130.630: continued

(c) Orientation and ongoing education for registered nurses including the theoretical framework and skills required to practice in the Level IB Continuing Care Nursery.
(d) If therapeutic formulas are made on-site, preparation and sealing of containers to prevent tampering.
(e) Management of infants with mild apnea of prematurity, neonatal abstinence syndrome or substance exposure, a PICC line, oxygen therapy and feeding related issues.
(f) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

130.640: Level IIA and IIB: Community-based Maternal and Newborn Service with a Special Care Nursery

(A) Level IIA Service. Level IIA capabilities include the management of pregnancies of 34 weeks gestation or greater, and the management of pregnancy complications not requiring the facilities and resources of Level IIB or Level III services. Level IIA capabilities include the care and management of the stable to moderately ill newborn, well newborns, premature infants and infants who require special care services (including retro-transferred infants).

A service shall be eligible to apply for designation as a Level IIA service with a special care nursery if one of the following conditions is met:

(1) the service has a minimum of 1,500 births per year in any one of the past three years prior to the initiation of the service designation request; or
(2) the service has satisfactorily demonstrated to the Department that a minimum volume of 1,500 births per year will be reached in the next three years; or
(3) the service has satisfactorily demonstrated to the Department that the hospital meets Level IIA quality and competency requirements and therefore the designation is warranted. Following the designation, a Level IIA service shall maintain a minimum volume of 1,500 births.

(B) Level IIB Service. Level IIB capabilities include the care and management of pregnancies of 32 weeks gestation or greater, and the management of pregnancy complications not requiring the facilities and resources a Level III service. Level IIB capabilities include the care and management of the stable to moderately ill newborn, well newborns, premature infants and infants who require special care services (including retro-transferred infants). Level IIB service includes the care of infants requiring Continuous Positive Airway Pressure (CPAP), in compliance with guidelines established by the Department.

A service shall be eligible to apply for designation as a Level IIB service with special care nursery if one of the following conditions is met:

(1) the service has a minimum of 2,000 births per year in any one of the past three years prior to the initiation of the service designation request; or
(2) the service has a minimum volume of 2,500 births for each of the two years after the designation as a Level IIA services; or
(3) the service has satisfactorily demonstrated to the Department that the hospital meets Level IIB quality and competency requirements and therefore the designation is warranted. Following the designation, a Level IIB service shall maintain a minimum volume of 2,000 births.

(C) The Level IIA or IIB Community-based Maternal-Newborn Service shall meet the requirements of a Level I service and those requirements contained in 105 CMR 130.601 through 130.630 and 130.640(D) through (E), unless otherwise specified.

(D) Maternal Service.
(1) Administration and Staffing.
(a) Nursing.
1. The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Level II service. At a minimum, such nurse shall be prepared at the baccalaureate level and have additional education in the specialty area. She or he shall also have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

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2. In a Level IIA service, a registered nurse educator, prepared at the baccalaureate level (master's preferred) shall have dedicated responsibility for coordinating and providing education activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.

3. In a Level IIB service, at a minimum a full time master's prepared clinical nurse educator, preferably a specialist with clinical experience in perinatology or neonatology or a neonatal nurse practitioner shall be available with dedicated responsibility for coordinating education for maternal and newborn staff.

(b) A licensed social worker with experience in maternal and child health shall be available to provide services to mothers and families.

(2) Services. Each Level II Maternal Service shall provide the following:

(a) Radiology, in-house, 24 hours a day.

(b) Clinical laboratory services including microchemical fetal blood sample monitoring, in house, 24 hours a day.

(c) Ultrasound and amniocentesis services in-house, 24 hours a day.

(d) Specialty services for the mothers including, but not limited to, general surgery, cardiology, urology, internal medicine, hematology and neurology.

(e) Access to genetics counseling.

(3) Policies and Procedures. Each Level II Maternal Service shall have written policies and procedures as required by 105 CMR 130.601 through 130.628 and, in addition, the following:

(a) n organized plan for a team approach to deliveries that requires the presence of a pediatrician and an anesthesiologist in the delivery room and properly defines their responsibilities. The hospital's perinatal committee shall establish policies, definitions, and conditions of delivery requiring a team approach.

(b) Other policies and procedures as deemed appropriate by the hospital perinatal committee. Such policies shall be submitted to the Department upon request.

(E) Special Care Nursery.

(1) Administration and Staffing.

(a) A neonatologist certified by the American Board of Pediatrics in neonatology shall be designated the medical director of the Special Care Nursery. A pediatrician meeting the requirements of 105 CMR 130.640(E)(1)(b) shall be designated to act in the absence of the director.

(b) A neonatologist certification in neonatology by the American Board of Pediatrics shall be available on-call 24 hours a day.

(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Special Care Nursery service. At a minimum, such nurse shall be baccalaureate-prepared and have additional education in the neonatology specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

(2) Special On-site Staffing Requirements. Each hospital providing special care nursery services shall provide on-site coverage 24 hours a day by either a neonatologist, pediatrician or a physician who meets the requirements of 105 CMR 130.640(E)(2)(a) or neonatal nurse practitioner who meets the requirements of 105 CMR 130.640(E)(2)(b), who shall be immediately available to the special care nursery and the delivery room.

(a) Pediatricians. A pediatrician qualified to provide on-site coverage in the special care nursery shall be either a pediatric resident who, at a minimum, has completed the second year of post-graduate residency training with at least two months neonatal intensive care unit rotations or a pediatrician. Pediatricians shall meet the hospital's requirements for special care nursery privileges. Pediatric residents shall meet criteria for special care nursery coverage established by the Director of the special care nursery. At a minimum, criteria for privileges and coverage shall include the specific clinical skills to provide emergency newborn resuscitation in the delivery room and essential special care nursery skills such as intubation, emergency pneumothorax management, umbilical artery catheterization, and drawing arterial blood gases. Before assignment to provide on-site coverage, pediatricians and residents shall successfully complete the American Heart Association/American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

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(b) Neonatal Nurse Practitioner.

1. A neonatal nurse practitioner qualified to provide on-site coverage in the special care nursery shall:

a. be certified as a neonatal nurse practitioner by a nationally recognized organization; and

b. be authorized to practice as an advanced practice registered nurse by the Massachusetts Board of Registration in Nursing.

2. Before assignment to provide on-site coverage, each neonatal nurse practitioner shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

3. Neonatal nurse practitioners shall be credentialed through the hospital's nursing department and medical staff. The neonatal nurse practitioner shall engage in prescriptive practice in accordance with written guidelines mutually developed and agreed upon between the nurse practitioner and the physician supervising the nurse practitioner's prescriptive practice. The written guidelines will conform to 244 CMR 4.07(2)(b). Neonatal nurse practitioners shall also meet the criteria for delivery room and special care nursery coverage established by the director of the special care nursery. Criteria shall include the skills necessary to provide emergency care to newborns as outlined in 105 CMR 130.640(E)(3)(a).

4. The nurse practitioner providing Level II coverage shall have at least one year's recent experience functioning as a neonatal nurse practitioner on a service that provides high risk obstetrical and neonatal intensive care unit services.

5. Neonatal nurse practitioners shall be part of a team providing patient care and not retained only to provide off hour or holiday coverage at the level II service. The schedule for coverage of the delivery room and special care nursery shall reflect that pediatricians and neonatal nurse practitioners who are members of the team share responsibility for covering all shifts and collaborate in the ongoing care of infants and their families and in professional education activities.

6. There shall be written policies and procedures outlining the specific criteria for summoning pediatrician or neonatologist back-up coverage for consultation and for on-site assistance in the delivery room and special care nursery.

(3) Services. Each Level IIA or IIB Special Care Nursery shall provide the following, unless otherwise specified:

(a) Provision of a neutral-thermal environment.

(b) Continuous and long-term oxygen administration *via* nasal cannula and hood, including oxygen saturation monitoring.

(c) Pharmacological treatment of apnea of prematurity.

(d) Capabilities to insert and maintain intravenous therapy for hydration and medication administration, in house, 24 hours a day.

(e) Umbilical artery and venous catheter insertion and maintenance.

(f) Continuous electronic cardio-respiratory monitoring.

(g) Blood transfusion capability (exchange transfusion optional).

(h) Naso-gastric, oro-gastric and oro-jejunal feedings.

(i) Parenteral nutrition.

(j) Access within the facility or through arrangement with Level III facilities to subspecialty services or consultation with pediatric surgery, neurology, cardiology and genetics.

(k) CPAP services in compliance with guidelines established by the Department.

(4) Policies and Procedures for Transfer.

(a) In a Level IIA service a mechanical ventilator or CPAP may be initiated and used in a Special Care Nursery prior to a transfer to a Level III service when the Medical Director of the Special Care Nursery approves such use and when all of the following conditions are met:

1. A neonatologist remains immediately available in the hospital at all times.

2. A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.

3. The Special Care Nursery is arranging for transport of the infant to the Level III service.

4. The mechanical ventilator is used only while the infant is awaiting the transport.

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(b) In a Level IIB service a mechanical ventilator may be initiated and used in a Special Care Nursery prior to a transfer to a Level III service when the Medical Director of the Special Care Nursery approves such use and when all of the following conditions are met:

1. A neonatologist remains immediately available in the hospital at all times.
2. A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.
3. The Special Care Nursery is arranging for transport of the infant to the Level III service.
4. The mechanical ventilator is used only while the infant is awaiting the transport.

(5) Other Policies and Procedures. The Special Care Nursery shall have written policies and procedures for the following:

(a) Orientation and ongoing education for registered nurses including the theoretical framework and skills required to practice in the Special Care Nursery.

(b) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

(6) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the record of a newborn treated in a Special Care Nursery shall also contain documentation of the following:

(a) Diagnostic and treatment modalities.
(b) Family-infant interactions.
(c) Parents' understanding of infant's condition, progress and treatment.
(d) Parent education and involvement in both normal and specialized care-giving.
(e) Where indicated, the plan for and patient response to infant stimulation program.
(f) Referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.

(7) Environment and Equipment. The Special Care Nursery shall contain, at a minimum, the following equipment and be responsible for appropriate maintenance, per hospital policy:

(a) Incubators.
(b) Cardio-respiratory monitors with high/low alarm.
(c) Warming table(s).
(d) Infusion pumps.
(e) Oxygen humidification and warming system.
(f) Oxygen analyzer.
(g) Umbilical artery/vein catheterization equipment.
(h) Neonatal resuscitation medications and equipment as described by the American Academy of Pediatrics Neonatal Resuscitation Program guidelines.

(8) Construction and Arrangement of Special Care Nursery. The construction and arrangement of the Special Care Nursery shall permit immediate observation and accessibility of infants to personnel. Total nursery space, exclusive of anteroom, shall provide an average floor space of 50 square feet for each incubator or bassinet.

130.650: Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services

(A) Level III Service. The Level III maternal and newborn service has the capabilities to provide care for stable to severely ill newborns, well newborns, premature infants, and infants who require neonatal intensive care services. The maternal service has the capability to manage complex maternal conditions with the expertise of a Critical Care Obstetrics Team.

(B) A service shall be eligible for designation as a Level III service with a neonatal intensive care nursery if one of the following conditions is met:

(1) the service has a minimum of 2,000 births per year in any one of the past three years; or

(2) the service has satisfactorily demonstrated to the Department that a minimum volume of 2,000 births per year will be reached in the next three years; or

(3) the service has satisfactorily demonstrated that the percent of low birth weight infants (< 2,500 grams) delivered is no less than 10% of the annual births.

130.650: continued

(C) The Level III service shall meet the requirements of a Level I, IIA, and IIB service, and those requirements contained in 105 CMR 130.601 through 130.628 and, in addition, the requirements set forth in 105 CMR 130.650(D) and (E).

(D) Maternal Service.

(1) Administration and Staffing.

(a) A physician certified by the American Board of Obstetrics and Gynecology with a subspecialty (special competency) in maternal-fetal medicine shall be designated medical director of the maternal service. This obstetrician shall collaborate with the neonatologist responsible for the neonatal intensive care unit in the medical management of the maternal and newborn service.

(b) An obstetrician with full privileges shall be available in-house 24 hours a day.

(c) At a minimum, a second obstetrician or obstetrician in training who has completed the second year of post-graduate residency shall be immediately available to the unit, in-house, 24 hours a day.

(d) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour a day nursing management of the Level III Maternal Service. At a minimum, such nurse shall be master's-prepared and have additional education in the maternal specialty area. She or he shall also have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.

(e) Qualified registered nurses shall be on duty to care for maternal patients 24 hours a day. The team of nurses shall demonstrate competencies in critical care as required by hospital policies and be Advanced Cardiac Life Support certified or have equivalent training and experience.

(f) A dietician registered by the Commission on Dietetic Registration with expertise in both normal and high risk maternal and newborn nutritional needs and with access to neonatal nutritional resources shall be available seven days a week.

(2) Services. The Level III Maternal Service shall provide the following:

(a) Anesthesia, in-house, 24 hours a day.

(b) Radiology and imaging, in-house, 24 hours a day.

(c) Clinical laboratory services including on-unit capabilities for microchemical fetal blood sample monitoring 24 hours a day.

(d) Access within the facility or through referral to another Level III facility to intrauterine transfusions and surgery.

(e) Adult subspecialty services including general surgery, thoracic surgery, neuro-surgery, cardiology, urology, internal medicine, hematology, neurology, genetics and psychiatry.

(f) Intensive care unit services and invasive cardio-vascular monitoring.

(3) Policies and Procedures. In addition to the policies and procedures required pursuant to 105 CMR 130.601 through 130.628, a Level III service shall develop policies and procedures for the following:

(a) Admission and transfer criteria.

(b) Maternal/fetal research.

(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

Such policies and procedures shall be submitted to the Department upon request.

(E) Neonatal Intensive Care Unit. The Neonatal Intensive Care Unit shall meet the requirements of a Level I, IIA, IIB, and III service, as well as those requirements contained in 105 CMR 130.601 through 130.628 and 130.650(D) and (E).

(1) Administration and Staffing.

(a) A board-certified neonatologist shall be designated the medical director of the Neonatal Intensive Care Unit. The medical director or his or her designee shall be available on-call 24 hours a day.

(b) A neonatologist shall be available in-house 24 hours a day.

(c) At a minimum, a pediatrician or a pediatrician-in-training who has completed the second year of post-graduate residency shall be present in-house and immediately available to the unit, 24 hours a day.

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(d) A nurse designated by the hospital shall be responsible for the 24 hours a day nursing management of the neonatal intensive care service. At a minimum, this nurse shall be masters-prepared and have experience and advanced education in caring for sick newborns. She or he shall have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.

(e) Qualified registered nurses shall be on duty to care for newborns 24 hours a day. The team of nurses shall demonstrate competencies in critical care as defined by hospital policy and be Neonatal Resuscitation Program (NRP) certified.

(f) A freestanding pediatric hospital with a neonatology subspecialty shall meet the requirements for a nurse educator stipulated in 105 CMR 130.640(D)(1)(a).

(g) A masters-prepared licensed social worker with experience in assessment of perinatal patients (mother/infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patient needs.

(h) A respiratory therapist trained in the neonatology specialty area shall be available to the unit 24 hours a day.

(i) A lactation consultant shall be available seven days a week. Lactation consultants shall have training and experience in providing care and services to infants with special needs and their families.

(2) Services. The Neonatal Intensive Care Unit shall be located within either a hospital with Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services.

The Level III Neonatal Intensive Care Unit shall provide the following:

(a) Access to emergency transport team for transferring sick newborns from the birth hospital to the neonatal intensive care unit.

(b) Ventilatory assistance and/or complex respiratory management including high-frequency ventilation.

(c) Capability of continuous intravenous administration of vasopressor agents.

(d) Insertion and maintenance of all types of venous and arterial lines.

(e) Nitric oxide therapy.

(f) Exchange transfusions.

(g) Cardio-respiratory monitoring including oxygen saturation monitoring.

(h) Complex nutritional and metabolic management including total parenteral nutrition.

(i) Full range of emergency pediatric radiology and subspecialty services available 24 hours a day.

(j) Full range of laboratory services including microchemistry and full service blood bank available 24 hours a day.

(k) Access to emergency surgical interventions in the newborn (or written agreements with other institutions providing subspecialty surgical procedures) available 24 hours a day.

(l) Post-surgical care.

(m) Access to pediatric subspecialty consultation and services including surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics available 24 hours a day.

(n) Availability of developmental consultation, including occupational and physical therapies.

(o) Continuous involvement of parents in infant's care and opportunity for mothers to room-in for pre-discharge education in caring for the infant.

(p) Crisis-oriented support and ongoing psychosocial services including social work service and the availability of psychiatric consultation for the parents. (Provision for parent support group is recommended.)

(q) Transport capabilities to return patients to a hospital with a Level I or II service.

(r) Ethics committee for ongoing review of complex patient care issues with focus on parental involvement in decision making.

(s) Professional education program, including educational offerings to collaborating community hospitals.

(t) Parent education appropriate to meet the needs of the infant and family.

130.650: continued

(3) Policies and Procedures. The neonatal intensive care unit shall have written policies and procedures for the following:

(a) Orientation and ongoing education for registered nurses in the theoretical framework and skills required to practice in the NICU.

(b) Emergency transport of infants from collaborating hospitals. These policies shall require the presence of a physician, physician assistant with neonatology training or neonatology specialty-trained nurse on the transport team and access to telephone consultation with a neonatologist.

(c) Newborn pain and substance exposure management.

(d) Each hospital with a Level III maternal and newborn service shall develop and maintain quality improvement initiatives including participation in the Vermont Oxford Network's Very Low Birth Weight Database, and shall make Vermont Oxford Network data reports available to the Department upon request.

(e) Other policies and procedures as determined by the hospital perinatal committee or the multidisciplinary neonatal intensive care committee.

(4) Records. In addition to meeting the requirements for records contained in 105 CMR 130.627(B), the newborn's record shall also contain documentation of the following:

(a) Diagnostic and treatment modalities.

(b) Family-infant interactions.

(c) Psychosocial evaluation.

(d) Staff-parent communication and parental response to the infant's condition.

(e) Parent education and involvement in both normal and specialized care-giving.

(f) The process used to make decisions where ethical questions are raised, including parental involvement in the process.

(g) Application of research protocols in the care of the infant.

(h) Where need identified, a plan for and patient response to positive infant stimulation program.

(i) Written discharge plans with referrals to community agencies such as parent support groups, visiting nurse associations and early intervention programs.

(5) Environment and Equipment. The Neonatal Intensive Care Unit shall contain at a minimum the following equipment and be responsible for appropriate maintenance per hospital policy:

(a) Sleeping space shall be provided for parents who spend extended periods of time with the infant.

(b) A consultation/demonstration room for private discussions shall be located convenient to the neonatal intensive care unit.

(c) Availability of breastfeeding pump room.

(d) Percutaneous oxygen monitor.

(e) Arterial and venous catheterization equipment.

(f) Ventilators with heated humidity and alarm systems

(g) Transducers for invasive cardiac monitoring.

(h) Transport isolette(s).

(i) Separate nutrition support area.

130.660: Minimum Lengths of Stay

The minimum length of inpatient stay for mothers and infants shall be 48 hours following a vaginal delivery and 96 hours following a cesarean section. These time periods begin at the time of the infant's birth. Inpatient stays of less than these time frames shall constitute early discharge. No discharge shall occur between the hours of 8:00 P.M. and 8:00 A.M. without the mother's agreement. Any decision to shorten these minimum stays shall be made by the attending practitioners for both mother and infant in consultation with and upon agreement by the mother. For the purposes of 105 CMR 130.660, attending practitioner shall include obstetrician, pediatrician, family physician, or otherwise qualified attending physician, certified nurse midwife, or nurse practitioner.

130.661: Early Discharge Protocols

Each hospital operating a maternal and newborn service shall develop protocols governing early discharge for mothers and infants. Protocols shall be developed in collaboration with obstetric, pediatric and nursing practitioners, and shall be consistent with guidelines and early discharge criteria set forth by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) and at a minimum shall provide that early discharge may be considered only when the simultaneous discharge of the mother and infant is feasible and only after environmental and other risk factors affecting the well-being of the mother and infant have been assessed. Nothing in 105 CMR 130.661 shall affect the right of a mother to voluntarily choose an early discharge.

130.662: Notices

Mothers shall be informed in writing, at the time of admission and with any pre registration materials, in language understandable to the mother and in their own language, by the hospital, payers or insurers subject to the provisions of St. 1995, c. 218, of their rights under 105 CMR 130.660 through 130.669. The notice shall include, but not be limited to, information about the minimum lengths of inpatient stay of 48 hours following a vaginal delivery and 96 hours following a cesarean section; the right to home visits as provided for in 105 CMR 130.665 following early discharge; and the process and telephone number for filing appeals, if they feel their rights have been violated.

130.663: Discharge Plans

The hospital shall develop a comprehensive written discharge plan for each mother and newborn for whom an early discharge is contemplated. Said discharge plan, at a minimum, shall identify the mother's and newborn's primary health care providers and specify and arrange for existing, appropriate home care services consistent with ACOG and AAP early discharge guidelines.

130.664: Transfer of Clinical Information

Each hospital operating a maternal and newborn service shall develop protocols for the transfer of pertinent clinical information concerning the mother and infant to the professional or agency providing the home care services. A minimum standard for content should include specific information on the timing and necessity of performing newborn screening as well as information regarding relevant prenatal, birth and hospital postpartum course of care.

130.665: Home Visits

Eligible mothers and infants who participate in early discharge shall be provided, upon agreement by the mother, a minimum of one home visit. The first home visit shall occur within 48 hours following discharge of the mother and infant and shall be conducted by a registered nurse, physician, or certified nurse midwife trained in maternal and infant care. Any subsequent visits determined to be clinically necessary shall be provided by a licensed health care professional or appropriately trained individual under the supervision of a licensed health care professional. Subsequent home visits for the mother and infant shall be based on need as determined by the attending practitioners in consultation with the mother. Minimum content of the first home visit includes review of relevant health history, physical examination of the mother and infant, performance of newborn screening tests, assessment/teaching of maternal self-care, infant care, breast/bottle feeding, and the need for social support communication with primary obstetric and pediatric health providers and referral to appropriate follow-up resources. Refusal of any services as specified in 105 CMR 130.665 shall be documented.

130.666: Appeals

Denial of benefits under St. 1995, c. 218 may be appealed to the Department of Public Health. Appeals may be filed by contacting the Department by telephone. The Department shall establish a toll-free telephone number to receive such appeals.

130.667: Notification and Request for Information

Upon receipt of the appeal, the Department shall immediately contact the hospital, post hospital provider, payers or insurers subject to the provisions of St. 1995, c. 218 as appropriate, and may require that portions of the patient's record be immediately furnished to the Department.

130.668: Appeal Decision

Upon review of all relevant information, the Department shall make a determination regarding whether the mother or infant has been denied benefits pursuant to 105 CMR 130.660 through 130.669. Such decision shall be communicated to the patient and to the hospital, post hospital provider, payers or insurers subject to the provisions of St. 1995, c. 218, by telephone immediately following the receipt of all requested information. The Department shall send written confirmation of its decision within a reasonable period of time.

130.669: Stay Pending Appeal

The filing of an appeal shall stay any proposed early discharge of the mother and the infant during the pendency of the appeal.

130.700: Definitions applicable to 105 CMR 130.720 through 130.761

Terms used in 105 CMR 130.720 through 130.761 shall be interpreted as set forth in 105 CMR 130.700.

General Pediatric Service (Level II). A service that provides care for pediatric patients with medical and surgical problems who do not require the specialized pediatric intensive care and/or comprehensive specialized services found on a tertiary pediatric service (Level III). A Level II service must have a pediatric unit with suitable personnel and access to subspecialty consultation, supportive laboratory facilities, and ancillary services necessary to provide for the level of care offered.

Pediatric Patient. Any inpatient from birth through 21 years of age, other than an infant in a newborn nursery, an intermediate or special care nursery, or a neonatal intensive care unit. Pediatric patients younger than 15 years old must be admitted to a pediatric service. Pediatric patients 15 years of age or older may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

Pediatric Specialty Service. A hospital or a unit of a hospital that limits the pediatric care it provides to a class of diseases or a subdivision of a department of medicine or surgery.

Pediatric Service. The combination of personnel, programs, and space needed to provide care for the diagnosis, treatment, and support of pediatric patients.

Pediatric Unit. The discrete area and equipment designated for the use of pediatric patients.

Tertiary Pediatric Services (Level III). A service that includes Level II pediatric care, pediatric intensive care, and comprehensive specialized services. A Level III service must have a wide range of pediatric specialists and subspecialists, 24-hour in-hospital medical coverage by physicians at a minimum in a pediatric residency program, appropriate pediatric laboratory facilities, and a medical school affiliation.

Uncomplicated Pediatric Service (Level I). A service that provides care and/or stabilization for pediatric patients with uncomplicated medical and surgical problems who do not require the specialized pediatric intensive care and/or comprehensive specialized services found on a tertiary pediatric service (Level III). A Level I service may perform emergency and selected elective pediatric surgical procedures requiring general or spinal anesthesia in accordance with guidelines developed by the Department. A Level I service need not have a pediatric unit but it must admit all pediatric patients younger than 15 years old to a room or rooms designated primarily for the use of pediatric patients.

130.720: Requirements for all Pediatric Services (Levels I-III)

Pediatric services (Levels I-III) shall comply with the following requirements:

(A) Hospitals providing inpatient care to children younger than 15 years old must admit these patients to a level I pediatric area as described in 105 CMR 130.730(C) or a level II pediatric unit or sub-unit, or a level III pediatric unit, with the exception of those patients who require specialized care that cannot be provided in such a pediatric area, unit or sub-unit, such as obstetrics or other care designated by the Department.

(B) (1) Any patient 21 years of age or older may be admitted to a pediatric service when in the opinion of the Chiefs of Pediatrics, and the Director of Nursing or their designees, he or she has a condition most appropriately treated on a pediatric service.

(2) When a temporary medical emergency fills the medical/surgical service, and the admission to a pediatric unit or sub-unit of certain medical/surgical patients 21 years of age or older poses no danger to pediatric patients, such a medical/surgical patient may be admitted to a pediatric unit or sub-unit with the approval of the Chief of Pediatrics and the Director of Nursing or their designees, provided:

(a) No such patient occupies a bed in the same room as a pediatric patient, and

(b) The hospital keeps a log of each such admission, which is available for the Department's inspection.

(C) A pediatric service shall establish an advisory multidisciplinary Pediatric Committee, chaired by the Chief of Pediatrics, that meets regularly to advise it on issues related to the service.

(D) A pediatric service shall develop and implement written policies and procedures for patients, including but not limited to, requiring transfer and/or consultation, parental involvement to the extent practicable, known or suspected child abuse or neglect, and behavioral health issues.

(E) At least one pediatric patient room shall be available for isolation use.

(F) A pediatric service shall have appropriately sized equipment and supplies and be responsible for appropriate maintenance per hospital policy, including, but not limited to, resuscitation equipment readily available in all areas and services providing care to pediatric patients

(G) The clinical laboratory services available for pediatric patients shall be defined by the Director of Laboratory Services in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(H) The diagnostic radiological procedures available for pediatric patients shall be defined by the Chief of Radiology in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(I) All personnel providing direct care to pediatric patients shall participate in a pediatric orientation program that meets the needs of the hospital and its patients.

(J) Only Level III pediatric services may have pediatric intensive care units. Ordinarily, patients younger than 15 years old requiring intensive care shall be admitted to pediatric intensive care units in hospitals with Level III pediatric services. When this is inadvisable, such a patient may be admitted to an adult intensive care unit (ICU) if the ICU meets the following criteria for the duration of the pediatric patient's stay:

(1) A physician who is capable of pediatric resuscitation is available in-hospital 24 hours a day.

(2) There is a consultation with a pediatrician for every pediatric patient younger than 15 years old admitted to the ICU.

(3) A registered nurse with clinical pediatric experience is available to the ICU for nursing consultation and/or care whenever a pediatric patient requires it.

(4) Emergency pediatric drug dosages are available in the ICU.

130.811: continued

(2) The Director of Medical Affairs shall be responsible for advising and consulting with the medical staff of the birth center on all matters related to medical management of pregnancy, birth, post-partum, newborn and gynecologic health care including policies, procedures and protocols that are outside the scope of midwifery practice.

(C) Required Staffing at Births.

(1) Birth Attendant. A certified nurse-midwife, or an obstetrician or family practitioner with obstetrical privileges in the parent or nearby hospital shall attend each woman in labor from the time of admission; during labor; during the birth; and through the immediate postpartum period. Such attendance may be delegated only to another certified nurse midwife or physician.

(2) Birth Assistant. A second staff person shall also be present at each birth. The second staff person must be either a nurse-midwife, or a licensed nurse.

(3) Licensed nurses functioning as a birth assistant must have labor and delivery experience within the past year that includes through training or experience in:

(a) full adult and infant resuscitation;
(b) assessing the phases and stages of labor;
(c) psychology and physiology of labor and delivery; and
(d) equipment and supplies used for labor and delivery.

130.812: Equipment and Supplies

Each birth center shall have safe and adequate equipment is available to meet the needs of its patients, including those with disabilities, to include at a minimum:

(A) A standard neonatal warming device and a transfer incubator.

(B) A microscope for routine office examination of vaginal smears.

(C) A sufficient number of sphygmomanometers and auscultation equipment.

(D) Equipment and supplies for administration of intravenous fluids, and full adult and infant resuscitation as required by procedures outlined in the birth center's protocols.

(E) A supply of oxygen including portable oxygen available for emergency use.

(F) Portable suction available for both the mother and the infant.

130.813: Patient Records

A birth center shall maintain accurate and complete records on all of its patients that include at a minimum the following information with respect to each newborn:

(A) The condition of the infant at birth to include Apgar Score (or its equivalent) at one minute and five minutes, time of sustained respiration, details of physical abnormalities and pathological states.

(B) Date and hour of birth, birth weight and period of gestation.

(C) Number of cord vessels and any abnormalities of the placenta.

(D) Verification of eye prophylaxis.

(E) Metabolic screening.

(F) Treatments, medications and special procedures.

(G) Condition at discharge or transfer.

130.814: Care and Services

(A) The birth center shall provide a program of care to include at least the following:
(1) A personal and family history;
(2) A physical examination and appropriate laboratory tests;
(3) A program of prenatal care that shall include components of self-help, self-care, and fetal assessment;
(4) A program of prenatal education that shall include the importance of nutrition, preparation for birth and breast feeding, and information on adverse effects of smoking, alcohol and other drugs;
(5) Intrapartum and postpartum services that foster parental control and responsibility for the birth experience and infant parental bonding;
(6) Labor support for the mother and her family;
(7) Immediate postpartum care and newborn assessment;
(8) Required eye prophylaxis;
(9) Postpartum laboratory examination and program for prevention of Rh immunization;
(10) Newborn metabolic screening and other such tests as may be required;
(11) A postpartum examination and family planning; and
(12) A plan for well woman routine gynecologic health care.

(B) The birth center shall have access to diagnostic services including clinical laboratory, sonography, radiology, electronic monitoring.

(C) Mothers and infants shall be discharged or transferred within 24 hours after birth.

(D) Maternal and newborn examinations shall be performed by the birth center professional staff or a physician or certified nurse-midwife of the family's choice within 72 hours of birth. Such examinations shall include required laboratory tests for health screening.

(E) Each birth center shall develop and implement written policies and procedures for the prompt and safe transfer of the obstetrical patient and of the newborn for emergency treatment beyond that provided in the birth center.

(F) Each birth center shall have a written agreement with an obstetrician with full obstetrical privileges at a nearby or the parent hospital, and a written agreement with a pediatrician with full pediatric privileges at a nearby or the parent hospital for the care and transfer of patients for emergency treatment beyond that provided by the birth center.

(G) A birth center must conduct newborn infant hearing screening in accordance with the requirements regarding screening at 105 CMR 130.616(D)(2)(l). If a birth center does not have the equipment or ability to conduct such a screening, the birth center shall refer the newborn infant to a hospital or birth center able to conduct such screening. Prior to discharge, a birth center that is not able to conduct a hearing screening shall:
(1) make an appointment for a screening for each newborn infant at a screening site.
(2) provide written information in the language understood by the parent or guardian to the parent or guardian about the importance of the screening, coverage of the costs of the screening by third party payers, the time of any screening appointment scheduled, and the location and phone number of the hearing screening site.
(3) within two weeks of the birth of a child call to the parent or guardian of the newborn infant to verify the infant has received the hearing screening, and document the conversation about the performance of the screening.

130.815: Prohibited Practices

(A) Surgical procedures shall be limited to those normally accomplished during uncomplicated childbirth, such as episiotomy and repair.

(B) The following practices are prohibited in a birth center:
(1) Surgical procedures such as forceps delivery, tubal ligation, abortion, or Cesarean section.

130.815: continued

(2) The use of any analgesics subject to regulation under M.G.L. c. 94C for pain control during labor.
(3) Inhibition, stimulation or augmentation of the first or second stage of labor with controlled substances,
(4) The use of general or regional anesthesia. Local anesthesia for the infiltration of the perineum for episiotomy repair may be administered in accordance with patient specific standing orders written by the physician.
(5) The provision of controlled substances for self-administration outside of the birth center.

130.816: Off-hour Coverage

Each birth center shall make arrangements for the provision of services 24 hours a day. These requirements can be met through on call coverage by a certified nurse-midwife or physician on the staff of the birth center. These arrangements shall be reflected in a written policy that is made available to all the birth center's clients.

130.817: System for Referral

(A) The free-standing birth center shall have a written agreement with a board-certified obstetrician/gynecologist, and a pediatrician or neonatologist for the provision of 24 hour consultation, referral and transfer to appropriate hospital facilities for obstetric/newborn care.

(B) Each hospital-affiliated birth center shall develop written agreements or policies for the provision of 24 hour consultation with an obstetrician/gynecologist and a pediatrician or neonatologist with clinical privileges at the parent hospital. If the parent hospital does not provide obstetrics and newborn services, the birth center must meet the requirements set forth in 105 CMR 142.506(A).

130.818: Reporting Requirements

(A) Birth centers shall report all births to the Department, and to registrars and city or town clerks, in accordance with M.G.L. c. 46.

(B) Birth centers shall report any child with low birth weight, congenital abnormalities, and other high risk infants in accordance with guidelines as may be established by the Department.

130.821: Approval for Satellite Emergency Facility

No hospital shall operate a SEF without filing an application and proposal with and having received written approval from the Department.

130.822: Application and Proposal

A hospital proposing to establish an SEF shall file a written application and proposal with the Department at least 90 days prior to the date proposed for the opening the SEF.

130.823: Notice to Affected Parties

No later than the date of the filing of a hospital's application and proposal pursuant to 105 CMR 130.822, the hospital shall send written notice, *via* certified mail, to affected parties within the hospital's service area. Affected parties shall include but not be limited to local fire departments, ambulance services, police, regional EMS Councils designated pursuant to 105 CMR 170.000: *Emergency Medical Services System*, local boards of selectmen or mayors, and local boards of health. A copy of the notice shall be included with the application filed pursuant to 105 CMR 130.822.

130.824: Content of Notice

The notice required pursuant to 105 CMR 130.823. at a minimum, shall include:

130.824: continued

(A) a statement of the type of care that will be provided at the SEF;

(B) to the extent that there is a proposed modification in services currently provided at the site of the SEF, a description of the services that will no longer be available at the site;

(C) a description of the level of ambulance transport that will be appropriate at the proposed SEF; and

(D) a description of appropriate alternative facilities that offer emergency services and that are available to residents of the hospital's service area.

130.825: Public Meeting

No earlier than 60 days prior to submitting its application pursuant to 105 CMR 130.822 and not later than 60 days after it submits said application, a hospital proposing to establish an SEF shall hold a public meeting in its service area. At the public meeting, the hospital shall describe the services to be provided at the SEF and any proposed modifications in services provided at the site prior to the establishment of the SEF, and shall afford the opportunity for interested parties to present their comments on the hospital's proposal.

130.826: Public Notice

At least 30 days prior to the date of the meeting required pursuant to 105 CMR 130.825, the hospital proposing to establish a SEF shall publish a notice of the public meeting in the legal notice section of local newspapers serving residents of the hospital's service area. The notice shall contain as its caption, in 14 point type: "Public Announcement Concerning the Establishment of a Satellite Emergency Facility by (name of hospital)". The notice shall set forth the name and address of the proposed location of the SEF, briefly describe any modifications in existing services, if any, and indicate the date, time and location of the meeting. The hospital shall forward a copy of the notice to the Department.

130.827: Public Education

A hospital proposing to establish an SEF shall develop and implement a public education plan that, at a minimum, shall include:

(A) written notification to ambulance services and regional councils, of the services to be provided at the SEF and a description of the type of ambulance transport that is appropriate for the SEF;

(B) a public information campaign about the services available at the SEF, modifications in preexisting services, and the circumstances under which it is appropriate to call "911";

(C) the creation of a community network for the early and ongoing exchange of information regarding emergency services (for example, a hospital may establish a community advisory committee composed of representatives of ambulance services, local police and fire departments, public officials and other community members to assist in the development of an effective education campaign for all cities and towns in the hospital's service area);

(D) a list of meetings to be held with public officials and the affected parties listed in 105 CMR 130.823;

(E) a clear and understandable description of the services available at the SEF and any changes in services previously provided at the SEF site; a plan for the dissemination of the description of services at the hospital, providing copies to the affected parties listed in 105 CMR 130.823 and including it in a public information campaign using local print and electronic media;

(F) a list of alternative facilities that provide emergency services to residents of the hospital's service area;

130.827: continued

(G) a plan to provide accurate and appropriate road signage in the hospital's service area;

(H) notice of the date when the SEF will commence operations; and

(I) public information and education initiatives that address public safety issues and prevention including, but not limited to, operation of motor vehicles while under the influence of alcohol or drugs, seat belt awareness, helmet use, recognition of the symptoms of heart attack, stroke and pediatric illnesses.

130.828: Physician Staffing

A SEF shall be staffed at all times with at least one physician. All physicians working at the SEF shall be board certified or board eligible in emergency medicine as recognized by the American Board of Emergency Medicine (ABEM) or the American Board of Osteopathic Emergency Medicine (ABOEM). All physician staff of a SEF shall also provide traditional clinical emergency services at a full service hospital-based emergency department for at least 25% of their total working hours per year.

130.829: Nurse Practitioners and Physician Assistant - Qualifications

Nurse Practitioners and Physician Assistants employed at the SEF shall be ACLS, APLS or PALS certified, have a minimum of three years full time experience working in a full service hospital emergency department setting and provide traditional clinical emergency services at a full service hospital based emergency department for at least 25% of their total working hours per year.

130.830: Nursing Qualifications

Nurses employed at the SEF must be ACLS (Advanced Cardiac Life Support), APLS (Advanced Pediatric Life Support) or PALS (Pediatric Advanced Life Support) and CEN (Certified Emergency Nurse) certified, have a minimum of three years' experience working in a full service hospital emergency department and provide traditional clinical emergency services at a full service hospital emergency department for at least 25% of their total working hours per year.

130.831: Radio Communications

All radio communications between the SEF and pre-hospital providers shall be in compliance with applicable statewide emergency communications plans.

130.832: Medical Director - Responsibilities

The SEF's medical director shall oversee and validate the quality assurance processes of the pre-hospital system, which shall include mortality and morbidity case conferences.

130.833: Quality Assurance

SEF specific quality assurance screens shall be developed. These screens, at a minimum, shall include reviews of:

(1) patients who die in the SEF;

(2) if known to the SEF, patients admitted to a hospital within 72 hours of having been seen at the SEF;

(3) all patients transferred from the SEF to an inpatient hospital, in which case said reviews shall include the review of the management of the patient, whether transport was by ambulance, and whether transport was done at the appropriate level of care;

(4) walk-in patients who are transferred; and

(5) all patients arriving by ambulance.

130.833: continued

(B) Any appropriate Continuous Quality Improvement (CQI) processes evaluated at the main campus of the hospital shall also be evaluated at the SEF.

130.834: Ancillary Services and Support

Each SEF shall have:

(A) on site basic diagnostic radiology available 24 hours per day;

(B) the capability of performing on site basic laboratory testing with results available in less than one hour;

(C) laboratory services capable of performing blood gas analysis and routine hematology and chemistry available 24 hours per day;

(D) radiology services including CT scans and ultrasound with a clinically appropriate turnaround time from the ordering to the reporting of results; if done off-site the SEF must have in place appropriate transport protocols; and

(E) plain film radiography available on site with technicians available 24 hours per day.

130.835: Clinical Services and Equipment

Each SEF shall have:

(A) monitored and unmonitored beds in sufficient quality to meet projected patient volume;

(B) the availability, at all times, of pediatric and adult code carts and other standard and specialty equipment described in the hospital's policies and procedures;

(C) surgical or other emergency consultative services available, on site or at an appropriate full service hospital, within 30 minutes of a decision that said services are warranted;

(D) written policies that assure that all transfers from the SEF are carried out in accord with all applicable state and federal laws and the Massachusetts Statewide Interfacility Transfer Guidelines; and

(E) a written list of the medical conditions and problems that are appropriate and inappropriate for ambulance transport to the SEF based on the capability of the SEF and regional point of entry plans.

130.836: Reports

Each hospital operating an SEF shall submit a report to the Department on a quarterly basis for the first two years of operation. The report shall include:

(A) total patient volume, including the number of walk in patients and patients transported by either BLS or ALS ambulance;

(B) the number of patients transferred to other facilities categorized by method of transport to the SEF;

(C) if known, the number of patients admitted to a hospital within 72 hours of having been seen at the SEF;

(D) deaths occurring at the SEF; and

(E) detailed description of community education and training activities.

130.840: Definition

The following definition applies to 105 CMR 130.840 through 130.841.

Diversion Status System. A web-based application established by the Department to allow hospitals, CMED centers and ambulance services access to real-time information regarding the diversion status of all hospitals in Massachusetts licensed to provide emergency services or operate a satellite emergency facility.

130.841: Requirements Regarding the Diversion Status System

(A) A hospital that is licensed to provide emergency services, including satellite emergency facilities, shall participate in the Department's web-based diversion status system.

(B) The hospital or its designee shall keep current the web-based diversion status system with regard to:

(1) the status of the emergency department and any satellite emergency facility, including but not limited to, whether the emergency department or satellite emergency facility is open to all ambulances, on diversion status, or closed; and

(2) any other directly related data recommended by the diversion status advisory committee.

(C) If the hospital designates a third party to maintain current diversion status, the hospital shall establish a written agreement outlining the responsibilities of each organization.

130.850: Trauma Service

Hospitals must provide one of two levels of trauma services as described in 105 CMR 130.851 and 130.852 in order to be licensed to provide emergency services.

130.851: Trauma Service as a Designated Trauma Center

A hospital may provide a trauma service as a designated trauma center if:

(A) The hospital has been verified by the American College of Surgeons (ACS) as a level 1, 2 or 3 adult trauma center or a level 1 or 2 pediatric trauma center.

(B) The hospital enters into transfer agreements and provides consultation to lower level trauma centers and/or hospitals that are not Designated Trauma Centers;

(C) The hospital provides to the Center for Health Information Analysis (CHIA) the designated trauma center data set specified in Department guidelines; and

(D) The hospital meets such other standards as the Department may require.

130.852: Trauma Services at a Hospital That is not a Designated Trauma Center

A hospital that is not a Designated Trauma Center may be licensed to provide Emergency Services only if:

(A) The hospital provides to CHIA the trauma service hospital data set to be specified in 105 CMR 130.851(D); and

(B) The hospital enters into formal written agreements with one or more Designated Trauma Centers that address the transfer of patients to those centers.

130.853: Trauma Service Advertising

No hospital may use the terms "trauma facility", "trauma center", or similar terminology in its signs or advertisements or in materials and information it provides to the public unless it provides a trauma service as a Designated Trauma Center.

130.854: Change in Designation Status

Any Designated Trauma Center that plans to change its ACS verification status or take action that will result in a loss of designation as a Trauma Center shall notify its Regional EMS Council as defined in 105 CMR 170.020: *Definitions*, and the Department 90 calendar days prior to the proposed effective date of such change.

130.860: Surgical Technology Definitions

For the purposes of 105 CMR 130.861 the following terms have the following meanings:

Operating Room Circulator. A licensed registered nurse who is educated, trained and experienced in perioperative nursing, who is immediately available to physically intervene in providing care to a surgical patient.

Surgical Technologist. Any person who provides surgical technology services who is not licensed or registered under M.G.L. c. 112, §§ 2, 16, 74 or 74A, or who is not an intern, resident, fellow or medical officer who conducts or assists with the performance of surgery.

Surgical Technology. Surgical patient care including, but not limited to, one or more of the following:

(1) collaboration with an operating room circulator prior to a surgical procedure to carry out the plan of care by preparing the operating room, gathering and preparing sterile supplies, instruments and equipment, preparing and maintaining the sterile field using sterile and aseptic technique and ensuring that surgical equipment is functioning properly and safely;

(2) intraoperative anticipation and response to the needs of a surgeon and other team members by monitoring the sterile field and providing the required instruments or supplies;

(3) performance of tasks at the sterile field, as directed in an operating room setting, including:

(a) passing supplies, equipment or instruments;
(b) sponging or suctioning an operative site;
(c) preparing and cutting suture material;
(d) transferring and irrigating with fluids;
(e) transferring, but not administering, drugs within the sterile field;
(f) handling specimens;
(g) holding retractors; and
(h) assisting in counting sponges, needles, supplies and instruments with an operating room circulator.

130.861: Surgical Technology

(A) Each hospital that provides surgical services in operating rooms shall adopt policies and procedures that address the following requirements set forth in M.G.L. c. 111, § 229.

(1) The hospital may not employ or otherwise retain the services of any person to perform surgical technology tasks or functions unless such person:

(a) has successfully completed an accredited educational program for surgical technologists and holds and maintains a certified surgical technologist credential administered by a nationally recognized surgical technologist certifying body accredited by the National Commission for Certifying Agencies and recognized by the American College of Surgeons and the Association of Surgical Technologists;

(b) has successfully completed an accredited school of surgical technology but has not, as of the date of hire, obtained the certified surgical technologist certification required in 105 CMR 130.861(A)(1)(a); provided, however, that such certification shall be obtained within 12 months of the graduation date;

(c) was employed as a surgical technologist in a surgical facility on or before July 1, 2013;

(d) has successfully completed a training program for surgical technology in the Army, Navy, Air Force, Marine Corps or Coast Guard of the United States or in the United States Public Health Service which has been deemed appropriate by the commissioner; or

130.861: continued

(e) is performing surgical technology tasks or functions in the service of the federal government, but only to the extent the person is performing duties related to that service.

(2) A person employed or otherwise retained to practice surgical technology in a hospital may assist in the performance of operating room circulator duties under the direct clinical supervision, limited to clinical guidance, of the operating room circulator if:

(a) the operating room circulator is present in the operating room for the duration of the procedure;

(b) any such assistance has been assigned to such person by the operating room circulator; and

(c) such assistance is consistent with the education, training and experience of the person providing such assistance.

(B) A hospital may employ a surgical technologist who does not meet the requirements of 105 CMR 130.861(A)(1) if the hospital receives a waiver from the department signifying that the hospital has:

(1) made a diligent and thorough effort to employ qualified surgical technologists who meet the requirements of 105 CMR 130.861(A)(1); and

(2) is unable to employ enough qualified surgical technologists for its needs.

(C) Nothing in 105 CMR 130.861 shall prohibit a licensed registered nurse, licensed or registered health care provider or other health care practitioner from performing surgical technology tasks or functions if such person is acting within the scope of such person's license.

130.900: Standards for Operation of Hospital-based Invasive Cardiovascular Services

105 CMR 130.900 through 130.980 sets forth standards for the operation of hospital-based adult cardiac catheterization and electrophysiology laboratories. Cardiac catheterization procedures shall not be performed in a satellite facility or a freestanding clinic. Any hospital wishing to provide cardiac catheterization services shall be licensed by the Department.

130.915: Application to Provide Cardiac Catheterization Services

(A) Each hospital seeking approval to provide adult cardiac catheterization services, pediatric cardiac catheterization services, or electrophysiology services shall submit an application for review by the Department which demonstrates hospital adherence to the standards and requirements in 105 CMR 130.900 through 130.980, as applicable, and all corresponding Department guidelines.

(B) All applicants for approval of pediatric catheterization services shall at a minimum have a licensed Level III pediatric service.

130.930: Establishment of Invasive Cardiac Services Advisory Committee

The Department may establish an Invasive Cardiac Services Advisory Committee to advise the Department on issues related to invasive diagnostic and interventional cardiac services licensed by the Department. The Committee's membership shall be multidisciplinary and shall include but not be limited to physicians and nurses who are clinical experts in the field of cardiac catheterization, cardiac surgery and electrophysiology studies, hospital administrators and consumers. The committee shall be representative of the geographical areas of the Commonwealth and of community and tertiary hospitals.

130.935: Minimum Workload Requirements

(A) Each approved cardiac catheterization service shall maintain a minimum annual caseload volume in accordance with Department guidelines, based on guidelines and standards issued by American College of Cardiology, American Heart Association and Society for Cardiac Angiography and Interventions.

130.935: continued

(1) Any cardiac catheterization service providing fewer than the specified number of procedures per year shall, within 30 days of the end of the Department's fiscal year reporting period, submit to the Department a copy of the previous year's Quality Assessment and Performance Improvement (QAPI) quarterly reports required under 105 CMR 130.965(E).
(2) In addition to the requirements of 105 CMR 130.935(A)(1), any cardiac catheterization service providing fewer than the specified number of procedures per year shall, within 30 days of the end of the Department's fiscal year reporting period, request a review of the catheterization service by an appropriately qualified professional peer review organization or individual(s) approved by the Department. Any physician conducting the peer review shall certify that he or she does not have any conflict of interest regarding the hospital and physicians to be reviewed.

The results of the review shall be submitted to the Department within ten days of receipt.
(3) Based on a review of the QAPI reports and, if applicable, the results of the assessment of the quality of the cardiac catheterization service by an appropriately qualified peer review organization or individual(s) approved by the Department, the Department shall determine whether a facility will continue to be approved to provide the service and, if applicable, subject to any conditions determined to be appropriate.
(4) New services shall reach the minimum specified number of procedures within 24 months of approval of the service.

(B) If a hospital is required to submit its quarterly reports of the QAPI under 105 CMR 130.935, the hospital shall subsequently continue to submit the quarterly reports of the QAPI to the Department for review each quarter until the hospital receives a notice from the Department to discontinue submission of the reports.

130.940: Staff

(A) The hospital shall designate a licensed physician director who shall have responsibility for the cardiac catheterization service.
(1) The physician director of a cardiac catheterization service that performs diagnostic procedures shall be board-certified in cardiovascular disease. The physician director shall have training and experience in cardiac catheterization.
(2) The physician director of a cardiac catheterization service that performs interventional procedures shall be board certified in interventional cardiology.
(3) A hospital that performs diagnostic and interventional electrophysiology procedures (excluding those cardiac catheterization services that only implant pacemakers and perform no other electrophysiology procedures), shall designate a licensed physician director of electrophysiology services who is board-certified in clinical cardiac electrophysiology (CCEP).

(B) The cardiac catheterization service and electrophysiology service, if applicable, physician director(s) shall be responsible for the operational management of the environment and equipment, and the development and implementation of policies and procedures that include, at a minimum:
(1) Patient selection and exclusion criteria based on nationally accepted published guidelines of the American College of Cardiology/American Heart Association and the Heart Rhythm Society.
(2) Establishment and implementation of a quality assessment and performance improvement program.

(C) The physician director for the cardiac catheterization service and electrophysiology service, if applicable, with the hospital administration, shall establish criteria for granting privileges to licensed physicians to perform cardiac catheterization procedures and shall review and make recommendations regarding the applications for those privileges.

(D) Each cardiac catheterization service, shall have on staff at least two physicians who are board-certified in cardiovascular disease. Each physician who performs cardiac catheterization or EPS procedures shall be a fully credentialed member of the hospital staff.

130.940: continued

(1) Physicians who perform percutaneous coronary interventions (PCI) shall be board-certified in interventional cardiology.

Physicians who are within 12 months after completion of a fellowship in interventional cardiology, while awaiting board certification may perform PCI procedures under the supervision of a physician who is board certified in interventional cardiology and performs more than 125 procedures per year, until he or she becomes board certified.

(2) Each hospital shall specifically define the qualifications necessary for privileges to perform diagnostic and interventional electrophysiology services. At a minimum, electrophysiology services shall be performed by a physician board-certified in cardiovascular disease with training in electrophysiology services and cardiac arrhythmias.

(a) Physicians performing electrophysiology procedures (except for those physicians who only implant pacemakers and cardioverter-defibrillators and perform no other electrophysiology procedures) must be board-certified in clinical cardiac electrophysiology.

(b) Non-electrophysiologists wishing to implant cardioverter-defibrillators and cardiac resynchronization therapy devices must be trained in an American Council for Graduate Medical Education approved fellowship program and pass a competency exam offered by the International Board of Heart Rhythm Examiners.

(E) At least two persons shall assist the physician during the performance of all cardiac catheterization and electrophysiology procedures. At least one assistant shall be either a registered nurse, nurse practitioner or physician assistant.

(F) Appropriate staff shall be available to ensure all electronic and mechanical equipment is regularly checked and maintained in safe working order.

(G) A physician who has medical staff privileges in vascular surgery shall be available for consultation to the cardiac catheterization service staff consistent with written guidelines developed by the hospital.

(H) An individual qualified under the provisions of 105 CMR 120.020: *Registration of Radiation Machine Facilities and Services* shall be available for consultation for monitoring radiation safety for patients and personnel consistent with written guidelines developed by the hospital.

(I) All members of the cardiac catheterization/EPS team shall maintain current certification in advanced cardiac life support.

130.950: Equipment and Supplies

Each cardiac catheterization service and EPS shall appropriately equip itself and be responsible for appropriate maintenance, pursuant to hospital policy.

The service must make an intra-aortic balloon pump available to the laboratory.

130.960: Space

(A) A cardiac catheterization/EPS laboratory shall meet the cardiac catheterization laboratory standards set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines, as referenced in 105 CMR 130.107.

(B) The patient recovery area must be directly accessible from the procedure room and designed according to the standards applicable to recovery areas for ambulatory surgery set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines, as referenced in 105 CMR 130.107.

130.962: Assurance of Continuity of Care

Each hospital must develop and implement policies and procedures that assure the continuity of the patient care, from the pre-catheterization teaching and obtaining of written consent through post-procedure care and discharge.

130.965: Hospital-based Quality Assurance and Performance Improvement Program

(A) Each cardiac catheterization or electrophysiology service shall establish and maintain an effective, ongoing, data-driven, evidence-based quality assessment and performance improvement (QAPI) program for all catheterization procedures, including electrophysiology procedures, if applicable, that focuses on patient outcomes while assessing individual operator clinical proficiency as well as overall laboratory safety and efficiency.

(B) The hospital, through its QAPI program, shall:
(1) Identify quality measures, based on nationally accepted standards, that capture the quality of care provided and patient safety;
(2) Collect and maintain data pertaining to these measures in a systematic manner;
(3) Perform statistical analyses of the data for comparison with nationally accepted quality indicator benchmarks and longitudinally within the hospital on a routinely scheduled basis;
(4) Analyze comparison results and identify areas for improvement; and
(5) Develop, implement and evaluate evidence-based improvement interventions to address the identified areas, and incorporate feedback for catheterization service staff on the effectiveness of the solutions and/or triggers further opportunities for improvement.

(C) The program shall include but not be limited to assessments of the following:
(1) Appropriate patient selection (according to pre-established selection criteria, consistent with nationally accepted standards);
(2) The appropriateness of each cardiac catheterization or electrophysiology service procedure;
(3) Technical quality of the catheterization or electrophysiology service studies;
(4) Diagnostic accuracy and completeness of studies;
(5) All catheterization or electrophysiology procedure-related complications and adverse outcomes (including infections) identified or reported;
(6) Number of cases requiring interhospital transfer and the reason for transfer;
(7) The number and percent of diagnostic cardiac catheterization procedures determined to be normal (*i.e.*, no disease or physiologically insignificant coronary stenoses); and
(8) Patient experience measure data.

(D) Each cardiac catheterization service shall participate in a national data registry to help compare results and track complications.

(E) Cardiac catheterization or electrophysiology service medical records must include at a minimum the following information: type of procedure performed, indication for procedure, time course of procedural events, time and dose of all medications administered, fluoroscopy time, all catheter sheaths and special guide wires used, pertinent hemodynamic and/or electrophysiologic data, a detailed summary of the procedure, and a description of the angiographic or electrophysiologic findings and clinical recommendations.

(F) The hospital shall maintain quarterly written reports of QAPI findings, recommended actions, progress on implementation and supporting data, which shall be available for Department review upon request.

130.970: Reporting to the Department of Public Health

When requested by the Department, each hospital shall submit information regarding volume of procedures, patient outcomes and utilization.

130.975: Cardiac Catheterization Services without Cardiac Surgery Services

A hospital that operates a cardiac catheterization service and does not provide cardiac surgery services shall not perform procedures specified in Department guidelines and shall maintain a current written collaboration agreement with at least one tertiary hospital with a cardiac surgery program. The agreement shall include all of the following:

(1) Guidelines for the selection of patients appropriate for cardiac catheterization at the hospital without cardiac surgery.

(2) Provisions for emergency and routine transfer of patients including timely transfer of appropriate patient information. Language shall be included that describes the agreed upon cardiac catheterization image standard, to avoid redundant catheterization.

(3) Provisions that specify that cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency.

(4) Provisions that specify the responsibility for arranging transportation to the receiving hospital.

(5) Provisions for joint quality assurance reviews.

(6) Provisions for joint training and ongoing education of staff.

(7) Explicit description of responsibilities of each party to the agreement.

130.980: Prerequisites to the Performance of Electrophysiology Services (EPS)

Hospitals shall not perform electrophysiology procedures with the exception of implanting pacemakers, defibrillators and monitoring devices unless the hospital is approved to provide cardiac catheterization services.

130.1001: Definitions applicable to 105 CMR 130.1001 through 130.1008

As used in 105 CMR 130.1001 through 130.1008 the following definitions shall apply:

Advisory Committee. A committee composed of, but not limited to: the Department's director of infectious disease; a consumer to be selected by the commissioner; a technical expert to be selected by the commissioner; and a representative from the Massachusetts Nurses Association, the New England Association of Occupational and Environmental Medicine, the Massachusetts Medical Society and the Massachusetts Hospital Association.

Commissioner. The Commissioner of the Massachusetts Department of Public Health.

Department. The Massachusetts Department of Public Health.

Engineering and Work Practice Controls. Controls such as, but not limited to, sharps disposal containers, needleless systems, and sharps with engineered injury protection, that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Control Plan. A plan that includes an effective procedure for identifying and selecting existing sharps injury prevention technology.

Exposure Incident. A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee duties.

Health Care Worker. All workers employed by the hospital, working within the hospital but employed by other agencies, those providing patient care services without pay such as students, or providers who are delivering care but receiving compensation from sources other than the hospital.

Hospital. Any hospital licensed by the Department pursuant to M.G.L. c. 111, § 51.

Reportable Exposure Incident. An exposure incident that is a result of events that pierce the skin or mucous membranes.

130.1001: continued

Sharp. Any object that can penetrate the skin or any part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes and exposed ends of dental wires.

Sharps Injury Log. A log to be kept within acute and non-acute hospitals that records information concerning exposure incidents, including but not limited to, the type and brand of device involved in the incident.

Sharps Injury Prevention Technology. Devices or other technology that minimizes the risk of injury to health care workers from hypodermic syringes, needles or other sharps.

130.1002: Minimizing Risk of Injury

Every hospital shall:

(A) Ensure the provision of services to individuals through the use of safe needle devices or other technology that minimizes the risk of injury to health care workers from hypodermic syringes, needles, and sharps; and

(B) Except as provided in 105 CMR 130.1005, use only such devices designed to reduce risk of percutaneous exposure to bloodborne pathogens.

130.1003: Written Exposure Control Plans

Hospitals shall develop written exposure control plans that include an effective procedure for identifying and selecting existing sharps injury prevention technology consistent with the federal regulations concerning occupational exposure to bloodborne pathogens, 29 CFR 1910.1030, the Occupational Safety & Health Administration's (OSHA) Occupational Exposure to Bloodborne Pathogens Standards. Written exposure control plans shall be updated when necessary to reflect progress in sharps injury prevention technology as determined by the Department.

130.1004: Engineering or Work Practice Controls

Hospitals shall include sharps injury prevention technology as engineering or work practice controls to isolate or remove the bloodborne pathogens hazard from the workplace consistent with the federal regulations concerning occupational exposure to bloodborne pathogens, 29 CFR 1910.1030.

130.1005: Exemption from the Inclusion of Sharps Injury Prevention Technology

(A) Sharps injury prevention technology may be excluded as engineering or work practice controls in cases where the hospital or other appropriate party can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure.

(B) Where sharps injury prevention technology is not utilized, the hospital shall specify those circumstances, which shall include but not be limited to situations where the technology is medically contraindicated or not more effective than alternative measures used by the employer to prevent exposure incidents.

(C) In all cases the Department shall make the final determination as to whether a hospital or other appropriate party has demonstrated in a satisfactory manner those circumstances which warrant an exemption from the inclusion of sharps injury prevention technology.

130.1006: Sharps Injury Log

(A) Information concerning exposure incidents shall be recorded in a sharps injury log that includes, but is not limited to, the type and brand of device involved in the incident, the department or work area where the incident occurred, and an explanation of how the incident occurred;

(B) Sharps injury logs shall be kept within the hospital and shall be used as the basis for continuing quality improvement in reducing sharps injuries through the provision of education and the procurement of improved products; and

(C) Sharps injury logs shall be kept confidential.

130.1007: Reporting

Every licensed acute and non-acute care hospital shall report annually to the Department information from its sharps injury logs and such other information as the Department may require concerning exposure incidents. The Department shall supply each reporting hospital with guidelines indicating the specific data elements to be submitted.

130.1040: Definition of Emergency Contraception

For the purposes of 105 CMR 130.1041 through 130.1043, "emergency contraception" means any drug that is approved by the federal Food and Drug Administration and that is used as a contraceptive method after sexual intercourse.

130.1041: Emergency Contraception Information for Providers

Each hospital that is licensed to provide emergency services shall provide all persons who provide care to victims of sexual assault with medically and factually accurate written information prepared by the Department about emergency contraception.

130.1042: Emergency Contraception Information and Services for Rape Victims

Each hospital that is licensed to provide emergency services shall promptly provide the following to each female rape victim of childbearing age who presents at the emergency department:

(A) Medically and factually accurate written information provided by the Department about emergency contraception;

(B) An offer of emergency contraception at the hospital if medically indicated; and

(C) Dispensing of emergency contraception at her request unless medically contraindicated.

130.1043: Reporting the Dispensing of Emergency Contraception

(A) Each hospital shall report each time that it dispenses emergency contraception pursuant to 105 CMR 130.1042 on the Provider Sexual Crime Report that it completes in accordance with M.G.L. c. 112, § 12A½.

(B) The report of the dispensing of emergency contraception made pursuant to 105 CMR 130.1043(A) is not a public record as defined in M.G.L. c. 4, § 7.

130.1101: Interpreter Service - Requirement

Each acute care hospital licensed by the Department and that provides emergency services, shall provide competent interpreter services in connection with all emergency department services. Such competent interpreter services shall be provided to every non-English speaker who seeks or receives emergency care or treatment. In the provision of competent interpreter services, the hospital shall comply with the provisions of 105 CMR 130.1101 through 130.1108 and M.G.L. c. 111, § 25J.

130.1102: Interpreter Service - Policies and Procedures

Each acute care hospital shall develop written policies and procedures, consistent with 105 CMR 130.1101 through 130.1108 that govern the provision of interpreter services and that include the qualifications for a coordinator of interpreter services.

130.1103: Interpreter Service - Coordinator

In connection with its provision of emergency department service each acute care hospital shall designate a coordinator of interpreter services who shall be responsible for:

(A) conducting an annual language needs assessment of the service area that includes input from community-based organizations, and that includes identification of those languages for which notices shall be posted;

(B) developing written policies and procedures for use in the hospital's emergency department to assure timely early identification and ongoing access for patients in need of interpreter services;

(C) overseeing the training and assessment process for both interpreters and hospital staff who will be working with interpreters;

(D) developing an ongoing, documented quality assurance program that includes problem identification, action plans, evaluation and follow-up and which is a part of the hospital's ongoing quality assurance process;

(E) establishing and publicizing grievance procedures regarding access to interpreter services.

130.1104: Interpreter Service - Notices

Each acute care hospital shall provide oral and/or written notification to patients or individuals seeking or receiving emergency services in their primary language informing them of their right to receive interpreter services at no charge. Each acute care hospital shall also provide translated signage, as provided by the Department, that informs patients at key points of contact in the emergency department of the availability of no cost interpreter services. Each acute hospital shall have on file copies of M.G.L. c. 111, § 25J in languages identified by the needs assessment, and shall furnish such a copy in the language requested to any interested party on request.

130.1105: Interpreter Service - Access

Each acute care hospital shall provide all non-English speaking patients or individuals seeking or receiving emergency department services with access to competent interpreter services at no charge, by using bilingual staff, staff interpreters, or by contract arrangement. Provision and acceptance or refusal of interpreter services shall be documented in the patient's medical record. Interpreter services in the emergency department shall comply with the following standards:

(A) Interpreter services shall be available, at a minimum, on an on-call basis 24 hours per day, seven days per week.

(B) The collection of information from family members about family history and other collateral information is an acceptable practice, but does not substitute for the provision of interpreter services.

(C) The hospital shall refrain from requiring, suggesting or encouraging patients to use family members or friends as interpreters.

(D) The use of minor children as interpreters is prohibited.

130.1105: continued

(E) Hospitals shall develop policies and procedures that identify those situations in which it will employ or contract for the on-call use of one or more interpreters for particular languages when needed, or use competent telephonic or televiewing services, provided that telephonic or televiewing interpreter services shall be used only where it can be documented that there is either:

(1) no reasonable way to anticipate the need for employed or contracted interpreters for a particular language; or

(2) there occurs, in a particular instance, an inability to provide competent interpreter services by an employed or contracted interpreter.

(F) The hospital shall establish written protocols to assist staff in readily accessing telephone-based interpreting services.

(G) The hospital shall establish written procedures for timely and effective telephone communication with non-English speaking patients.

130.1106: Interpreter Service - Training Education and Qualifications

Each acute care hospital through its Coordinator of Interpreter Services shall:

(A) Ensure that staff and contract interpreters can demonstrate current bilingual proficiency and have received training that includes the skills and ethics of interpreting, and knowledge in both languages regarding the specialized terms (*e.g*. medical terminology) and concepts relevant to clinical or non-clinical encounters. If the hospital uses bilingual staff or volunteers for medical interpretation, these staff and volunteers shall receive the same training and can demonstrate the same skills as staff interpreters and/or contract interpreters.

(B) Require and arrange for ongoing education and training for administrative, clinical and support staff in culturally and linguistically competent service delivery, *e.g*., patient cultural and health belief systems and working effectively with interpreters.

130.1107: Interpreter Service - Patient and Other Records

Each acute care hospital shall ensure that the primary spoken language and self-identified race/ethnicity of all patients coming to the emergency department are included in the hospital's management information system as well as any patient records used by hospital staff.

130.1108: Interpreter Service - Translated Materials

Signage, commonly used written patient educational material, and vital documents, such as consent forms, discharge instructions, advanced directives, and applications for members of the predominant language groups in the hospital's service area as identified by the needs assessment in 105 CMR 130.1103 shall be translated and made available. For less commonly encountered languages, written notice of the right to receive competent oral translation of written materials should be provided in the primary language of non-English speaking patients.

130.1202: Cardiac Surgery Patient Outcome Monitoring Requirements

Each hospital that provides cardiac surgery services shall:

(1) Submit patient-specific cardiac surgery outcome data for each patient who receives cardiac surgery services to the DAC as specified in 105 CMR 130.1203;

(2) Require that each hospital with a cardiac surgery program is enrolled in and participates in the STS National Database in accordance with the rules of the STS; and

(3) Develop, implement and maintain administrative procedures that ensure the confidentiality of the patient-specific data submitted to the DAC and to the STS National Database, if any.

130.1203: Cardiac Surgery Patient Outcome Data Requirements

Each hospital that provides cardiac surgery services shall submit patient-specific data to the DAC for each of its patients who has cardiac surgery in a manner defined by the Department using STS National Database Standards and in accordance with requirements set forth by the Department in guidelines:

(1) Cardiac surgery data submitted by hospitals are subject to audit by the Department. All acute hospitals providing cardiac surgery services are subject to random data audits that may include re-abstraction of a sample of patient medical records by the Department or its contractor.

(2) Each hospital shall reimburse the DAC for the hospital's share of the DAC's expenses according to a formula established by the Department, which shall be based on the volume of cardiac surgery services that the hospital provides. The Department shall set forth the formula and the procedures for disbursement to the DAC in guidelines.

130.1302: PCI Patient Outcome Monitoring Requirements

Each hospital that provides PCI shall:

(1) Submit patient-specific PCI outcome data for each patient who receives PCI services to the DAC as specified in 105 CMR 130.1303;

(2) Require that each physician who performs PCI at the hospital is enrolled in and participates in the NCDR; and

(3) Develop, implement and maintain administrative procedures that ensure the confidentiality of the patient-specific data submitted to the DAC and to the NCDR.

130.1303: PCI Patient Outcome Data Requirements

Each hospital that provides PCI services shall submit patient-specific data to the NCDR and to the DAC for all of its patients who have PCI procedures. The hospital shall submit these data to the NCDR in full compliance with the NCDR 's requirements. The hospital shall submit these data to the DAC in a manner defined by the Department using NCDR standards and in accordance with requirements set forth by the Department in guidelines.

(1) PCI data submitted by hospitals are subject to audit by the Department. All hospitals providing PCI services are subject to random data audits that may include reabstraction of a sample of patient medical records by the Department or its contractor.

(2) Each hospital shall reimburse the DAC for the hospital's share of the DAC's expenses according to a formula established by the Department, which shall be based on the volume of PCI services that the hospital provides. The Department shall set forth the formula and the procedures for disbursement to the DAC in guidelines.

130.1401: Definitions applicable to 105 CMR 130.1401 through 130.1413

Acute Hemorrhagic Stroke (a Subtype of Acute Stroke). The relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute brain hemorrhage (either intracerebral or subarachnoid blood) or no evidence of blood on imaging in the presence of blood in the subarachnoid space by lumbar puncture.

Acute Ischemic Stroke (a Subtype of Acute Stroke). The relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute ischemic changes or no evidence of stroke.

Acute Stroke. The relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Acute stroke includes both ischemic and hemorrhagic stroke, and requires brain imaging to define the stroke subtype.

Acute Stroke Expertise. At least two of the following:

(1) completion of a stroke fellowship;

(2) participation (as an attendee or faculty) in at least two regional, national, or international stroke courses or conferences each year;

130.1401: continued

(3) eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease; or
(4) other criteria approved by the governing body of the hospital.

Acute Stroke Team. Physician(s) and other health care professionals, *e.g.*, nurse, physician's assistant, or nurse practitioner, with acute stroke expertise available for prompt consultation consistent with time targets acceptable to the Department.

Primary Stroke Service. Emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, seven days per week to patients presenting with symptoms of acute stroke.

Time Targets. Time frames established by the Department in guidelines regarding Primary Stroke Services.

130.1402: Application to Provide Primary Stroke Service

Each hospital seeking designation as a provider of a Primary Stroke Service shall submit an application to the Department, on forms prescribed by the Department, documenting how the hospital will meet the standards in 105 CMR 130.1404 through 130.1413.

130.1404: Stroke Service Director or Coordinator

The hospital shall designate a licensed physician with acute stroke expertise, who can represent the Primary Stroke Service and evaluate the hospital's capabilities to provide the required services, as the Stroke Service Director or Coordinator.

130.1405: Written Care Protocols

(A) The hospital shall develop and implement written care protocols for acute stroke. Such protocols shall include both the emergency and post-admission care of acute stroke patients by a multidisciplinary team. The hospital shall treat eligible patients according to its written care protocols consistent with time targets acceptable to the Department. These protocols shall address issues such as stabilization of vital functions, initial diagnostic tests, and use of medications (including but not limited to intravenous tissue-type plasminogen activator (t-PA) treatment), as applicable. These protocols shall be based on previously published guidelines or developed by a multidisciplinary team organized by the Stroke Service.

(B) Emergency Department (ED) Stroke Protocols. The hospital shall develop and implement written protocols, including, but not limited to:
(1) triage and treatment of patients presenting with symptoms of acute stroke in the Emergency Department (*e.g.*, use of thrombolytic therapy, management of increased intracranial pressure and blood pressure and post-thrombolysis management plan, as applicable).
(2) communicating effectively with Emergency Medical Service (EMS) personnel in the pre-hospital setting during transportation of a patient with symptoms of acute stroke. The ED must be able to efficiently prepare for the arrival, to receive, and to triage patients with symptoms of acute stroke arriving *via* EMS transportation.
(3) a specific, well-organized system for promptly notifying and activating the Acute Stroke Team to evaluate patients presenting with symptoms of acute stroke.

(C) Post-admission Care Protocols. The hospital shall develop and implement written protocols for the post-admission care of acute stroke patients.

130.1406: Neuroimaging Services

(A) The hospital shall promptly perform brain computed tomography (CT) or magnetic resonance imaging (MRI) scans, consistent with time targets acceptable to the Department.

130.1406: continued

(B) The hospital shall provide prompt interpretation after study completion by a physician with experience in acute stroke neuroimaging, consistent with time targets acceptable to the Department. Neuroimaging interpretation may be provided directly by a staff physician at the hospital or by contractual arrangement with consultant physician(s). Physicians providing neuroimaging interpretation shall be available in the hospital or through remote access (*e.g.*, teleradiology).

130.1409: Neurosurgical Services

(A) The hospital shall develop and implement written protocols for patient access to neurosurgical evaluation and/or intervention within a reasonable period of time, which may include transfer to another hospital, consistent with time targets acceptable to the Department.

(B) If the written protocol includes the transfer of patients to another hospital, the hospital shall maintain a transfer agreement that describes the responsibilities of each hospital and is signed by the Stroke Service Director, the Medical Director of each hospital or his or her designee, and the Chief Executive Officer of each hospital or his or her designee.

130.1410: Quality Improvement

(A) The hospital shall implement and maintain an effective, data-driven quality assessment and performance improvement program for the Primary Stroke Service.

(B) The hospital shall collect and analyze data, as defined by the Department, on patients presenting to the ED with acute stroke, to identify opportunities for improvement in the service.

(C) The hospital shall submit data, in a manner defined by the Department, and in accordance with protocols established by the Department in guidelines.

130.1411: Continuing Health Professional Education

The hospital shall provide hospital-based staff education that addresses the needs of physicians, nurses, allied health professionals, and Emergency Medical Services (EMS) personnel. The program shall include ongoing formal training of ED and EMS system personnel in acute stroke prevention, diagnosis and treatment.

130.1412: Community Education

The hospital shall offer community education that provides information to the public regarding prevention of stroke, recognition of stroke symptoms, and/or treatment of stroke.

130.1413: Primary Stroke Service Review

The Primary Stroke Service protocols referenced in 105 CMR 130.1405 shall be reviewed and revised as necessary and at least annually by a committee designated by the governing body of the hospital and including the Stroke Service Director or Coordinator. The committee's review must incorporate at a minimum the number of stroke patients, types of stroke evaluated, nature of any complications of thrombolytic therapy, and compliance with 105 CMR 130.1404 through 130.1413, including adherence to the time targets.

130.1501: Definitions applicable to 105 CMR 130.1501 through 130.1504

The following definitions apply in 105 CMR 130.1500 through 130.1504:

Affiliate Hospital. A hospital that is licensed by the department to provide a medical control service and agrees to provide medical control to a licensed service pursuant to an affiliation agreement.

Affiliation Agreement. An agreement between the hospital and a service that meets the requirements of 105 CMR 170.300: *Affiliation Agreements*.

130.1501: continued

Authorization to Practice. Approval granted to EMS personnel as defined in 105 CMR 170.020: *Definitions*.

CMED. The medical communications subsystem within the statewide EMS communications system.

EFR Service. An EMS First Response Service designated as a service zone provider pursuant to a Department-approved service zone plan for the purpose of providing rapid response and EMS in accordance with 105 CMR 170.000: *Emergency Medical Services System.*

Emergency Medical Services (EMS). The pre-hospital assessment, treatment and other services utilized in responding to an emergency or provided during the emergency or inter-facility transport of patients to appropriate health care facilities.

EMS System. All the EMS providers and equipment; communications systems linking them to each other; training and education programs; the Regional EMS Councils and all of their operations; EMS plans, protocols, statutes, regulations, administrative requirements and guidelines; and all other components of such system, and their interaction with each other and with patients, providing equally for all patients quality care, operating under the leadership and direction of the Department.

Emergency Medical Technician (EMT). A person certified by the Department to provide emergency medical services pursuant to 105 CMR 170.000: *Emergency Medical Services System*.

Medical Control. The clinical oversight by a qualified physician to all components of the EMS system, including, without limitation, Statewide Treatment Protocols, medical direction, training of and authorization to practice for EMS personnel, quality assurance and continuous quality improvement.

Medical Direction. The authorization for treatment established in the Statewide Treatment Protocols provided by a qualified medical control physician to EMS personnel, whether on-line, via direct communication or telecommunication, or off-line, *via* standing orders.

On-line Medical Direction. The authorization for treatment established in the Statewide Treatment Protocols provided by a qualified medical control physician to EMS personnel *via* direct communication or telecommunication.

Qualified Medical Control Physician. A physician who meets the requirements of 105 CMR 130.1504.

Regional EMS Council. An entity created pursuant to M.G.L. c. 111C, § 4 and designated by the Department to assist the Department in establishing, coordinating, maintaining and improving the EMS system in a region.

Service. A licensed ambulance service or EFR service as defined in 105 CMR 170.020: *Definitions*.

Statewide Treatment Protocols. The Emergency Medical Services Pre-hospital Treatment Protocols approved by the Department for application statewide.

130.1502: Standards for Hospitals that Provide a Medical Control Service

Each hospital that provides a medical control service shall:

(A) Enter into an affiliation agreement that meets the requirements set forth in 105 CMR 170.300: *Affiliation Agreements* with each service to which it provides medical control;

(B) Make on-line medical direction available 24 hours a day, seven days a week to all services with which it has an affiliation agreement;

130.1502: continued

(C) Designate an affiliate hospital medical director;

(1) The hospital shall ensure that the affiliate hospital medical director performs the duties specified in 105 CMR 130.1503.

(2) The hospital shall ensure that the affiliate hospital medical director meets the requirements set forth in 105 CMR 130.1504.

(D) Provide data regarding medical control to the Department upon request;

(E) Maintain operational communications equipment and participate in communications plan development, where appropriate, in compliance with the Massachusetts Emergency Medical Services Radio Communications Plan;

(F) Ensure that all field communication of emergency on-line medical direction is recorded by CMED, at the hospital, or by other means;

(G) Maintain and provide to the Department upon request a list of the physicians that provide on-line medical direction pursuant to the affiliation agreement and the requirements set forth in 105 CMR 130.1504;

(H) Ensure that there is a process for skill maintenance and review available to EMS personnel employed by the service with which the hospital has an affiliation agreement;

(I) Provide remedial training opportunities in the hospital emergency department and in operating rooms or skill laboratories, for remediation and education of all pertinent EMS skills and practices, including, but not limited to, advanced airway management;

(J) Operate an effective quality assurance/quality improvement (QA/QI) program that includes, but is not limited to, regular review of trip records and other statistical data pertinent to the operation of the service with which the hospital has an affiliation agreement, in accordance with the hospital's QA/QI standards and protocols, in those cases in which ALS services were provided or in which ALS established direct patient contact;

(K) Make available to the hospital's emergency department physicians and nurses and the EMS personnel employed by the service with which the hospital has an affiliation agreement, morbidity and mortality rounds and chart reviews at a frequency specified in the affiliation agreement;

(L) Provide to the Department and the Regional Medical Director upon request a list of ambulance services with which it maintains affiliation agreements; and

(M) Establish policies and procedures through which the service may obtain medications from the hospital's pharmacy.

130.1503: Duties of the Affiliate Hospital Medical Director

The Affiliate Hospital Medical Director shall:

(A) Provide oversight to and ensure the clinical competency of the EMS personnel employed by the service with which the hospital has an affiliation agreement, including, but not limited to, the following:

(1) Authorization to practice;

(2) Remedial education to those EMS personnel found to be deficient in clinical practice; and

(3) Notification to the Department within 48 hours of any instance in which he or she suspends, revokes, or restricts in any manner the authorization to practice of an affiliate EMS service's EMT or EFR. Such notice shall include the reasons for the suspension or revocation, and the affiliate hospital medical director's remediation plan for the EMT or EFR.

130.1503: continued

(B) Ensure that all on-line medical direction is in conformance with the Statewide Treatment Protocols;

(C) Provide appropriate orientation to all physicians who provide on-line medical direction pursuant to the affiliation agreement, including but not limited to information regarding local EMS providers and point-of-entry plans;

(D) Coordinate the QA/QI program described in 105 CMR 130.1502(J) with the participation of the hospital's on-line medical direction physicians and the service medical director, if different from the affiliate hospital medical director;

(E) Provide information requested by a Regional Medical Director to enable him or her to monitor the hospital's affiliation agreements; and

(F) Maintain appropriate skills and knowledge through continuing education.

130.1504: Standards for the Affiliate Hospital Medical Director and Physicians who Provide On-line Medical Direction

Each hospital that operates a medical control service shall ensure that each physician that provides on-line medical direction meets the following standards.

(A) Current credentialing to practice as a physician in a Massachusetts hospital emergency department. Such credentialing shall, at a minimum, include demonstration of the following:

(1) Education for proper provision of on-line medical direction, as evidenced by:

(a) Successful completion of an Emergency Medicine residency program; or

(b) Previous training and experience in medical direction.

(2) Proficiency in the clinical application of the current Statewide Treatment Protocols.

(B) Proficiency in EMS radio communications.

(C) In addition to the standards described in 105 CMR 130.1504(A) and (B), the affiliate hospital medical director shall be board-certified in emergency medicine.

130.1600: Rapid Response Method

(A) Each acute care hospital licensed by the Department, shall establish a Rapid Response Method (RRM) suitable for the hospital's needs and resources, to enable health care staff members, patients and family members to directly request additional assistance from a specially-trained individual(s) when a patient's condition appears to be deteriorating. The hospital shall ensure that the RRM is available 24 hours per day, seven days per week.

(B) Policies and Procedures. A hospital shall develop and implement written policies and procedures for a RRM that encourage staff members, patients and family members to seek assistance when a patient's condition appears to be deteriorating. These policies and procedures shall include at a minimum the following:

(1) Description of the RRM including criteria and methods for activating the RRM by staff members, patient(s) and/or family members when a patient's condition appears to be deteriorating.

(2) Criteria for selection, training and evaluation of staff members who will be responsible for responding to a request for additional assistance.

(3) Education of staff members, patient(s) and/or family members about the RRM including the means by which staff members, patients and family members may request additional assistance.

(4) Requirement of written documentation for each instance of activation of the RRM, including assessment of patient and family member satisfaction with the RRM.

(5) A mechanism for measuring the utility and effectiveness of the RRM, including but not limited to:

130.1600: continued

(a) documentation of rates and effectiveness of utilization of the RRM by staff, patients and family members; and

(b) measurement of rates of cardiopulmonary arrest, respiratory arrest and mortality before and after implementation of the RRM.

(6) Documentation of actions taken to improve the RRM and to address underlying organizational issues raised by review mechanism(s) and data collected pursuant to 105 CMR 130.1600(B)(5).

(C) The Department may issue guidelines updating or revising the minimum required policies and procedures in 105 CMR 130.1600(B).

130.1700: Definitions Applicable to Healthcare-associated Infection Data Collection, Submission and Reporting

The following definitions apply to 105 CMR 130.1701:

Healthcare-associated Infection (HAI). A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

(1) occurs in a patient in a hospital;

(2) was not present or incubating at the time of the admission during which the reaction occurs;

(3) meets the criteria for a specific site infection as defined by the federal Centers for Disease Control and Prevention in its National Healthcare Safety Network; and

(4) any additional elements as set forth in administrative guidelines of the Department based on the National Healthcare Safety Network.

National Healthcare Safety Network (NHSN). The HAI tracking system operated by the Federal Centers for Disease Control and Prevention.

130.1701: Healthcare-associated Infection Data Collection, Submission and Reporting

(A) In accordance with guidelines of the Department, specified hospitals shall:

(1) register with the NHSN; and

(2) grant access to the Department, in accordance with guidelines of the Department, to healthcare-associated infection data elements reportable to the NHSN.

(B) Each hospital shall collect and submit to the NHSN, and then grant access as provided under 105 CMR 130.1701(A) to the Department to healthcare-associated infection data elements.

(C) Each hospital shall collect and submit to the Department other data related to infection control, including process measures, in accordance with guidelines of the Department.

130.1800: Patient and Family Advisory Council

A hospital shall establish a Patient and Family Advisory Council to advise the hospital on matters including, but not limited to, patient and provider relationships, institutional review boards, quality improvement initiatives, and patient education on safety and quality matters to the extent allowed by state and federal law.

(1) a hospital shall prepare an annual written report documenting the hospital's compliance with 105 CMR 130.1800 and 130.1801 and describing the Council's accomplishments during the preceding year.

(2) The hospital shall make the report required in 105 CMR 130.1800(A)(1) publicly available through electronic or other means, and to the Department upon request.

130.1801: Policies and Procedures for Patient and Family Advisory Council

(A) A hospital shall develop and implement written policies and procedures for the Council, which shall address, at a minimum, the following:

130.1801: continued

(1) The Council's purposes and goals.
(2) Membership of the Council including qualifications, selection, retention, term of service, and duties and election of officers. The Department recommends that the chair or co-chairs be current or former patient(s) or family member(s), or a staff person and a patient or family member.
(3) Orientation, training and continuing education for members of the Council.
(4) Roles of members of the Council, which may include the following as examples:
(a) participation on hospital committees, task forces and/or advisory boards;
(b) review of publicly-reported quality information;
(c) participation on committees addressing patient safety issues;
(d) participation on search committees and in the hiring of new hospital staff;
(e) participation in reward and recognition programs;
(f) as co-trainers for clinical and nonclinical staff, in-service programs, and health professional trainees; and
(g) any other role in accordance with the hospital's policies and procedures.
(5) Responsibilities of members of the Council, including policies that address confidentiality of patient information.

(B) Required Policies and Procedures.
(1) The Council shall meet at least quarterly.
(2) Minutes of Council meetings shall be maintained for a minimum of five years.
(3) Minutes of Council meetings including Council accomplishments shall be transmitted to the hospital's governing body.
(4) At least 50% of the Council members shall be current or former patients and/or family members and should be representative of the community served by the hospital.

130.1900: Definitions applicable to 105 CMR 130.1901

The following definitions apply to 105 CMR 130.1901:

Appropriate Patient. A patient whose attending health care practitioner has:
(1) diagnosed a terminal illness or condition that can reasonably be expected to cause the patient's death within six months, whether or not treatment is provided, provided that the attending health care practitioner determines that discussion of the palliative care services is not contraindicated; or
(2) determined that discussion of palliative care services is consistent with the patient's clinical and other circumstances and the patient's reasonably known wishes and beliefs.

Attending Health Care Practitioner. A physician or nurse practitioner who has primary responsibility for the care and treatment of the patient within or on behalf of the hospital; provided that if more than one physician or nurse practitioner share that responsibility, each of them shall have a responsibility under 105 CMR 130.1901, unless there is an agreement to assign that responsibility to one such person.

Hospice Care Services. Care provided by an entity licensed pursuant to 105 CMR 141.000: *Licensure of Hospice Programs*.

Palliative Care. The attempt to prevent or relieve pain and suffering and to enhance the patient's quality of life, and may include, but is not limited to, interdisciplinary end-of-life care and consultation with patients and family members.

130.1901: Provision of Information on Palliative Care and End-of-life Options

(A) Each hospital shall distribute to appropriate patients in its care, directly or through professionally qualified individuals, culturally and linguistically suitable information regarding the availability of palliative care and end-of-life options. This obligation shall be fulfilled by providing the patient with:
(1) A Department-issued informational pamphlet; or
(2) A similar informational pamphlet that meets the specifications in 105 CMR 130.1901(B).

130.1901: continued

(B) At a minimum, the informational pamphlet shall include:
(1) A definition and explanation of advanced care planning, palliative care services and hospice services; and
(2) All other requirements defined in guidelines of the Department.

(C) Each hospital shall provide its attending health care practitioners the information in 105 CMR 130.1901(A) for distribution to appropriate patients in a timely manner.

(D) Each hospital shall have a policy to guide its attending health care practitioners for identifying appropriate patients and ensuring that they receive an informational pamphlet. Such policies shall be made available to the Department upon request.

(E) Each hospital shall inform all physicians and nurse practitioners providing care within or on behalf of the facility of the requirements of M.G.L. c. 111, § 227(c) to offer to provide end-of-life counseling to patients with a terminal illness or condition.

(F) Where the patient lacks capacity to reasonably understand and make informed decisions, the information in 105 CMR 130.1901(A) shall be provided to the person with legal authority to make health care decisions for that patient.

(G) The hospital shall make available to the Department proof that it is in compliance with 105 CMR 130.1901(A) and (C) through (E) upon request or at the time of inspection.

130.2000: Severability

The provisions of 105 CMR 130.000 are severable. If any provision herein is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining portions shall not be so affected.

REGULATORY AUTHORITY

105 CMR 130.000: M.G.L. c. 111, §§ 3, 51 through 56 and 70.