Agency Name: Department of Health and Environmental Control

Statutory Authority: 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40

Document Number: 4461

Proposed in State Register Volume and Issue: 38/5

House Committee: Medical, Military, Public and Municipal Affairs Committee

Senate Committee: Medical Affairs Committee

120 Day Review Expiration Date for Automatic Approval: 05/13/2015

Final in State Register Volume and Issue: 39/6

Status: Final

Subject: Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

History: 4461

By Date Action Description Jt. Res. No. Expiration Date

- 05/23/2014 Proposed Reg Published in SR

- 01/13/2015 Received by Lt. Gov & Speaker 05/13/2015

H 01/13/2015 Referred to Committee

S 01/13/2015 Referred to Committee

H 01/20/2015 Recalled from Committee on Agriculture,

Natural Resources and Environmental Affairs

H 01/20/2015 Referred to Committee

S 05/04/2015 Resolution Introduced to Approve 738

- 05/13/2015 Approved by: Expiration Date

- 06/26/2015 Effective Date unless otherwise

provided for in the Regulation

Document No. 4461

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40

61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

**Synopsis:**

Regulation 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, has sections pertaining to Perinatal Care Services. This revision is limited to provisions in the regulation relating to perinatal care. The Department amended the Perinatal Care Services Sections to account for evolving practices and to improve overall quality and effectiveness.

This amendment revises Section 1300, Perinatal Services, of *State Register* Document 4430 at <http://www.scstatehouse.gov/regs/4430.docx> that completed legislative review May 17, 2014, and took effect as law by publication in the *State Register* on June 27, 2014.

A Notice of Drafting was published in the *State Register* on March 28, 2014.

Section-by-Section Discussion of Revisions

Statutory authority for the regulation was added under the title of the regulation and before the table of contents for consistency with other regulations.

61-16.1301 Newborn Hearing Screening

This section was revised to clarify sections 61-16.1301.A, B and C to replace references of “must” and insert “shall.”

61-16.1302 Shaking infant video & infant CPR information for parents and caregivers of newborn infants and adoptive parents

This section was revised to clarify sections 61-16.1302.A and B to replace references of “must” and insert “shall.” In addition, section 61-16.1302.C was revised to conform to the statutory authority of Shaking Infant Video & Infant CPR, Section 44-37-50.

61-16-1303 Providing a Safe Haven for Abandoned Babies

This section was revised to clarify sections 61-16.1303 to replace reference of “must” and insert “shall.”

61-16.1305 Perinatal Organization

This section was revised to delete the Level II Enhanced (IIE) level of care designation and add Level IV designation in sections 61-16.1305.A and 61-16.1305.B. This section is revised to clarify a review of neonate mortality.

61-16.1306 Designation of Inpatient Perinatal Care Services

This section was revised to clarify a Basic Perinatal Care Center with Well Newborn Nursery (Level I), a Specialty Perinatal Center with Special Care Nursery (Level II) and Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). This section was revised to delete Enhanced Perinatal Center (Level IIE) requirements. This section adds language to clarify a Complex Neonatal Intensive Care Unit (Level IV).

61-16.1306.A

This section revises the licensing requirements for a Basic Perinatal Center with Well Newborn Nursery (Level I).

61-16.1306.B

This amendment clarifies the language for infants requiring ventilation support. This amendment adds language to this section to allow a certified Neonatal Nurse Practitioner to provide coverage for shared neonatology coverage. The added language is “For shared neonatology coverage, a certified Neonatal Nurse Practitioner having responsibilities limited to a single center and in house may provide coverage for that center.”

61-16.1306.C

This amendment revises this section to add language regarding the consultation services of a board-certified neonatologist. “A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day.” This amendment revises ventilatory support for over twenty-four (24) hours. This amendment adds the requirement for data collection for outcomes measurement and quality improvement.

61-16.1306.D

This amendment revises the language requirement for ongoing education, coordination and development from the Regional Perinatal Centers to the Level I, Level II, and Level III facilities.

61-16.1306.E

This amendment adds the Complex Neonatal Intensive Care Unit (Level IV) designation requirements.

61-16.1307 Personnel

This section was revised to delete the Level IIE references and add Level III and Level IV requirements.

61-16.1313 Evaluation of Perinatal Care

This section revises Section 61-16.1313.A to delete the Level references and replace with all hospitals. This amendment revises Section 61-16.1313.C to delete “Each hospital” and replace with Level I and Level II hospitals. Additionally, Section 61-16.1313.E was revised to delete Level IIE reference.

**Instructions:** Amend R.61-16 pursuant to each individual instruction provided with the text of the amendments below.

**Text:**

**61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.**

**Add statutory authority under the title of R.61-16 and before the Table of Contents.**

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40.

**Revise Section 61-16.1301 to read:**

**1301. Newborn Hearing Screening.**

A. A facility that averages greater than 100 deliveries a year shall conduct a hearing screening on each newborn prior to discharge. In addition, the facility shall provide educational information about the screening procedure, the importance of the screening and the importance of having a complete audiobiological evaluation after discharge if the need is indicated.

B. If a facility averages fewer than 100 deliveries a year, a hearing screening is not required for each newborn, but the facility shall give the parents of each newborn educational information concerning the hearing screening procedure and the importance of having the screening procedure after discharge.

C. Each facility required to conduct newborn hearing screening shall regularly report the results of the screening to the Department in the required format.

**Revise Section 61-16.1302 to read:**

**1302. Shaking infant video & infant CPR information for parents and caregivers of newborn infants and adoptive parents.**

A. A facility shall provide to the parents of each newborn baby delivered in the facility a video presentation on the dangers associated with shaking infants and young children. The facility shall also make available information on the importance of parents and caregivers learning infant CPR.

B. The facility shall request that the maternity patient, the father, or the primary caregiver view the video. Those persons whom the facility requests to view the video shall sign a document prescribed by the Department of Health and Environmental Control stating that they have been offered an opportunity to view the video.

C. The facility shall only use a video approved by the Director, or his/her designee, of the Department of Health and Environmental Control.

**Revise Section 61-16.1303 to read:**

**1303. Providing a Safe Haven for Abandoned Babies.**

Facilities and outpatient facilities shall:

A. Accept temporary physical custody of an infant under thirty days of age who is voluntarily left by a person who does not express an intent to return for the infant and the circumstances create a reasonable belief that a person does not intend to return for the infant.

B. Be in full compliance with EMTALA rules and regulations and perform any act necessary to protect the physical health or safety of the infant.

C. Offer the person information concerning the legal effect of leaving the infant by delivering to the person the information brochure supplied by the state DSS. Ask the person to identify any parent other than the person leaving the infant. Attempt to obtain from the person information concerning the infant’s background and medical history as specified in the forms provided by DSS and appropriate forms available from facility files.

D. Using the DSS form, an attempt must be made to get information concerning use of controlled substances by the infant’s mother and other pertinent health information which might determine medical care required by the infant.

E. If the person does not wish to provide or is unable to provide the information to the facility, the person must be offered the DSS form with a prepaid envelope supplied to the facility by DSS.

F. No later than the close of the first business day, after the date on which the facility takes possession of the infant, the facility must notify DSS that it has taken temporary physical custody of the infant. DSS will have legal custody of the infant upon receipt of this notice and DSS will assume physical custody no later than 24 hours after receiving notice that the infant is ready for discharge.

**Revise Sections 61-16.1305 to read:**

**1305. Perinatal Organization.**

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.

B. Each Level I, II, III, and IV hospital shall maintain and document a relationship with its designated RPC for consultation, transport and continuing education. All patients shall be transferred to the appropriate RPC when medically appropriate, if beds are available. This agreement/relationship shall include the ability to share data, as appropriate, related to these functions.

C. Labor and delivery shall occur in a hospital capable of meeting the expected needs of both the mother and the neonate. Ongoing risk assessment shall occur to determine the appropriate level of care.

**Revise Section 61-16.1306 to read:**

**1306. Designation of Inpatient Perinatal Care Services.**

A. Basic Perinatal Center with Well Newborn Nursery (Level I). Level I hospitals shall provide services for normal uncomplicated pregnancies. Level I hospitals shall identify maternity patients requiring transfer to a facility providing the appropriate level of care for the fetus, consult with the RPC on such matters, and offer a basic level of newborn care to infants at low risk. Level I hospitals shall have personnel who provide care for physiologically stable infants born at or beyond 35 weeks of gestation and stabilize ill newborn infants born at less than 35 weeks of gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided. Level I hospitals shall have personnel and equipment available to provide neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy term newborn infants. Level I hospitals shall have the capability to begin an emergency cesarean delivery within an interval based on timing that best incorporates maternal and fetal risks and benefits. When it is anticipated or determined that these criteria will not be or have not been met, consultation and a plan of care shall be initiated and mutually agreed upon with the RPC and documented in the medical record, immediately after the patient is stabilized. Level I hospitals shall provide care of postpartum conditions and make provisions of accommodations and policies that allow families, including their other children, to be together in the hospital following birth. Appropriate anesthesia, radiology, and laboratory and blood bank services shall be available on a twenty-four (24) hour basis. Management shall include emergency resuscitation and/or stabilization for both maternal and neonatal patients in preparation for transfer/transport for more specialized services. 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.

B. Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with all requirements of Section 1306.A, Level II hospitals shall provide services for both normal and selected high-risk obstetrical and neonatal patients. Level II hospital care shall include management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams and problems expected to resolve rapidly (neonates not in need of sub-specialty services on an urgent basis). Level II hospitals shall provide care for infants convalescing after intensive care. Level II hospital shall stabilize infants born before 32 weeks of gestation and weigh less than 1500 grams until transfer to a neonatal intensive care facility. Level II hospitals shall have experienced personnel capable of providing continuous positive pressure airway pressure or mechanical ventilation for a brief period (less than 24 hours) or both until the infant’s condition improves or the infant can be transferred to a higher-level facility. Level II hospitals shall have equipment (e.g. portable x-ray equipment, blood gas laboratory) and personnel (e.g. physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) available at all times to provide ongoing care and address emergencies. Referral to a higher level of care should occur for all infants when needed, for medical or subspecialty intervention. Support personnel shall include respiratory therapists, radiology technicians, laboratory technicians, and a lactation consultant. A board-certified or board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. There shall be no limit on the duration of Nasopharyngeal Continuous Positive Airway Pressure (NCPAP) or Nasal Prong Continuous Positive Airway Pressure (NPCPAP) when cared for by a neonatologist.The provision of CPAP or mechanical ventilation beyond the immediate stabilization period requires the immediate availability of respiratory therapists with neonatal training (including intubation of premature infants), nursing support with training to identify and respond to complications of ventilation, and the immediate availability of personnel and equipment to evacuate a pneumothorax. Level II hospitals with a board certified or board eligible neonatologist having responsibilities limited to a single center and in house or within 30 minutes of the unit at all times may provide care for patients requiring mechanical ventilation for up to 24 hours. For shared neonatology coverage, a certified Neonatal Nurse Practitioner having responsibilities limited to a single center and in house may provide coverage for that center. Neonates requiring the initiation of mechanical ventilator support beyond 24 hours of age shall be referred to the RPC. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years based on the individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Level II units shall not transport neonates between hospitals. 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.

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also 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. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution. A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall 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. 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. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC’s, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates’ condition and care requirements are within the capability of those hospitals.

E. Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with all requirements of Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. Level IV hospitals shall have capability to perform surgical repair of complex congenital or acquired conditions (e.g. Congenital malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). Level IV hospitals shall maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the facility. Not all Level IV hospitals need to act as regional centers. Regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and return transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Level IV hospitals shall collect data to assess outcomes within their facility, and to compare with other hospitals within their level, if applicable.

**Revise 61-16.1307 to read:**

**1307. Personnel.**

A. Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*.

B. The following medical specialists and subspecialists shall have medical staff credentials and/or written consultative agreements as follows:

1. Level I shall include:

a. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

b. Consultation: Obstetrician, pediatrician, general surgeon.

2. Level II, in addition to Level I requirements, shall include:

a. Membership: General surgeon, pathologist, radiologist, obstetrician, pediatrician, and anesthesiologist;

b. Consultation: Maternal-fetal medicine specialist, neonatologist, and pediatric surgeon.

3. Level III and RPC, in addition to Level II requirements, shall include:

a. Membership: Maternal-fetal medicine specialist or effective consultation with Maternal-Fetal medicine specialist, (available 24 hours a day, 7 days a week) via telemedicine, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

b. Urgent Consultation: Pediatric subspecialists including cardiology, neurology, hematology, genetics, endocrinology, nephrology, gastroenterology-nutrition, infectious diseases, pulmonology, immunology, pathology, metabolism and pharmacology. Pediatric surgical subspecialists, to include cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology.

c. For Level III hospitals: Pediatric medical subspecialists, pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists may be at the site or at a closely related institution by prearranged consultative agreement. Prearranged consultative agreements can be performed using, for example, telemedicine technology, or telephone consultation, or both from a distant location.

4. Level IV, in addition to Level III requirements, shall include: Membership and on-site: Maternal-fetal medicine specialist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

**Revise 61-16.1313 to read:**

**1313. Evaluation of Perinatal Care.**

A. Review of maternal and neonate mortality and morbidity shall be conducted at least every three months by the medical staff or designated committee, regardless of the size or designation of the perinatal service. A perinatal mortality and morbidity review committee composed of representatives from the pediatric, obstetrical, and nursing staffs, with additional participation from other professionals, depending upon the cases to be reviewed, shall be established at all perinatal centers.

B. In all perinatal centers, selected case reviews shall include, but not be limited to:

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;

2. Analysis of perinatal morbidity and related factors.

C. Level I and II hospitals shall review all live births or fetal/neonatal deaths in which the neonate weighed at least 350 grams and less than 1500 grams, utilizing the Department’s *Very Low Birthweight Self-monitoring Tool*. Each completed self-monitoring DHEC form shall be retained by the facility and a copy made available to the Department as specified in the self-monitoring tool.

D. Each event shall be evaluated for potential opportunities for intervention with the intervention and follow-up described, if applicable. Written minutes of committee meetings shall be maintained and made available to the Department for review

E. Each Level I, II, and III perinatal center shall annually review and document the findings from these case reviews with its designated RPC. Minutes of these meetings shall be maintained and made available to the Department for review.

**Fiscal Impact Statement:**

The regulation will have no substantial fiscal or economic impact on the sale or its political subdivisions. Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or State government due to any inherent requirements of this regulation.

**Statement of Need and Reasonableness:**

The Department’s Bureau of Health Facilities Licensing formulated this statement determined by analysis pursuant to S.C. Code Ann Section 1-23-115 C(1)-(3) and (9)-(11) (2005).

DESCRIPTION OF REGULATION: R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.*

Purpose: This revision is limited to provisions in the regulation relating to perinatal care. The Perinatal Care Services Sections were revised to account for evolving practices and to improve overall quality and effectiveness.

Legal Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40.

Plan for Implementation: Upon approval from the S.C. General Assembly and publication of this amendment as a final regulation in the South Carolina State Register, a copy of Regulation 61-16, that incorporates these revisions, will be made available electronically on the Department’s regulation development website at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/> under the Health Regulations category and subsequently on the South Carolina Legislature Online website in the S.C. Code of Regulations. Printed copies will be available for a fee from the Department’s Freedom of Information Office. Staff will educate the regulated community on the provisions of the Act and the requirements of the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department last amended the perinatal sections of R.61-16 on April 26, 2002. SC Code Section 1-23-120(J) (Supp. 2012) requires state agencies to perform a review of its regulations every five years and update them if necessary.

Issues found in the review, requests from the perinatal community and the necessity for overall updates render these amendments needed and reasonable. The amendments improve the perinatal hospital designation assignments by creating a new designation level and following the *Guidelines for Perinatal Care.* The regulation is an overall improvement for public health by seeking to secure volume requirements without jeopardizing other providers who currently provide services.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or State government due to any inherent requirements of these amendments.

External Costs: There are no external costs anticipated.

External Benefits: The amendments update the perinatal sections for hospitals providing perinatal care while maintaining the interests of patient health and safety and lessening provider burdens. The amendments allow the community to maintain current perinatal care while adding new hospital designations.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

There will be no effect on the environment.

The amendments will reasonably account for evolving practices and improve overall quality and effectiveness of the perinatal community. The amendments will improve perinatal care within South Carolina by allowing new hospital perinatal care designations and be aligned with the current *Guidelines for Perinatal Care.*

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There would not be a detrimental effect on the environment.

If the revision is not implemented, unnecessary burdens will be placed on hospital facilities that provide perinatal care services.

**Statement of Rationale:**

The Department revised this regulation pursuant to the S.C. Code Ann. Section 1-23-120(J) (Supp. 2012) requirement that state agencies perform a review of its regulations every five years and update them if necessary. The regulation introduces a new designation to be aligned with the current *Guidelines for Perinatal Care.* The regulation is an overall improvement for public health by seeking to secure volume requirements without jeopardizing other providers who currently provide services.