so that it can be read to modify both the requirement for 1500 deliveries annually and the 100 Neonate Management Provision. Again, this convoluted interpretation turns a prospective Level III neonate management provision into a retrospective threshold that must be met before SMC can qualify to become a Level III NICU. This forced construction advocated by MUHA further violates the rule of construction that laws should be interpreted “without resorting to subtle or forced construction which limits or expands the statute’s operation.” *Hudson*, 336 S.C. at 246, 519 S.E.2d at 581 (Ct. App. 1999).

Finally, MUHA and SMC disagree about the interpretation to be given to the maternal transfer standard contained in the last sentence of the 100 Neonate Management Provision. This requirement allows a provider to add to its calculation of managed neonate admissions the number of high-risk expectant mothers it transfers to a higher-level perinatal hospital. MUHA interprets the standard to apply only to expectant mothers who were admitted to a provider and then transferred to a higher-level perinatal hospital prior to the delivery in the higher-level facility of a

newborn who weighed less than 1500 grams, required ventilatory support for more than 24 hours, or who required surgery.

SMC asserts that the plain language of the maternal transfer standard allows a provider to count all expectant mothers, inpatient or outpatient, who were transferred prior to delivery to a higher-level perinatal hospital due to being identified as a high-risk case requiring the services of the higher-level perinatal hospital. As referenced earlier herein, although not germane to its ultimate ruling, the Court believes that MUHA is correct on this point.

Under Reg. 61-16 § 1305(A), a hospital requesting initial designation as a Level III provider is required to “demonstrate capability to comply with requirements of a particular designation by submitting to the Department documentation pertaining to the request for desired designation.” (Emphasis added).⁶⁴ To be “capable” means “having attributes (such as physical or mental power) required for performance or accomplishment.” *See “capable,”* Merriam-Webster.com (2023), *available at* <https://www.merriam-webster.com/dictionary/capable>. Demonstrating the “capability” to do something speaks to the ability to do it, not the actual doing. When read in the context of the entire licensing scheme, including § 1305 above, it is clear that MUHA’s forced reading of the 100 Neonate Management Provision as applying to SMC – before SMC even applies for licensure – cannot be the Department’s intended interpretation.

Ms. Murdock testified at the hearing that the CON division does not make licensing decisions and that she does not know whether the Department’s licensing division has or would have interpreted the 100 Neonate Management Provision to be prospective or retrospective. No witnesses from the Department’s licensing division, which administers and enforces section 1306(C), were presented to provide evidence concerning the Department’s interpretation and

64. The actual text of S.C. Code Ann. Regs. 61-16 § 1305(A), reads as follows:

- A. Each hospital providing perinatal services shall request designation as a Level I, II, III, or IV perinatal hospital, or regional perinatal center (RPC) by letter to the Department. Initially, a hospital shall demonstrate capability to comply with requirements of a particular designation by submitting to the Department documentation pertaining to the request for desired designation. For licensure renewals, along with maintaining compliance with the requirements of Section 1306, the hospital shall have birth weight-specific neonatal mortality data readily available for Department review relative to hospitals in the state of the same designation.

application of section 1306(C).⁶⁵ In the absence of an actual licensure application from SMC and input from the Department on SMC's capability to meet the requirements for Level III licensure, the Court is not inclined to decide between the interpretations offered by SMC and MUHA in this CON proceeding.

According to Ms. Murdock, regardless of whether the Neonate Management Provision is interpreted to be retrospective or prospective, once SMC actually applies for licensure, it can request and receive, in the discretion of the Department, an exception to the licensing requirements on patient safety and other factors. In other words, at the time that SMC requests designation as a Level III provider (which is the time at which it will actually be subject to compliance with the Licensing Regulations), the Department has the discretion to grant an exception to the 100 Neonate Management Provision in section 1306(C), provided that SMC can demonstrate that the health and welfare of the community requires enhanced access to Level III perinatal services. As expressed in its Order on Motion to Lift Stay, the Court is uncomfortable relying on this exception; nevertheless, because of the determination that section 1306(C) is not applicable at this stage of the proceedings, any issue about the exception Ms. Murdock referenced is speculative in the instant case.

As an aside, SMC presented undisputed evidence that it meets and exceeds the 1500 annual deliveries averaged over the prior three years. SMC also presented evidence that its Level II program made an average of 63 direct transfers of mothers and/or neonates from SMC to MUHA over the three-year period from 2018 to 2020. SMC also presented evidence that in South Carolina there are currently three non-RPC Level III programs that are not managing the volume of admissions required by the 100 Neonate Management Provision and that those programs are not being closed for failure to comply with the Level III licensing standards. The Department presented evidence that the Department's licensing division recently reported no quality issues with these lower volume Level III programs. This evidence indicates that the Department is currently allowing Level III programs that do not comply with section 1306(C) to remain licensed.

65. As the party asserting that SMC cannot comply with the requirement of section 1306(C) as interpreted by MUHA, MUHA had the burden of proving these allegations, including presenting evidence from Department witnesses as necessary. *See Pike v. S.C. Dept. of Transp.*, 343 S.C. 224, 231, 540 S.E.2d 87, 91 (2000) (“[i]t is a well-established rule that the party pleading an affirmative defense has the burden of proving it.”).

Based on SMC's data, and the Department's lack of enforcement of the section 1306(C) requirement on existing Level III programs, the Court finds SMC has adequately demonstrated that it has the capability of being licensed as a Level III NICU under Reg. 61-16 § 1306(C). Therefore, to the extent necessary to its ultimate conclusion in this matter, the Court concludes that SMC complies with PRC 14, "Ability to Complete the Project" as it has demonstrated that it has the ability to complete its project within the timeframe anticipated in its CON application.

Lastly, the Court concludes the following:

1. MUHA has not demonstrated by a preponderance of evidence that its CON application is competing with SMC's CON application. Both projects were approved under separate sections of the Health Plan that were designed for specific purposes. One was designed to allow high volume Level II programs to be approved for Level III status if the Level II could satisfy certain delivery and patient day volume thresholds. The other was designed to allow an existing Level III or IV NICU to apply if it had a need for additional bassinets even though there was not a numerical need showing in the plan. Moreover, given the testimony of SMC and MUHA's witnesses concerning the current utilization at MUHA, and the projected utilization of the NICU bassinets by both applicants, the Court concludes as a matter of law that the approval of both applications will not exceed the need for NICU services in the service area. *See* S.C. Code Ann. Regs. 61-15 § 103.6.

2. A project does not have to satisfy every criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one or more of the criteria. S.C. Code Ann. Regs. 61-15 § 801.3.

3. MUHA has not demonstrated by a preponderance of evidence that SMC's project does not comply with the Health Plan. The Court concludes as a matter of law that SMC's project satisfies Standard 1(e) of the Health Plan because SMC met and continues to meet the required patient day and delivery thresholds. Therefore, SMC's project satisfies PRC 1, Need.

4. MUHA has not demonstrated by a preponderance of evidence that SMC's project does not comply with PRC 2, Community Need Documentation. The Court concludes as a matter of law that SMC's project complies with PRC 2 because SMC identified its target population, made reasonable projections of future growth, demonstrated that its project is needed in the

location proposed, and documented that it will have sufficient utilization to justify the establishment of a NICU.

5. MUHA has failed to demonstrate by a preponderance of the evidence that SMC's project does not comply with PRC 3, Distribution/Accessibility. The Court concludes as a matter of law that SMC complies with PRC 3 because the establishment of a NICU at SMC will not result in the unnecessary duplication of services, and it will increase the accessibility of patients to its proposed service, including medically underserved patients.

6. MUHA has failed to demonstrate by a preponderance of the evidence that SMC's project does not comply with PRC 13, Record of the Applicant. The Court concludes as a matter of law that SMC complies with PRC 13 because its record is one of successful operation, and it has more than sufficient sources of assistance through HCA and its affiliates. Moreover, MUHA's failed to demonstrate by a preponderance of evidence that SMC was out of compliance with state regulatory programs.

7. MUHA has not demonstrated by a preponderance of evidence that SMC's project is not financially feasible. The Court concludes as a matter of law that SMC's project satisfies PRC 15, Financial Feasibility, because its pro forma projections appear to be reasonable and based on sound assumptions.

8. MUHA has not demonstrated by a preponderance of the evidence that SMC's project does not satisfy PRC 23, Adverse Effects on Other Facilities. The Court concludes as a matter of law that SMC's project satisfies PRC 23 because its effect on MUHA's occupancy rates and staffing will be negligible, and MUHA will have more NICU utilization in the future than it does today; MUHA's NICU operates at a significant positive contribution margin; MUHA is a statewide healthcare operation with billions in both net revenue and debt capacity and a healthy projected positive net income.

9. MUHA has not demonstrated by a preponderance of evidence that SMC's project does not satisfy the purposes of the CON Act. The Court concludes as a matter of law that SMC's project satisfies the purposes of the CON Act set forth in S.C. Code Ann. § 44-7-120 because SMC has demonstrated the need for its project, such that it will not be one that unnecessarily duplicates services; the project will foster cost containment; and the project will provide high quality services that best meets the public's needs.

10. As explained above, SMC's position in this contested case is that because the projects are not competing, both can be approved on their respective merits. SMC did not challenge the approval of MUHA's project based on the individual PRC, Health Plan standards or the purposes of the CON Act. The Court, therefore, concludes as a matter of law that MUHA's project complies with the Health Plan, the applicable PRC, and the CON Act.

ORDER

IT IS THEREFORE ORDERED that the Department's decisions to approve SMC and MUHA's CON applications be upheld, and that MUHA and SMC be issued CONs for their respective NICU projects.

AND IT IS SO ORDERED.

A handwritten signature in black ink, appearing to read 'M. Kimpson', with a long horizontal flourish extending to the right.

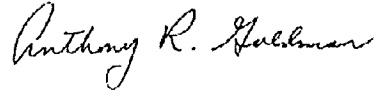
August 7, 2023
Columbia, SC

Milton G. Kimpson, Judge
South Carolina Administrative Law Court

CERTIFICATE OF SERVICE

I, Anthony R. Goldman, hereby certify that I have this date served this Order upon all parties to this cause by depositing a copy hereof in the United States mail, postage paid, or by electronic mail, to the address provided by the party(ies) and/or their attorney(s).

August 7, 2023
Columbia, SC



Anthony R. Goldman
Judicial Law Clerk

RECEIVED

Nov 06 2023

CERTIFICATE OF SERVICE

S.C. SUPREME COURT

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Medical University Hospital Authority, d/b/a MUSC Shawn Jenkins Children's Hospital and Pearl Tourville Women's Pavilion, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) via electronic mail, to the following address(es):

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November 6, 2023